IACUC Creating Protocol Applications

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Chapter 1. **IACUC Protocol Application Process Overview**

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IACUC Protocol Application Process

Overview of the IACUC 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 the IACUC Full Board for review. If the IACUC Full Board is not required to review, a Designated Reviewer is assigned to the Protocol Application.

• 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

• Principal Investigator entering protocol application has access to Topaz. If you need to be granted access, please see additional information located at:
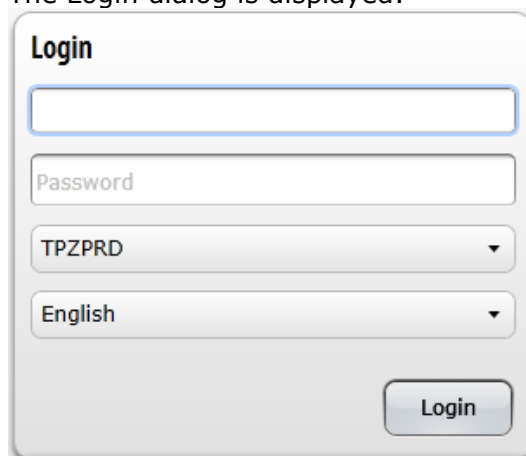http://research.fiu.edu/iacuc/pages/topaz.html

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.
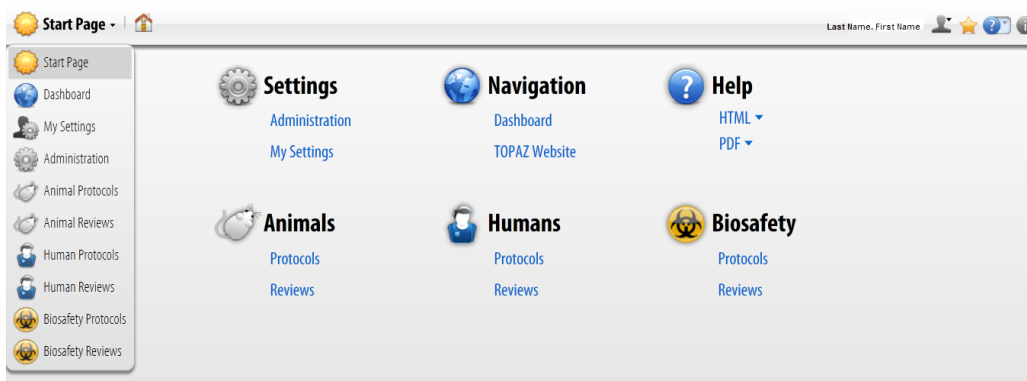   The Login dialog is displayed:

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:

2. 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.*

3. 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.
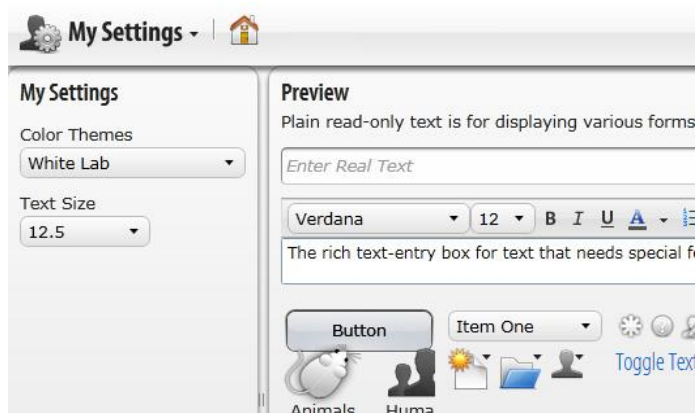
2.4. USING MY DASHBOARD

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. When using the Quick Filter, please note that it will only apply to those protocols that are currently displayed on the screen depending on the number that is set for display (e.g., 100, 250, 500, 1000). If you want to apply a filter to "all protocols" (including those that are not displayed on the first

page of the screen) then you will need to use the Advanced Filter to do a search through all of the protocols (regardless if they are displayed on the screen).

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. **Creating Protocol Application Steps**

Note: Please reference the Division of Research Topaz website found at
http://research.fiu.edu/compliance/topaz/ for assistance logging into Topaz.
If you encounter any technical issues (i.e., logging on, error message) please stop and
contact topaz-help@fiu.edu immediately.
Remember to **Save** often, especially after any changes are made to previously entered
answers.

3.1. CREATING PROTOCOL APPLICATIONS

3.1.1. **Accessing an Original Protocol Application**

There are two ways to access a Protocol Application form. You can access protocol
application forms from the system's start page, or from the toolbar at any screen.

1. From the **Start Page**, select the **Animals Protocols** link:

2. From any screen's toolbar, select the upside down triangle to access the dropdown
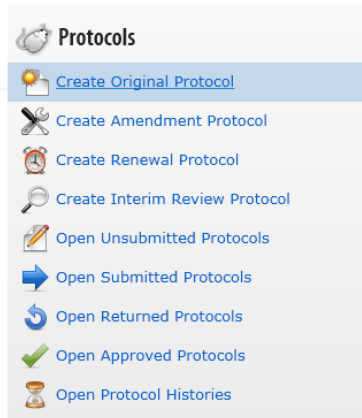menu - select Animal Protocols:

3. After you click Animal Protocols from the drop-down menu, the Animal Protocols
Toolbar and two panels appear: The Protocols Panel and the Reports Panel.
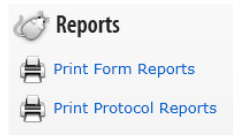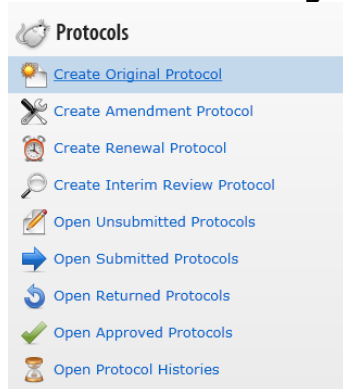
Animal Protocols Toolbar
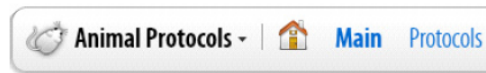
Protocols Panel

Reports Panel

Start Procedure

3.1.2. **Creating an Original Protocol Application**

1. To create an original **Protocol Application**, begin at the **Protocols Panel**.
    Select the **Create Original Protocol** link:

2. After you click the Original Protocol link, the Select Form screen appears.
    There are two ways to open the form: double click the form, or select the form by
    checking off the box to the left of the form and click the OK button.

3. The **Protocol** and **Outline** panels appear:

   Note: Protocol Outline Icon Descriptions located in *Chapter 2. General Information.*

   Protocol Outline

   Note: Protocol Outline Icon Descriptions located in the Appendix

   Protocol Panel

   Note: Protocol Panel Icon Descriptions located in the Appendix

4. Begin to create your new protocol application by answering the questions in the **Protocol Panel**.

**Note:** Remember to SAVE often while completing the protocol application.

3.1.3. **Pre-submitting Protocols**

The pre-submission process allows other staff members besides the Core Team (PI, Co-Investigator, Author, Co-Author and Creator) to review the protocol application before formal submission. When a pre-submission reviewer is chosen, it allows the appropriate user read-only access to the application.

1.　　After you save your changes, you can select the **Presubmit** icon to allow the application to be viewed by a pre-submission reviewer(s):
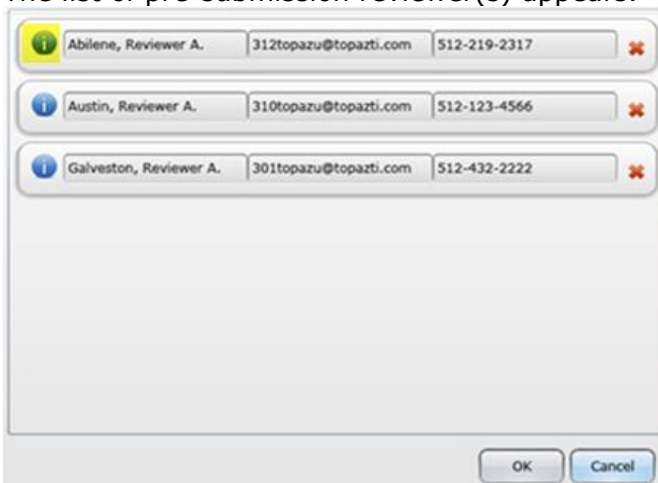

2.　　The **Set Presubmission Reviewers** screen appears. Click the Select Staff human silhouette icon for a list of staff members:
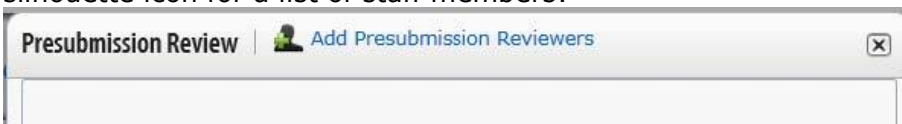
3.　　Select the staff name(s) that will receive your pre-submission protocol and select the Add button to chose the staff names. After you have chosen all reviewers click **OK**.
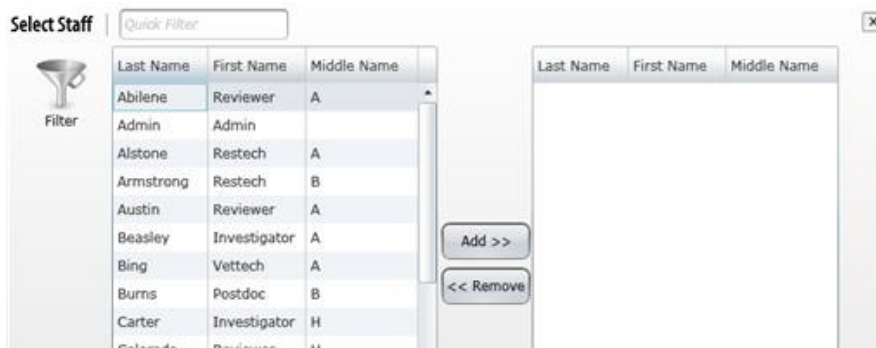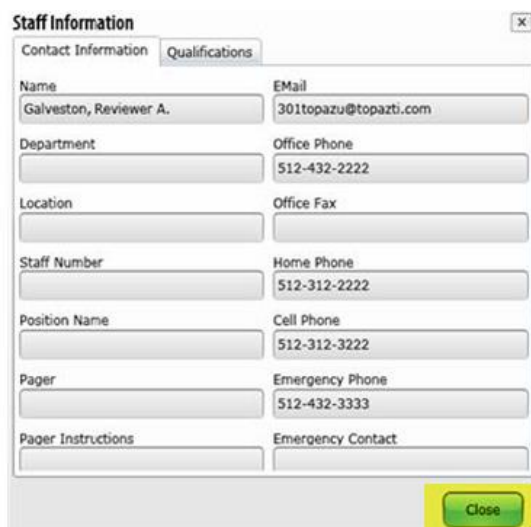

4.　　The list of pre-submission reviewer(s) appears.

5.　　To view a staff member's contact information and qualifications, select the

information button: ⓘ .

6.   Select the close button [Close] the staff information screen.

Staff Information

Contact Information	Qualifications

Name	EMail
Galveston, Reviewer A.	301topazu@topazti.com

Department	Office Phone
	512-432-2222

Location	Office Fax

Staff Number	Home Phone
	512-312-2222

Position Name	Cell Phone
	512-312-3222

Pager	Emergency Phone
	512-432-3333

Pager Instructions	Emergency Contact

[Close]

7.   Select the **Delete** button: ✳ to delete a staff name from the list, select the **OK** button to set staff names for your protocol review or select the **Cancel** button to cancel the reviewer selection process.

ⓘ	Abilene, Reviewer A.	312topazu@topazti.com	512-219-2317	✳
ⓘ	Austin, Reviewer A.	310topazu@topazti.com	512-123-4566	✳
ⓘ	Galveston, Reviewer A.	301topazu@topazti.com	512-432-2222	✳

[OK] [Cancel]

8.   After you select the **OK** button, the Pre- Submission Reviewer email template appears. You will need to enter your email address in the space provided on the email message in order for the Pre-Submission Reviewer to be able to communicate his/her comments to you.
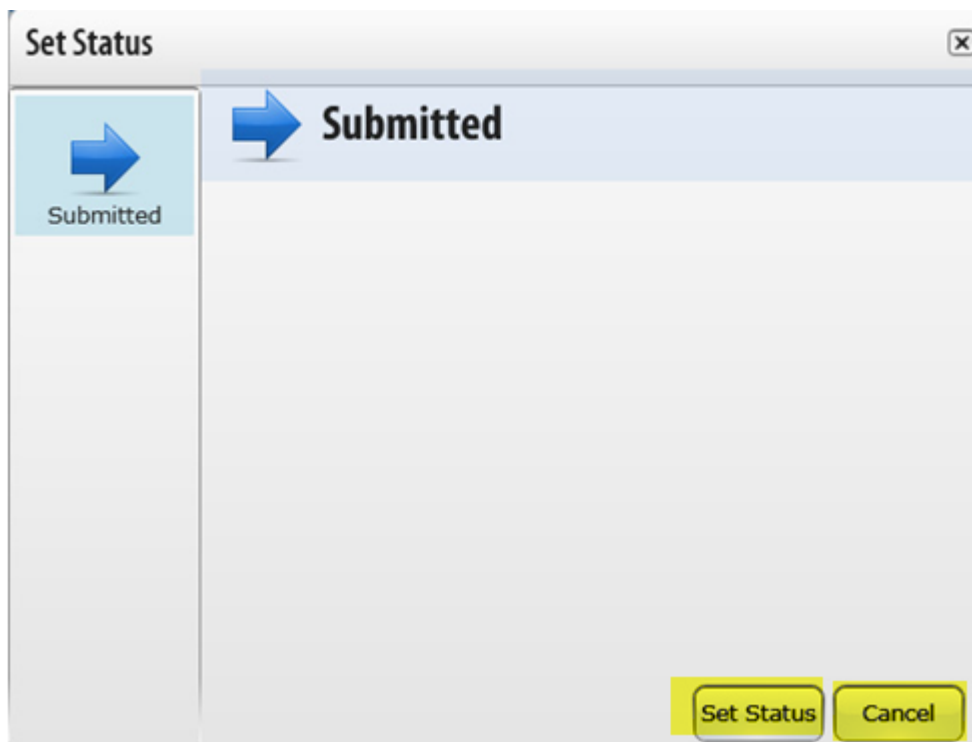
End Procedure.

3.1.4. **Formal Submissions**

Follow the steps below for Formal Submission to the Review Committee.

NOTE: Once the application has been formally submitted, you will be unable to make any modifications (unless the Coordinator returns it to you for modifications).

1. Click **Save** to save all changes.

2. Click on the **Submit** Icon.

3. The **Set Status** screen appears. Select **Set Status** to submit your application. To cancel out of this screen select the **Cancel** button.


End Procedure.

3.1.5. **Return for Modification**

After a protocol has been returned for modification you can retrieve it and make all recommended modifications. The Outline panel will help narrow your search of reviewers' comments.

1. To open a protocol that has been returned for modification, navigate to the main protocol panel and click Open Returned Protocols. Status of protocols can also be obtained in the dashboard and opened from that page as well.

2. The Select Protocol Panel opens. Select the protocol application to be modified.
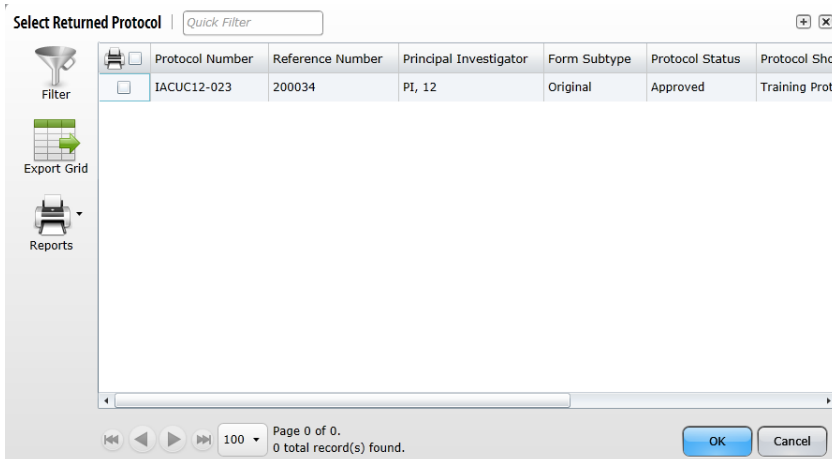
3. To locate questions that contain summary comments, select the **Questions with Summary Comments** icon, ,on the Outline panel. The Outline panel will display a list of items that have summary comments:
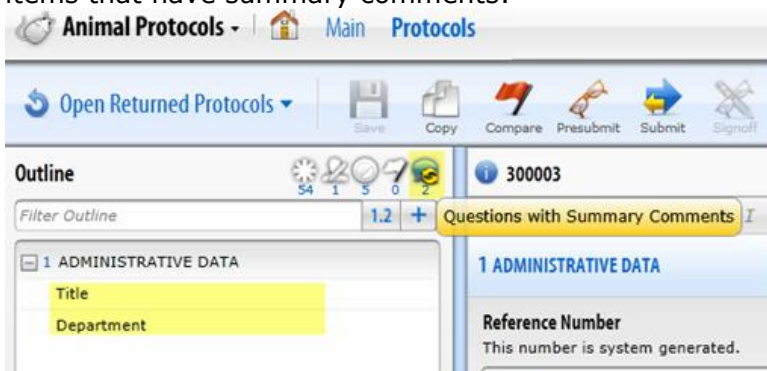
4. The summary comments will appear on the protocol panel highlighted in yellow. After you have located all the questions with comments, you can make modifications by editing the question.

5. Click **Save** to save all changes.

6. When modifications have been completed, click on the **Submit** icon to formally re-submit the application or withdraw if applicable.

Note: Once a protocol has been withdrawn, you will not be able to modify it or re-submit it, since it will be sent to protocol histories.

End Procedure.

3.1.6. <u>Creating Amendments, Renewals, and Interim Reviews for Protocols</u>

When creating an amendment, renewal, or interim review application, the system automatically creates a copy of the most recent protocol submission without needing to search through multiple versions to find the latest one to renew or amend. These applications contain an additional section at the top of the form for supplemental information, such as to provide the reason for the amendment.
Some questions may be blocked for copying. When this occurs, you must answer the affected questions again.

Note: The system <u>does not</u> allow you to submit an amendment, a renewal, or an interim submission if you already have a pending application (regardless of the type of pending application). For example, if the PI currently has an amendment under review, but has a renewal that is due soon, he/she would need to withdraw the amendment in order to submit the renewal. In such cases, the PI should contact the Coordinator to determine the best plan of action on having the protocol returned to the PI. If necessary, the Coordinator will be able to provide the investigator with an Event Reporting Form that can be submitted outside of the TOPAZ system (for situations where an Event needs to be reported immediately).

The following example is for an Amendment however you can follow the same steps for Renewals and Interim Reviews.

1. To create an amendment, navigate to the **Protocols** panel, and click on **Create Amendment Protocol**.

2. A list of original protocols appears. Select the protocol requiring the amendment.

3. Select the **OK** button to open the protocol.

4. At the **Select Form** screen, click on the amendment form:

5. Select the **OK** button to open the amendment. Fill out the amendment section of the form and enter modifications to the body of the application. When completed, save and submit amendment application for approval.

End Procedure.

Note: To create **Renewal and Interim Review Applications**, repeat the steps 2 through 5 above.
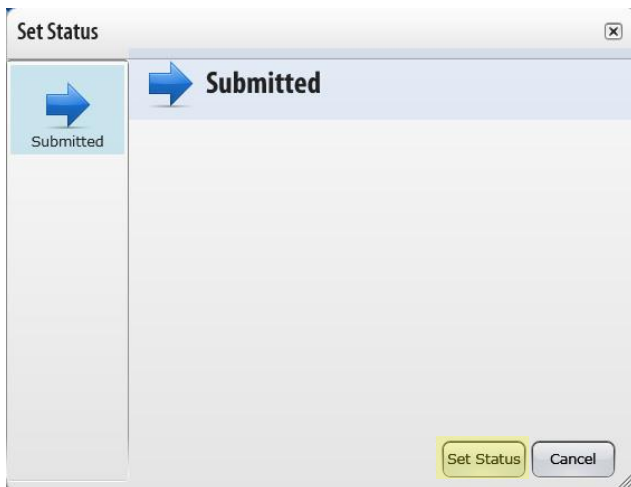
3.1.7. **Open Unsubmitted Protocols**

1. To work with protocols that have not been submitted and are in draft form, navigate to the **Protocols** panel. Select the link - **Open Unsubmitted Protocols.**
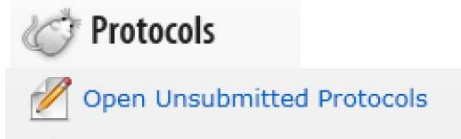
2. The **Select Protocol** screen appears displaying a list of unsubmitted protocols. To open the protocol application, double click the application, or select the application and click the **OK** button. (Unsubmitted Protocols can also be accessed from the Dashboard.)

3. After you have completed filling out the protocol application click **SAVE**.

4. Select the **Submit/Withdraw** icon, to submit the protocol. After selecting the **Submit/Withdraw** icon, the Set Status panel appears. Select the Set Status button at the bottom to formally submit the application.

End Procedure.

3.1.8. <u>**Accessing Read Only Protocols**</u>

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 application.

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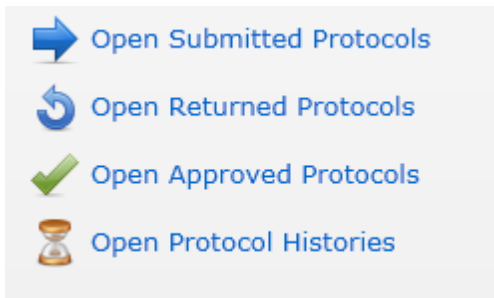
2. The **Select Protocol** panel appears. Select the protocol to be viewed or compared.
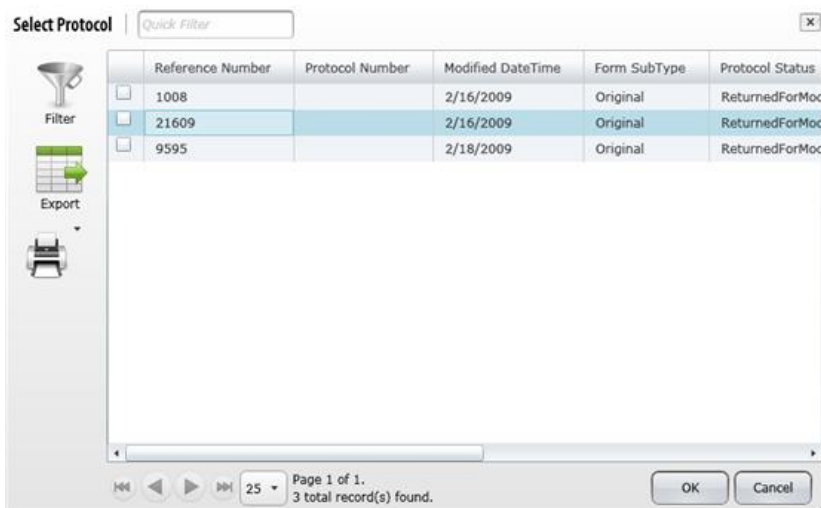
End Procedure.

3.1.9. **Copying Information from Another Protocol**

It is possible to copy information from an existing protocol into in a new original application. This can be useful when you have a similar protocol that you would like to utilize for a new original submission. You can copy from a protocol that you're associated with, so long as it is classified as "not submitted", "submitted" or "approved".

Note: It is important that the copy be done prior to completing the questions in the new original application form. Otherwise, the information that you have already inputted into the new original application form will be overwritten with the information from your existing protocol.

1. Create an original application and select **SAVE**.

2. To copy the answers from another form, select the copy icon:

Copy

3. The copy dialogue appears indicating that all information from another protocol will replace all matching questons. To proceed with the copying process, click the **OK** button.

Copying answers from another protocol will replace ALL matching answers. Do you want to continue?

OK   Cancel

4. Be sure to scroll through the new protocol application to check the information that was populated. Update any information as needed.

End Procedure.