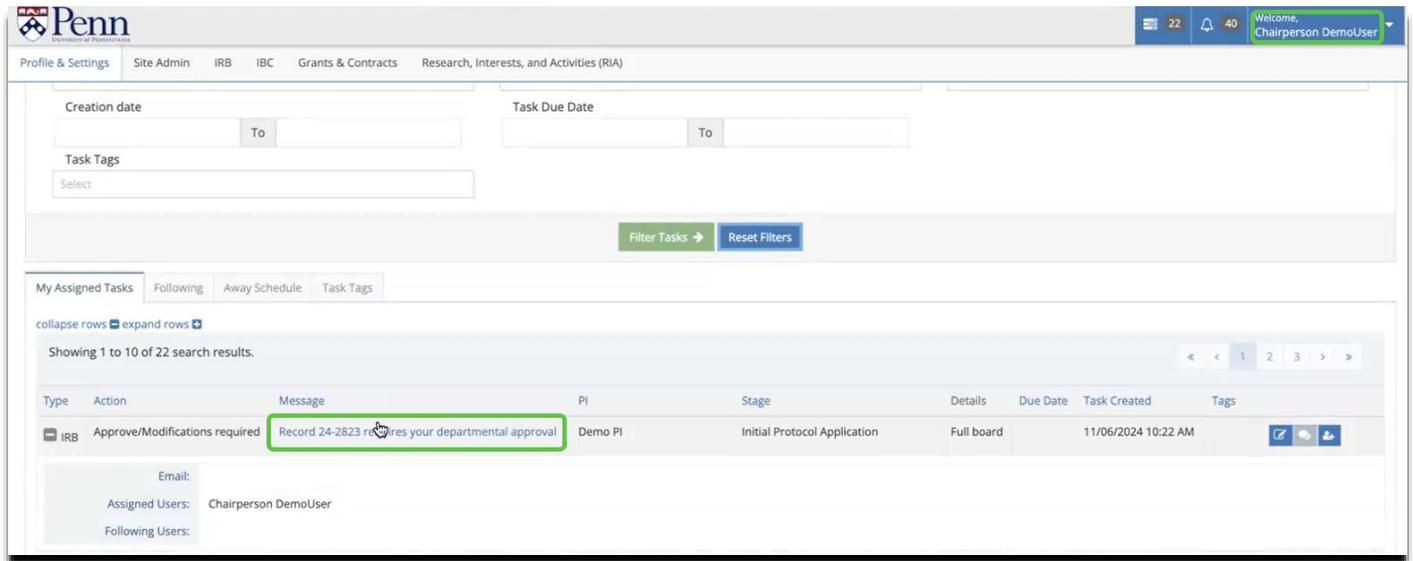


**Penn eIRB Overview:  
PI Approval Process for Initials, Amendments, and Continuing Reviews**

## Reviewing a New IRB Protocol (Principal Investigator Perspective)

When the eIRB application has been completed and is submitted, the Principal Investigator (PI) will receive a task to review and approve the protocol.

In the eIRB Menu, go to IRB tasks. You will have a task similar to the one below in the screenshot. It will say [Submission type, e.g., Initial] Submission for IRB Protocol ##-#### requires your PI approval.



The screenshot displays the eIRB application interface. At the top, there is a navigation menu with options like 'Profile & Settings', 'Site Admin', 'IRB', 'IBC', 'Grants & Contracts', and 'Research, Interests, and Activities (RIA)'. Below the menu, there are search filters for 'Creation date' and 'Task Due Date', along with a 'Task Tags' dropdown. A 'Filter Tasks' button and a 'Reset Filters' button are visible. The main content area shows 'My Assigned Tasks' with tabs for 'Following', 'Away Schedule', and 'Task Tags'. A table of tasks is displayed, with the following columns: Type, Action, Message, PI, Stage, Details, Due Date, Task Created, and Tags. The first task is highlighted with a green box:

Type	Action	Message	PI	Stage	Details	Due Date	Task Created	Tags
IRB	Approve/Modifications required	Record 24-2823 requires your departmental approval	Demo PI	Initial Protocol Application	Full board		11/06/2024 10:22 AM	

Below the table, there is a section for 'Email:' and 'Assigned Users: Chairperson DemoUser'.

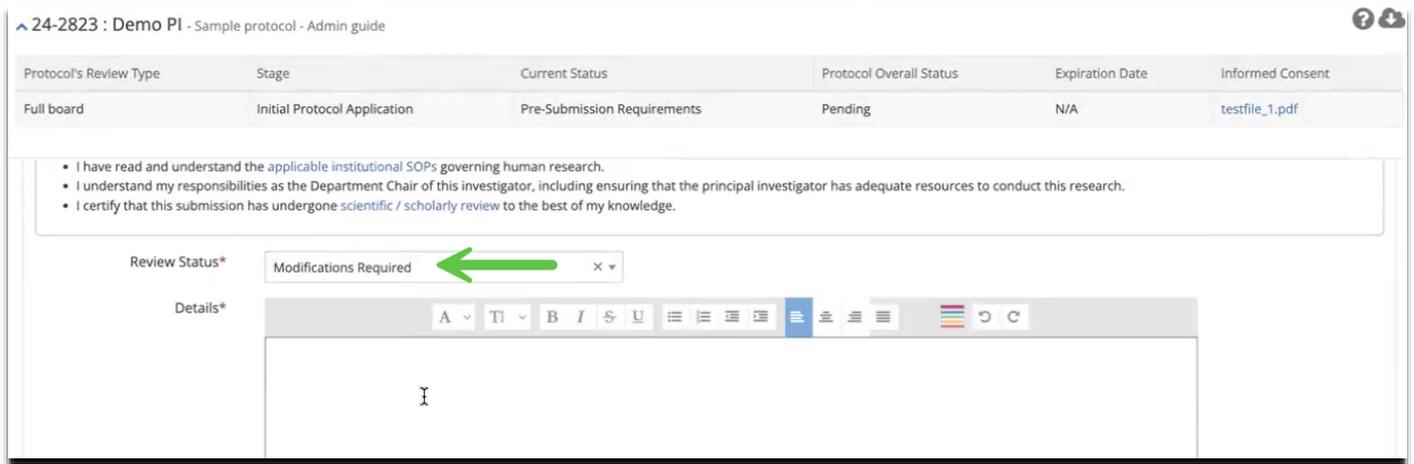
Upon clicking on that task message, the PI can review the protocol submission. Once the PI's review is complete, they can use the left hand menu to navigate back to the top of the eIRB application.

An approval form to document their review should be at the top of the application. The PI can select one of two options:

- Modifications Required
- Approved

If **Approved** is selected, the application moves to the Department Chair for review. The task to review should leave the PI's task list upon refresh.

If **Modifications Required** is selected, the protocol goes back to the study team to revise. In the Details box, the PI can add details regarding why the record is being sent back and what is required.



Using the left hand menu to navigate to the Requirements panel, the study team can see the workflow. If the study team clicks on the Modifications required blue text, the comments from the details box will appear. Click Submit.

The protocol is now unlocked for the requested changes to be made. The study staff should **address review comments and resubmit**. Upon executing the requested changes, the study team will select “Review and Submit.”

Status	Requirement	Completion State	Revision	Completed by	Completed Date
Draft Submission Pending	Submit Protocol	✓Completed	#1.1	PI, Demo	11/06/2024 10:22 AM
PI Certification Pending	Certify Protocol (PI)	✓Completed	#1.1	PI, Demo	11/06/2024 10:22 AM
Pre-Submission Requirements	Approval by Department Chair: Chairperson DemoUser	✓Modifications required - Modifications Required #1.1		DemoUser, Chairperson	11/06/2024 10:27 AM
	Address review comments and resubmit	Ready to Start			
	Department Approve Revised Protocol	Not Ready to Start			
Pre-Approval Requirements	Ancillary Human Stem Cell Research Advisory Committee review	Ready to Start			
	Complete Human Subjects training on Citi: Demo PI	Ready to Start			
	Complete COI Disclosure: Demo PI	Ready to Start			

They can then view the “IRB Protocol Comparison View” page where the study team can see the changes that were made side-by-side. Revisions are called out and text changes are highlighted.

Additional changes can be made by selecting the “Continue Editing” button. Clicking Confirm and Resubmit will send the protocol back to the PI for re-review.

### IRB Protocol Comparison View

[Go back to current record](#)

Your changes have been saved but THIS RECORD HAS NOT YET BEEN SUBMITTED FOR APPROVAL. Please review your changes from the previous submitted version, reflected below. If you need to make additional modifications, go back to input those changes before submitting. Otherwise, please confirm your submission.

[CONTINUE EDITING](#)

[CONFIRM AND SUBMIT](#)

collapse all | expand all

#### Requirements

##### Revisions You Are Comparing

Title: Sample protocol - Admin guide  
Revision #: #1.1  
Stage: Initial Protocol Application  
Status: Pre-Submission Requirements  
Date: 11/06/2024 10:22 AM

Title: Sample protocol - Admin guide  
Revision #: #1.2  
Stage: Initial Protocol Application  
Status: Pre-Submission Requirements  
Date: 11/06/2024 10:27 AM

#### Review Comments

Review comments for revision #1.1.

Revision

#1.2

#### Protocol Description

Discuss the patient's diagnosis and disease status  
Demo

Please detail rationale for the investigational treatment and why the investigational product is preferable over available treatment options. This should include an assessment of the risks in relation to the potential benefit.

Demo

Discuss the patient's diagnosis and disease status  
Demo updated

Please detail rationale for the investigational treatment and why the investigational product is preferable over available treatment options. This should include an assessment of the risks in relation to the potential benefit.

New Change

#### Privacy & Confidentiality