

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

It is highly recommended to become familiar with the Full Guide prior to utilizing this Quick Reference Guide.

Please reference the Division of Research Topaz website found at: <http://research.fiu.edu/irb/pages/topaz.html> for assistance logging into Topaz. The Topaz online protocol submission system is located at: <https://topaz.fiu.edu>.







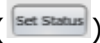
If you encounter any technical issues (i.e., logging on, error message) please stop and contact topaz-help@fiu.edu.

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




Creating an IRB Protocol Application

1. Start Page
2. Select **Protocols** located under the Animals header (There is also a dropdown menu on the Start Page which can be selected to navigate to the Animals Protocols).
3. Select **Create Original Form** 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.

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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/Withdraw** icon () to submit or withdraw the application.
16. Select the **Set Status** button ()



Managing an IRB Application Request that has been returned for modification

1. On the **Dashboard**, select a protocol request with **status of "Returned for Modification."**
2. Select the Questions that require modifications by selecting the Summary Comments filter icon () in the Protocol Outline.
3. Each question requiring a review and possibly modification will have a yellow field containing the comment below the question. After viewing the *Comment Summaries*, make the recommended modifications and select **Save**.
4. To resubmit the protocol request, select on the Submit/Withdraw icon () . Select the **Set Status** button to submit ()

Creating an IRB Amendment, Renewal, or Interim Application

1. **Start Page**
2. Select **Protocols** located under the Animals header (There is also a dropdown menu on the Start Page which can be selected to navigate to the **Animal Protocols**).

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- 3.** Select the Application being created: **Create Amendment Protocol, Create Renewal Protocol, or Create Interim Review Protocol.**
- 4.** Select the protocol that you would like to use.
- 5.** Select the appropriate form.
- 6.** 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 the Submit/Withdraw icon (). Click the **Set Status** button () to submit.