

IRB Topaz Elements Overview

This document provides guidance in the following areas:

- Creating an IRB Protocol Application
- Managing an IRB Application Request that has been returned for modification
- Creating an IRB Amendment, Renewal, or Interim Application
- Pre-submitting Protocols
- Copying Information from Another Protocol

Please reference the Office of Research and Economic Development Topaz website found at: <http://research.fiu.edu/irb/topaz/> for assistance logging into Topaz.

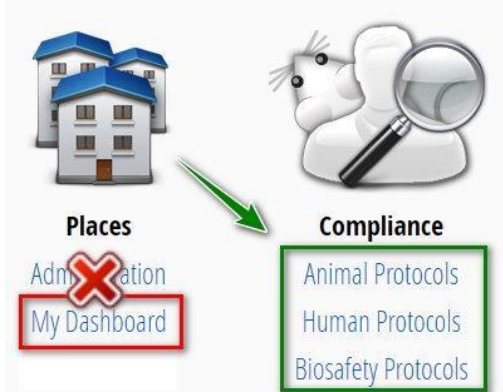
The Topaz online protocol submission system is located at: <https://topaz.fiu.edu>.

If you encounter any technical issues (i.e., logging on, error message) please stop and contact topaz-help@fiu.edu.

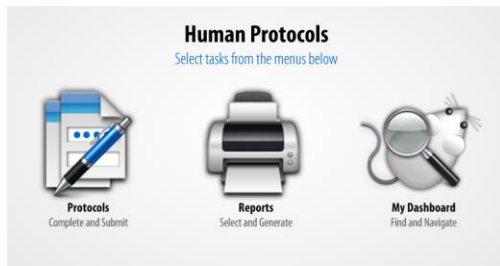
Remember to **Save** often, especially after any changes are made to previously entered answers.

Creating an IRB Protocol Application

1. Once logged in to topaz.fiu.edu with your MyAccounts login information (i.e., Panther ID and password), select **Human Protocols**. Do **NOT** select **My Dashboard**:



2. Select **Protocols** located under the Human Protocols header (There is also a dropdown menu which can be selected to navigate to the Human Protocols).



3. Select **Create Original Protocol** under the Protocols section.

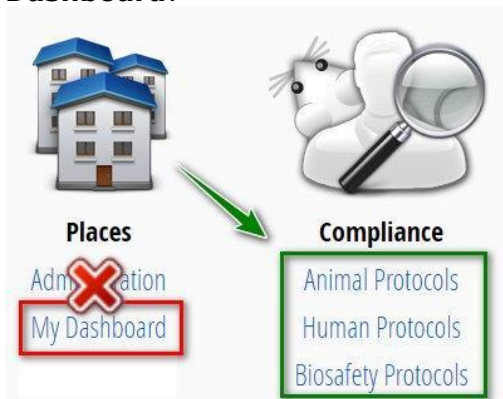


4. Select the appropriate **Form**.
5. Populate required information for each section of the protocol request and select the **Save** icon (💾). Make sure to **save often**.
6. The Required question filter icon (🔴) on the Protocol Outline indicates the questions that must be completed prior to submitting the protocol application.
7. The Unanswered question filter icon (🔴) on the Protocol Outline indicates the questions which have not been completed. (They are updated after completed and saved).
8. The View Help icon (❓) appears in the upper right hand corner throughout select questions. Selecting this icon will provide helpful information for the particular question.
9. The Add icon (+) appears in the upper right hand corner throughout select questions. Selecting this icon will provide a predefined list to choose information from.
10. Select questions may require you to add staff from a predefined list. Select the (👤) icon and a list of staff will appear to choose from.
11. Select questions may require you to add an attachment. Select the (📎) icon on those questions to add an attachment when necessary for completing the application.
12. Throughout the protocol application, there may be conditional questions indicated by a (⊕) in the outline and numbering sequence in either the outline or main panel (i.e. [1.10.1.1](#)).

13. On select questions, you may see an E-signature icon (). Once this question has been populated and saved, the signature box will appear. Enter the currently logged in user's TOPAZ **User Name** (Panther ID) and **Password**.
Note: The Assurance Statement e-signature question must be completed by the Principal Investigator.
14. Select the **Save** icon ().
15. Select on the **Submit** icon () to submit the application.

Managing an IRB Application Request that has been returned for modification


1. Once logged in to topaz.fiu.edu, select **Human Protocols**. Do **NOT** select **My Dashboard**:



2. Select **My Dashboard**:

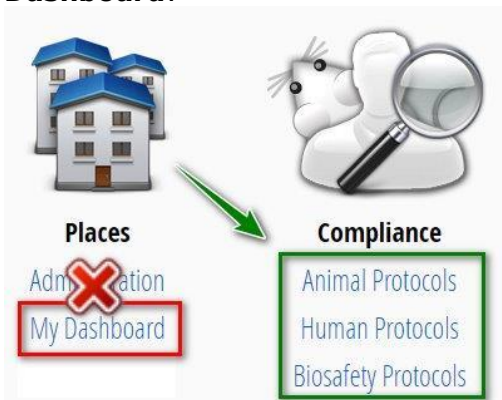


3. On the **Dashboard**, select a protocol request with **status of "Returned for Modification."**
4. Select the Questions that require modifications by selecting the Summary Comments filter icon () in the Protocol Outline.

- Each question requiring a review and possibly modification will have a yellow field containing the comment next to the question. After viewing the *Comment Summaries*, make the recommended modifications and select **Save**.
- Select on the **Submit** icon () to submit the application.

Creating an IRB Amendment, Renewal, or Interim Application

- Once logged in to topaz.fiu.edu, select **Human Protocols**. Do **NOT** select **My Dashboard**:



- Select **Protocols** located under the Human Protocols header (There is also a dropdown menu which can be selected to navigate to the Human Protocols).
- Select the Application being created: **Create Amendment Protocol, Create Renewal Protocol, or Create Interim Review Protocol**:



- Select the protocol that you would like to use.
- Select the appropriate form.
- Complete the upper section of the application. If requesting changes, update the applicable lower sections of your application to reflect your proposed changes.

7. Select **Save**.

8. Select on the **Submit** icon () to submit the application.

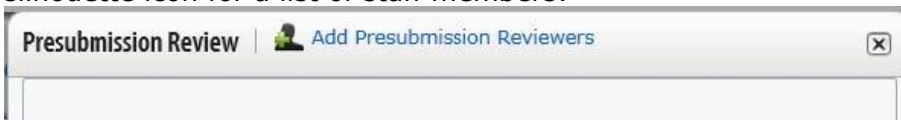
Pre-submitting Protocols

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.

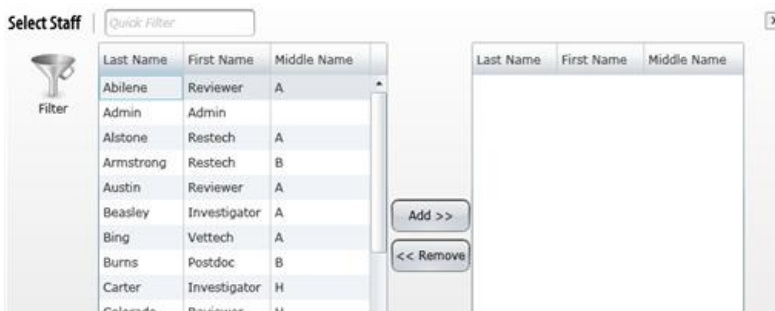
1. After you save your changes, you can select the **Presubmit** icon to allow the application to be viewed by a pre-submission reviewer(s):



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 choose the staff names. After you have chosen all reviewers click OK.





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

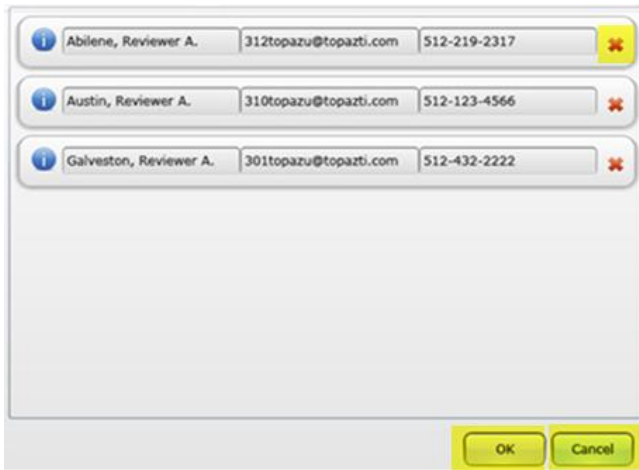


- To view a staff member’s contact information and qualifications, select the information button:



- Select the close button  the staff information screen.

- 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.



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.

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:



3. The copy dialogue appears indicating that all information from another protocol will replace all matching questions. 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.