

Step-by-Step Process for Submission of a PI Change

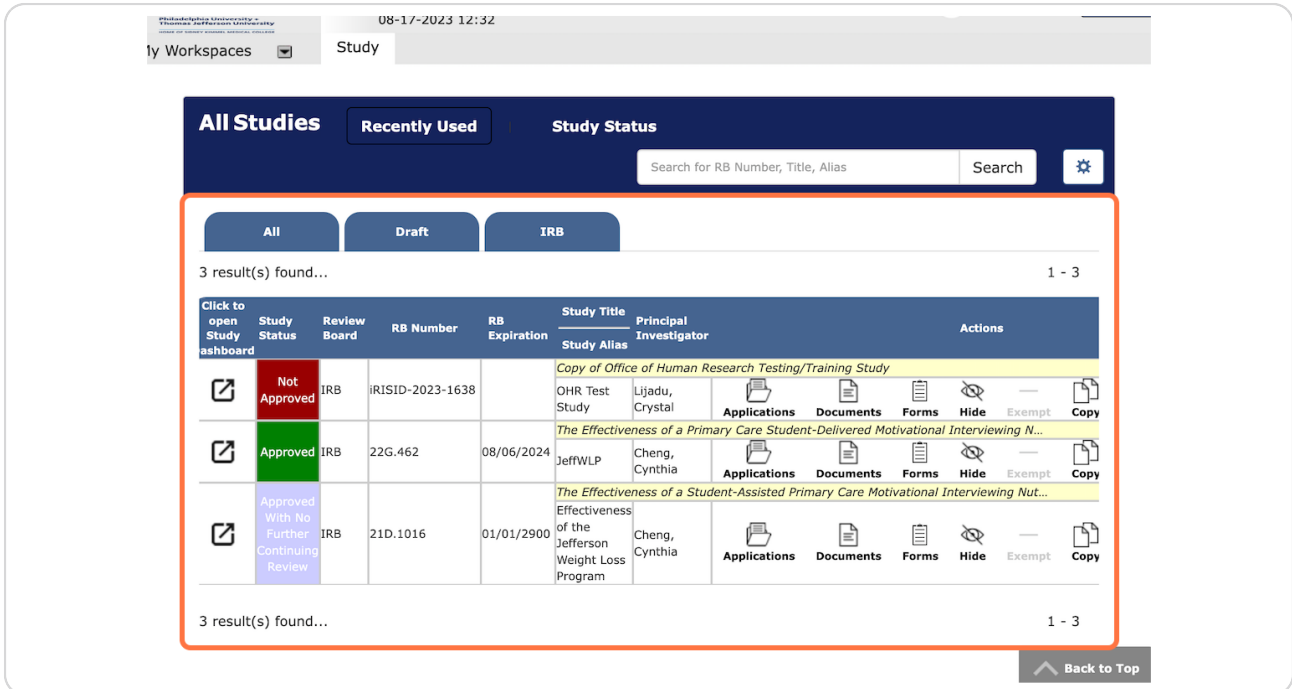
16 Steps [View most recent version on Tango.us](#) 

Created by
Steven Muller

Creation Date
August 17, 2023

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August 17, 2023

STEP 1

Navigate to the All Studies section of the homepage.

08-17-2023 12:32






















Study

All Studies Recently Used Study Status


Search for RB Number, Title, Alias Search

All Draft IRB

3 result(s) found... 1 - 3

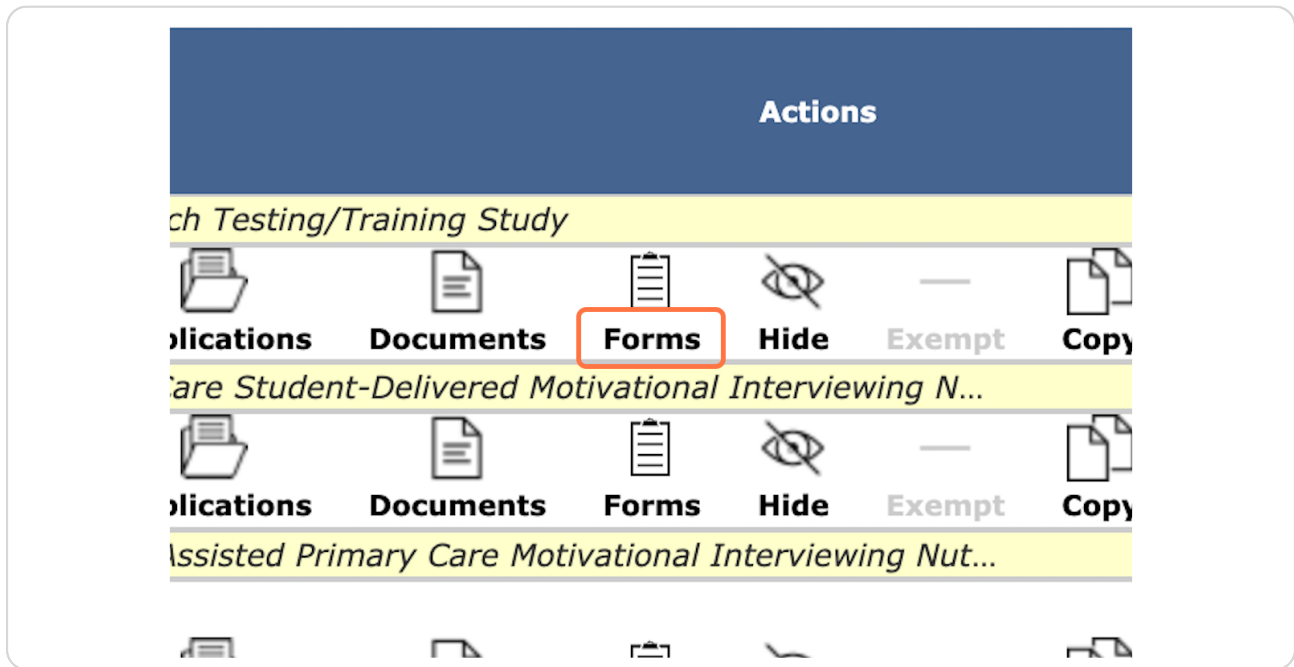
Click to open Study Status	Study Status	Review Board	RB Number	RB Expiration	Study Title	Principal Investigator	Actions
					Study Alias		
	Not Approved	IRB	iRISID-2023-1638		Copy of Office of Human Research Testing/Training Study	OHR Test Study	     
	Approved	IRB	22G.462	08/06/2024	The Effectiveness of a Primary Care Student-Delivered Motivational Interviewing N...	JeffWLP	     
	Approved With No Further Continuing Review	IRB	21D.1016	01/01/2900	The Effectiveness of a Student-Assisted Primary Care Motivational Interviewing Nut...	Effectiveness of the Jefferson Weight Loss Program	     

3 result(s) found... 1 - 3

 Back to Top

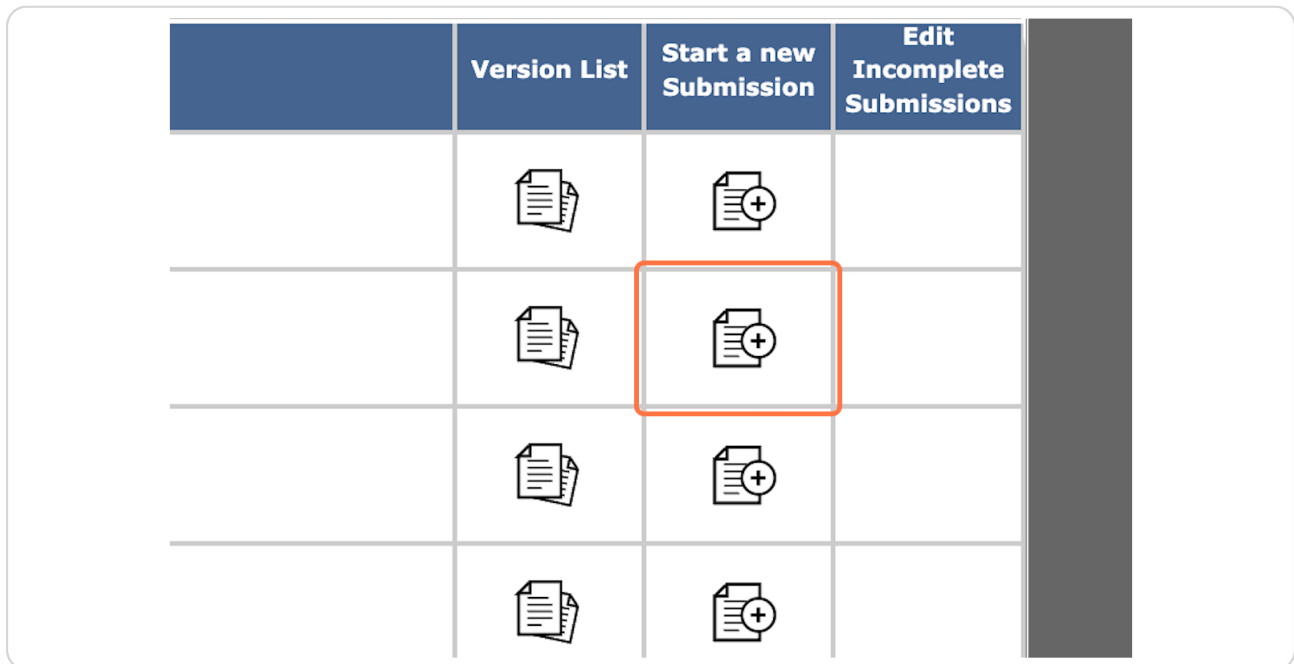
STEP 2

Click on Forms.



STEP 3

Start a new Amendment to Research Protocol form



STEP 4

The first page just has information, click on Save and Continue to Next Section.

Help My Profile Log out

Search Protocol - Back

Save Section Save and Continue to Next Section

a Jefferson Principal Investigator, Co-

STEP 5

Click on Change of Principal Investigator (PI) to indicate the Amendment contains a PI Change.

Entire view of the Form

2.0 Office Of Human Research Amendment to Research Protocol (OHR-12)

2.1 This amendment contains:

- ☐ Revision to consent form only
- ☐ Revisions to Master Application and/or Separate Protocol
- ☐ Revisions to Master Application/Protocol and Consent Form
- ☐ Addition of Non-Jefferson site(s) and/or Investigators*
- ☒ Change of Principal Investigator (PI)
- ☐ Other (e.g., advertising, supplementary materials, etc.)

2.2 Financial Information:

ORA ACCOUNT NUMBER (if applicable):

DEPARTMENT CHARGE CODE:

2.3 Summarize key points of the amendment separating major and minor changes:

STEP 6

Attach the Master Application

Note: The master application will not be immediately change to reflect the PI change. However, it will update the next time you create a new version.

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

Form

Entire view of the Form

Search

3.0 Attach Application and Document Uploads

in

3.1 Attach the application and make modifications

ent to

Click here to attach the application.

No Application has been associated with this submission.

The study application must be included with the amendment application. Attach the study application here. If you have not already created a study application, you must create it before you can attach it here. **You cannot proceed with the amendment application until the study application has been attached in this section.**

If modification to the study application is part of the amendment, you can make the modifications in the study application once it has been attached. If you are creating the study application for the first time, you will not be able to indicate your revisions in the application itself. In this case, please be sure to clearly describe these modifications in section 2.3 of this amendment.

and

3.2 If applicable, attach revised consent form(s) below:

Select or Revise Existing

Add a New Consent

Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
No Consent(s) have been attached to this form.								

STEP 7

Add a New Consent forms with new PI identified (if applicable).

Print Friendly

Refresh Constant Fields

Save Section

Save and Continue to Next Section

Form

Entire view of the Form

Search

3.2 If applicable, attach revised consent form(s) below:

in

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ent to

Select or Revise Existing

Add a New Consent

Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
No Consent(s) have been attached to this form.								

and

3.3 If applicable, attach document(s) below:

Add a New Document

Add Multiple Documents

Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

STEP 8

Include any documents where the new PI will need to be identified.

This may include protocols, flyers, contact cards, etc.

Entire view of the Form

If modification to the study application is part of the amendment, you can make the modifications in the study application once it has been attached. If you are creating the study application for the first time, you will not be able to indicate your revisions in the application itself. In this case, please be sure to clearly describe these modifications in section 2.3 of this amendment.

3.2 If applicable, attach revised consent form(s) below:

Select or Revise Existing Add a New Consent

Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
No Consent(s) have been attached to this form.								

3.3 If applicable, attach document(s) below:

Documents may include the revised protocol, a detailed summary of changes, and other relevant revised documents.

Add a New Document Add Multiple Documents

Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

STEP 9

Click on Save and Continue to Next Section.

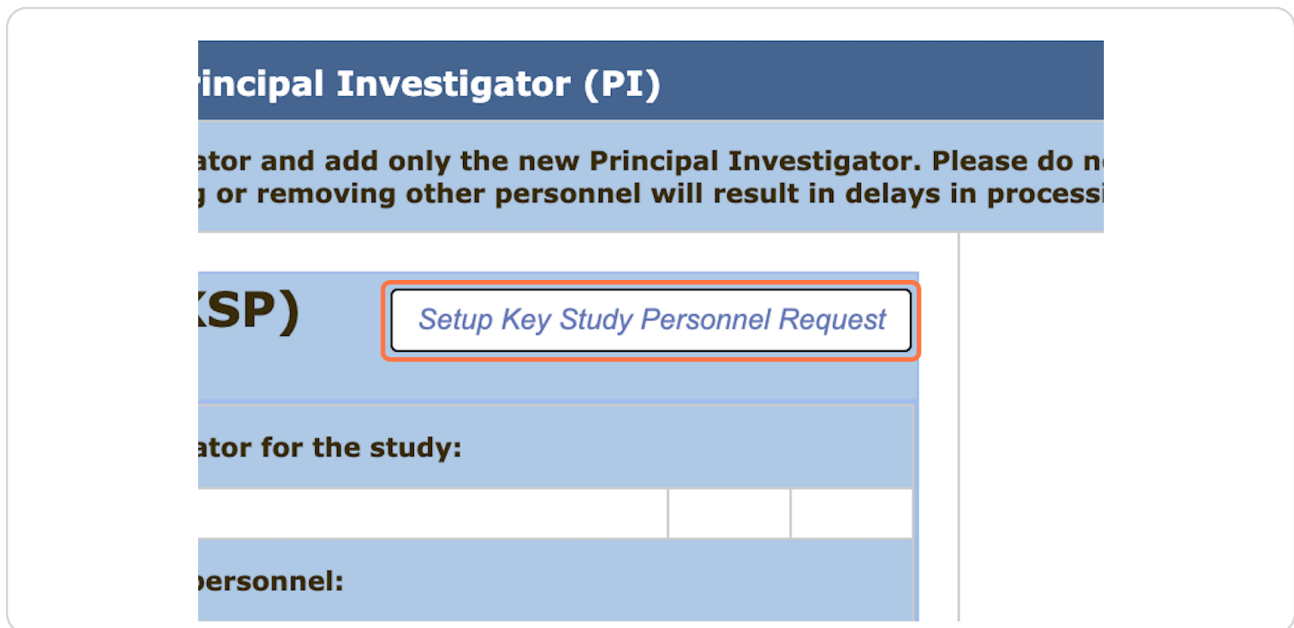
Search Protocol - **Back**

Save Section **Save and Continue to Next Section**

Make the modifications in the study application for the first time, you will not be able to indicate your revisions in the application itself. In this case, please be sure to clearly describe these modifications in section 2.3 of this amendment.

STEP 10

Click on Setup Key Study Personnel Request.



Principal Investigator (PI)

Investigator and add only the new Principal Investigator. Please do not add or removing other personnel will result in delays in processing.

(KSP)

[Setup Key Study Personnel Request](#)

Investigator for the study:

Name	Role

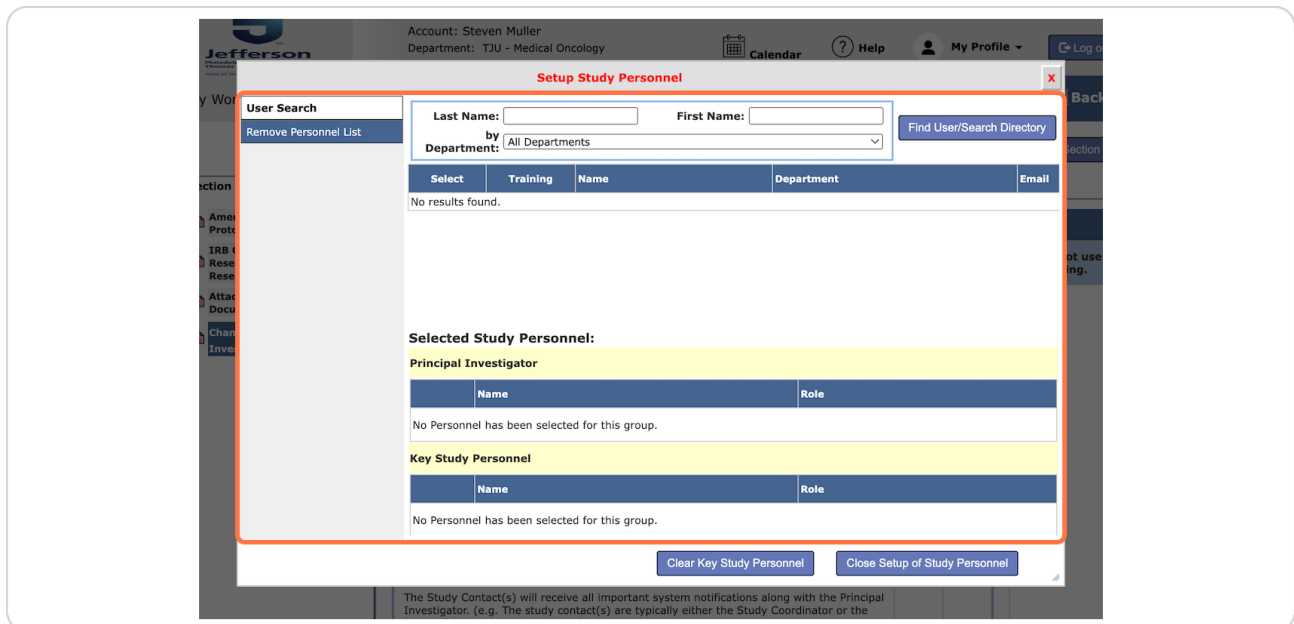
Personnel:

Name	Role

STEP 11

Indicate the New Principal Investigator.

Please do not add any other research personnel in this area unless the PI is remaining on the study as a Co-Investigator.



Account: Steven Muller
Department: TJU - Medical Oncology

Calendar ? Help My Profile Log out

Setup Study Personnel

User Search
Remove Personnel List

Last Name: First Name: Find User/Search Directory
by Department: All Departments

Select	Training	Name	Department	Email
No results found.				

Selected Study Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Key Study Personnel

Name	Role
No Personnel has been selected for this group.	

Clear Key Study Personnel Close Setup of Study Personnel

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the

STEP 12

Click on Remove Personnel List.

The screenshot shows the Jefferson University portal interface. At the top, the account information is displayed: "Account: Steven Muller" and "Department: TJU - Medical Oncology". The main navigation bar includes "My Work" and "Setup Study P". A dropdown menu titled "User Search" is open, with the option "Remove Personnel List" highlighted. Other options in the menu are "Create My Personnel Pool" and "Create My Personnel Pool". To the right of the dropdown, there are search filters: "Last Name: gerwitz" and "Department: All Departments". Below these filters is a table with columns "Select", "Training", and "Name". The table contains one row with a person icon, a graduation cap icon, and the name "Gerwitz, G". At the bottom of the page, the text "Selected Study Personnel:" is visible.

STEP 13

Remove the old Principal Investigator

If you notice there are additional personnel who should be removed, please submit a separate personnel change. This will allow the proper documentation and outcome letter to be issued.

The screenshot shows a "Save Selections" dialog box. At the top, there is a "Save Selections" button. Below the button is a table with the following structure:

Role on the Study
Principal Investigator
Study Contact
Study Contact
Study Contact
Study Contact
Study Contact

The "Principal Investigator" role is highlighted with a red border. The dialog box also includes a "Calendar" button at the top left and a "Back" button at the top right.

STEP 14

Click on Close Setup of Study Personnel

The screenshot shows a web form titled "Setup Key Study Personnel Request". It features two identical sections, each with a yellow header bar and a blue header bar labeled "Role". The first section contains the text "Study Contact". At the bottom of the form, there is a blue button labeled "Personnel" and a button labeled "Close Setup of Study Personnel" which is highlighted with a red rectangle.

STEP 15

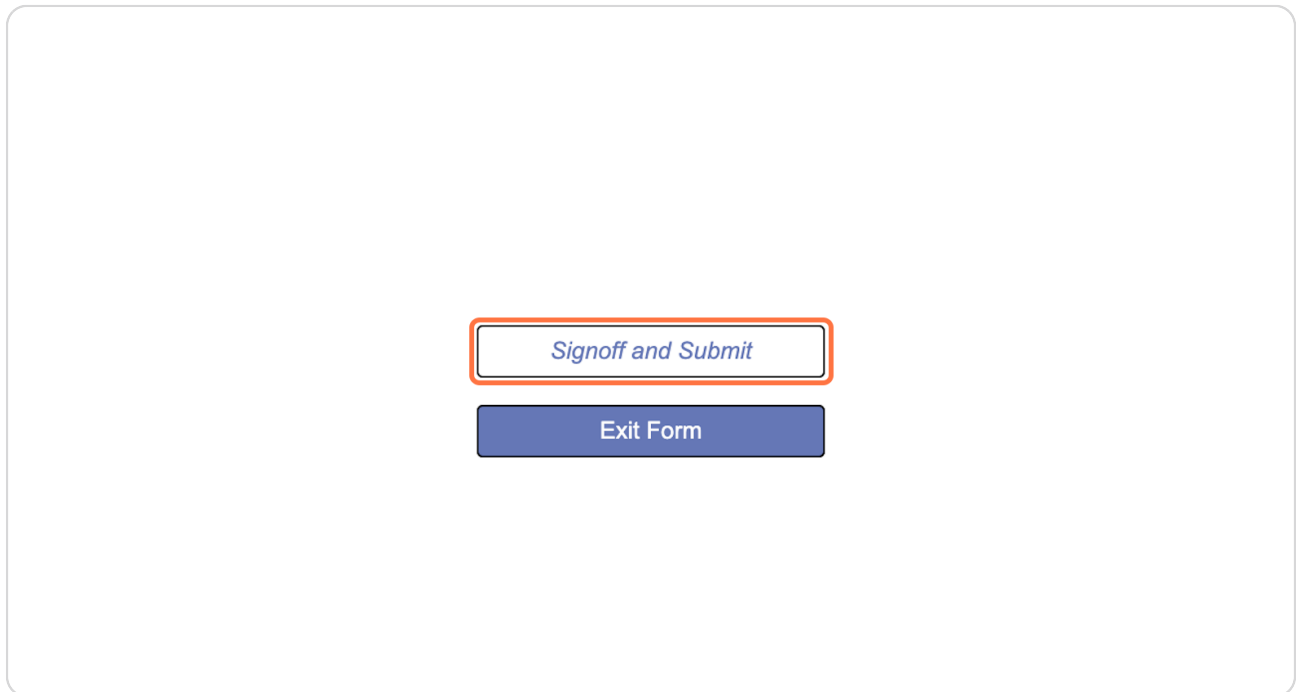
Click on Save and Continue to Next Section

The screenshot shows a web form titled "Search Protocol -". It has a top navigation bar with a "Help" icon, a "My Profile" dropdown menu, and a "Log out" button. Below the title bar, there is a "Back" button. At the bottom of the form, there are two buttons: "Save Section" and "Save and Continue to Next Section", with the latter highlighted by a red rectangle. A blue bar at the bottom of the page contains the text "Setup Key Study Personnel Request".

STEP 16

Click on Signoff and Submit

This submission should be routed to the new PI for signoff. If the new PI is from a different department, the department chair and business administrator of the new PI.



The image shows a form interface with two buttons centered on the page. The top button is white with a thin orange border and contains the text "Signoff and Submit" in a blue, italicized font. The bottom button is solid blue with white text that reads "Exit Form".