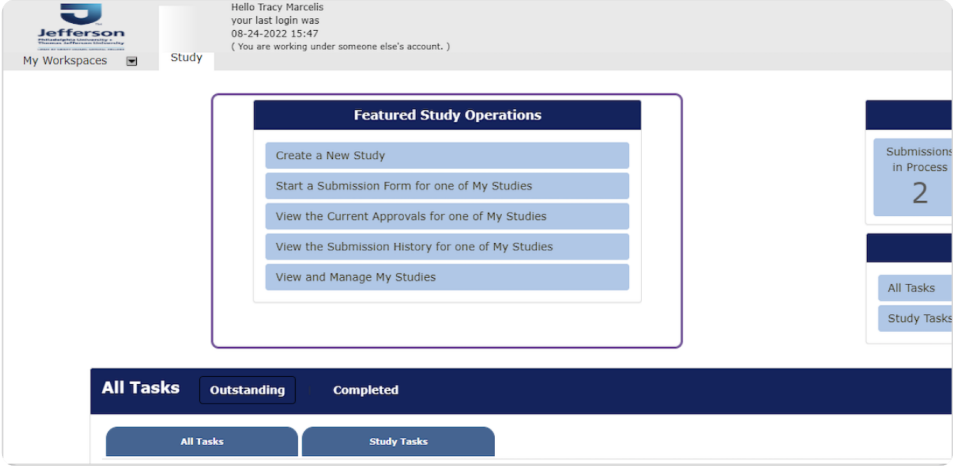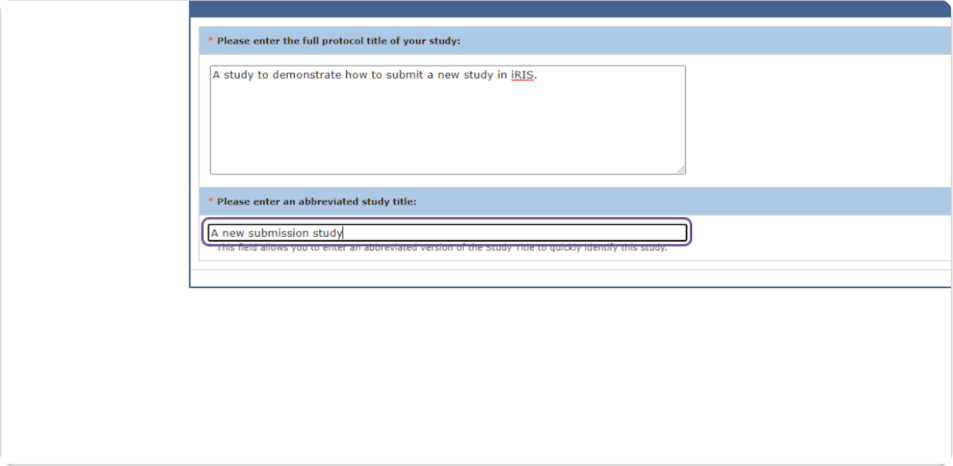# Submitting a New Study

⚠️ **The following workflow is intended to walk a user through submitting a New Study for review. Although this walks a user through an exempt study submission, the basics stay the same for all submissions.**

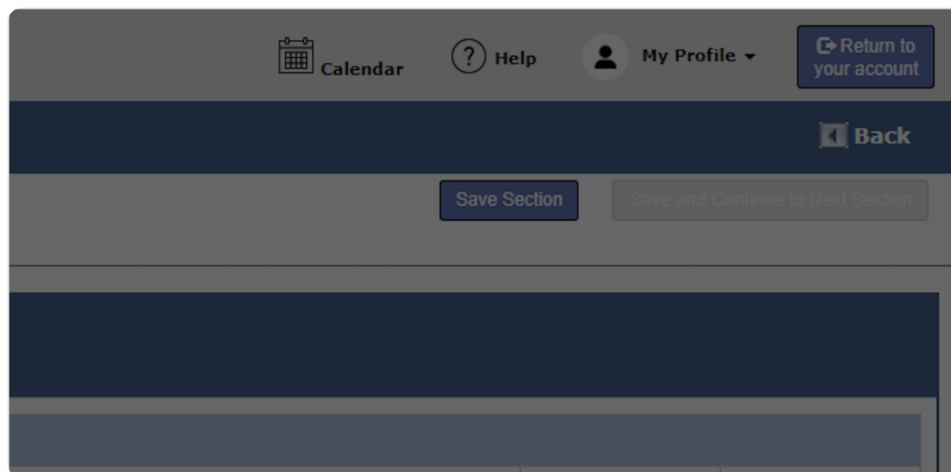**Step 1: From the homepage, locate Featured Study Operations and click Create a New Study.**

Step 2: Enter the full protocol title and the abbreviated title.

Step 3: Click on _Save and Continue to Next Section._
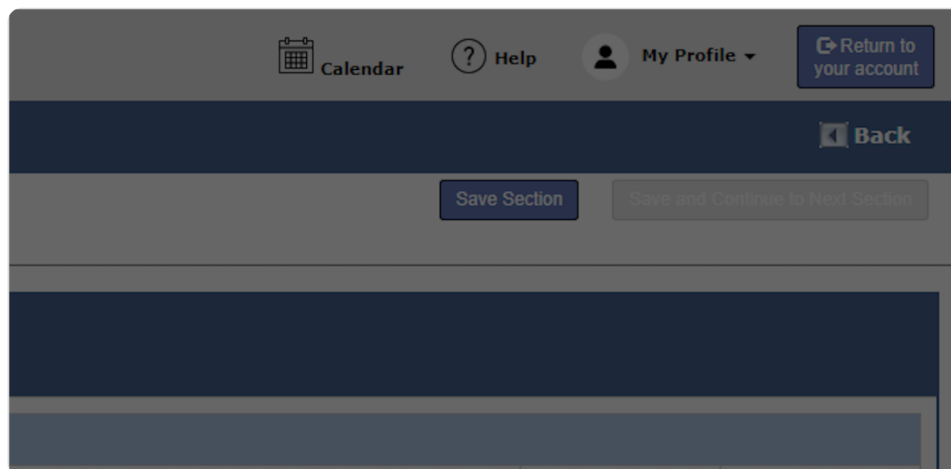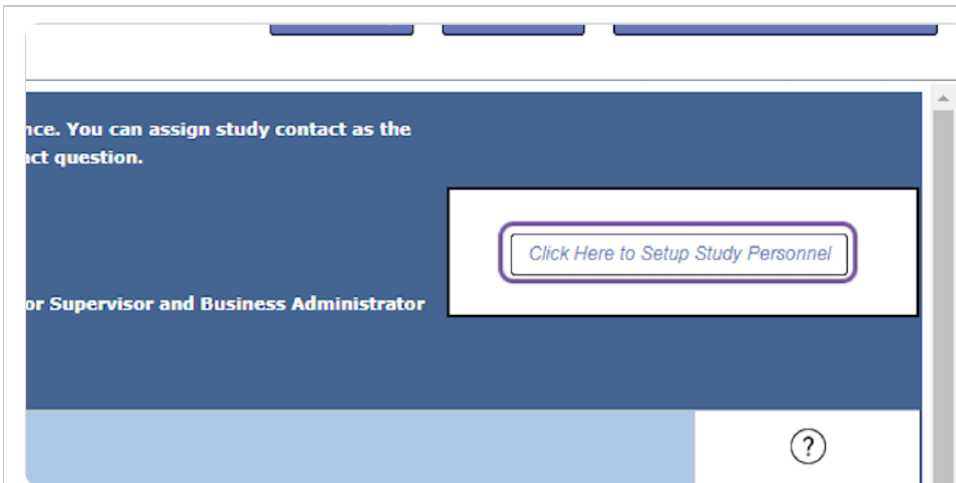
Step 4: Ensure the department displayed is correct. *If you see the message that is displayed below, please Add Department and select the appropriate department.*
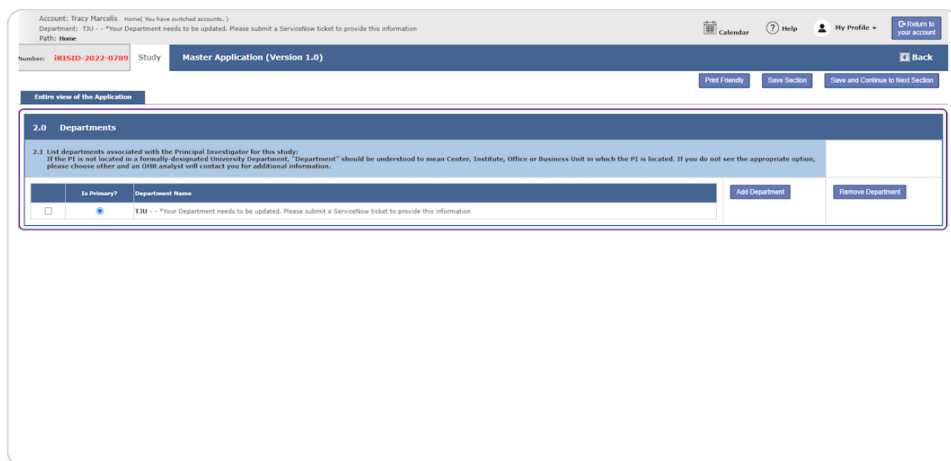
Step 5: Click on *Save and Continue to Next Section*

Step 6: Click on *Click Here to Setup Study Personnel*

nce. You can assign study contact as the
ct question.

Click Here to Setup Study Personnel

or Supervisor and Business Administrator

(?)

Step 7: Enter the last name of your first study team member.

(You have switched accounts.)

Setup Study Personnel

Last Name: Muller
User Search by Study: All Departments

Select	Training	Name	Department
No results found			

Step 8: Click *Find User/Search Directory*

X

Return to your account

Find User/Search Directory

Back

Next Section

Email

el

Step 9: You can check to ensure the users CITI training to complete before submitting the protocol.

Last Name: Muller

User Search by Study: All Departments

Select	Training	Name
👤⊕	🎓	Muller, Steven

click to see the users training details

used to build the list of
ne study. User Search
s you to search for a
and associated them
the study.

Step 10: Select the User

h by Study

Last Name: Muller

User Search by Study: All Departme

is section is used to build the list of
rsonnel on the study. User Search
Study allows you to search for a
med person and associated them
th a role on the study.

Select	Training	Name
👤⊕	🎓	Muller, Steven

Step 11: Assign the user a role and choose Yes or No to make them a study contact.

Last Name: Muller   First Name:

User Search by Study: All Departments

Find User/Search D

used to build the list of
e study, User Search
you to search for a
nd associated them
he study.

Select	Training	Name	Department	Email
👤⊕				sym058@jefferson.edu

Add Personnel Role

Select the Role for Steven Muller :

◉ **Principal Investigator**

○ **Key Study Personnel:** --none--

○ **Study Contact(s):**

○ **Signatories:**
Refer to Signatory Requirements in 3.0 --none--

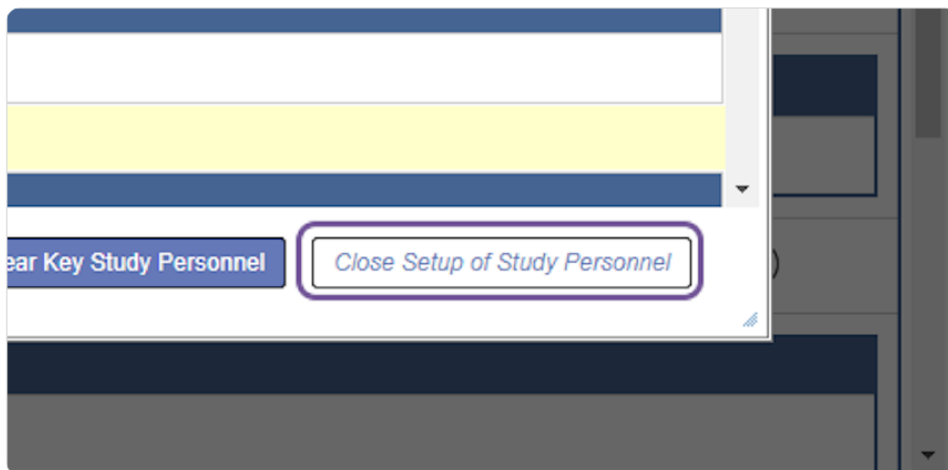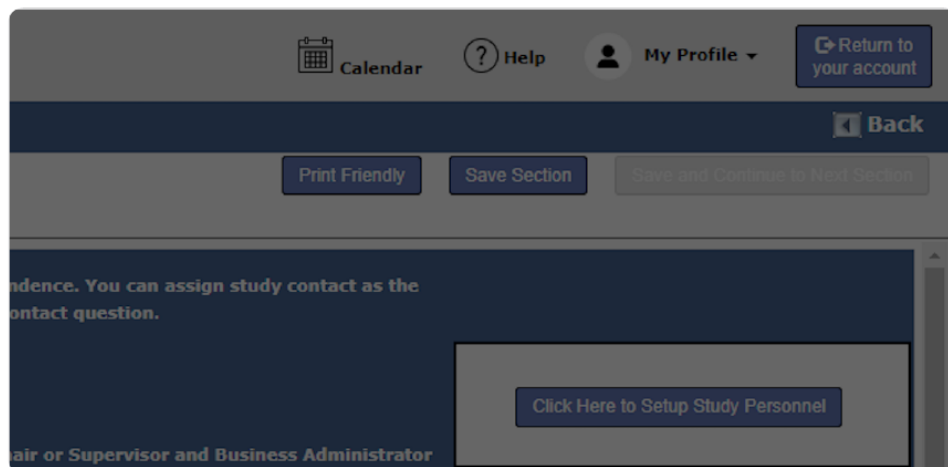Would you like to include as a Study Contact ? ◉ Yes ○ No

Selected

Principal

No Person

Key Study

No Person

IRIS Subm

No Person

Cancel   Save

Step 12: Click *Save*

Cancel   *Save*

Clear Key Study Personnel   Close Setu
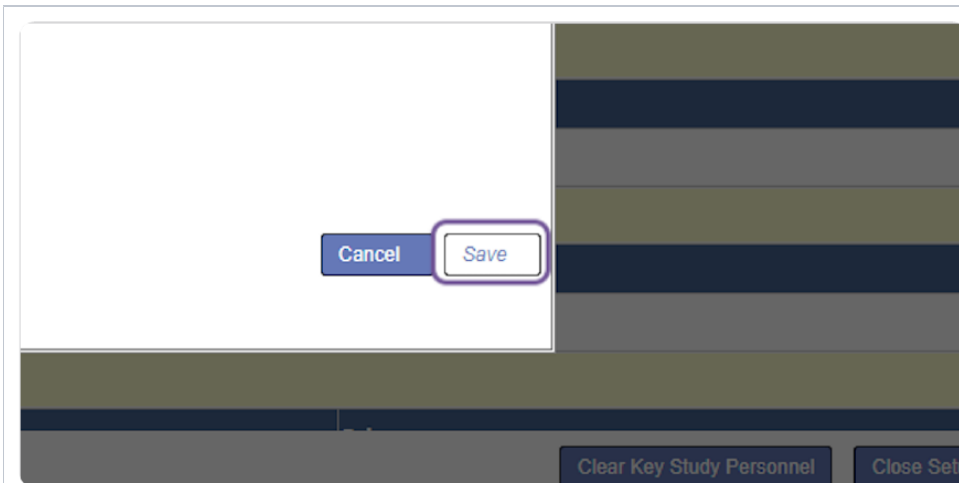
Step 13: Once you have added all study team personnel, click *Close Setup of Study Personnel*

ear Key Study Personnel   *Close Setup of Study Personnel*

Step 14: Click on *Save and Continue to Next Section*

📅 Calendar   ⑦ Help   👤 My Profile ▾   ⮌ Return to your account

◀ Back

Print Friendly   Save Section   Save and Continue to Next Section

ndence. You can assign study contact as the
ontact question.

Click Here to Setup Study Personnel

air or Supervisor and Business Administrator

Step 15: Answer the questions in Section 4.0.

Step 16: Click on *Save and Continue to Next Section.*

Step 17: Answer the questions in section 5.0 regarding the IRB of record.

Step 18: Click on *Save and Continue to Next Section.*

Step 19: Answer the General Information questions in section 6.0 (formerly the OHR-1)

Step 20: In section 6.7, provide a brief description of your research and justification for requesting exemption.

Step 21: In section 6.8, indicate whether you have received approval from the listed departments.

Step 22: In section 6.9, answer the COI questions.

6.9 CERTIFICATION OF FINANCIAL CONFLICTS OF INTEREST:

This section is addressed to the Principal Investigator, and applies to the Principal Investigator, Co-Investigato
The PI should check the appropriate boxes and provide the required information as needed. Refer to University Policy 107.

Do you (the PI) or a family member maintain a relationship with the sponsor OR do you maintain an ownershi

Note: Family member includes spouse, dependent children, and all other persons living in the same household.

○ Yes   ○ No

Are you aware of any study personnel identified for this study who have relationships or interests as describe

○ Yes   ○ No

Note: If the COI Committee has issued a COI management plan for any research personnel identified on this study, please
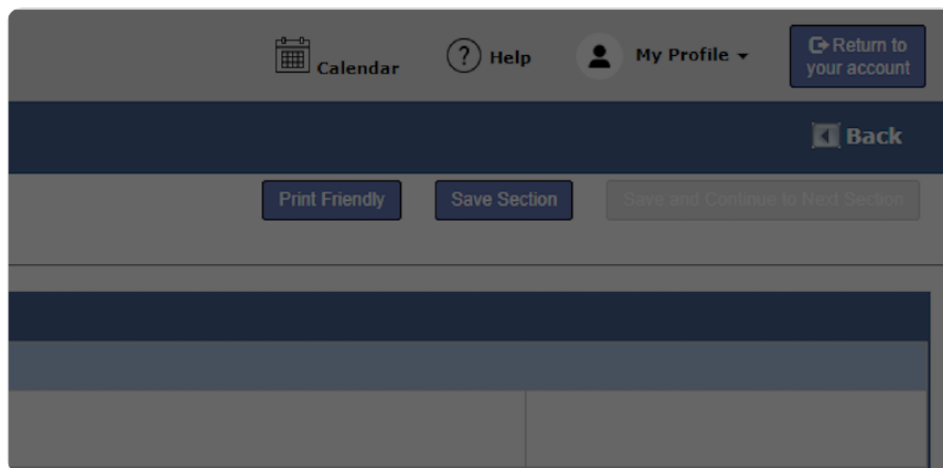
Step 23: Click *Save and Continue to Next Section*

Step 24: In section 7.0, answer the questions regarding study activity locations.
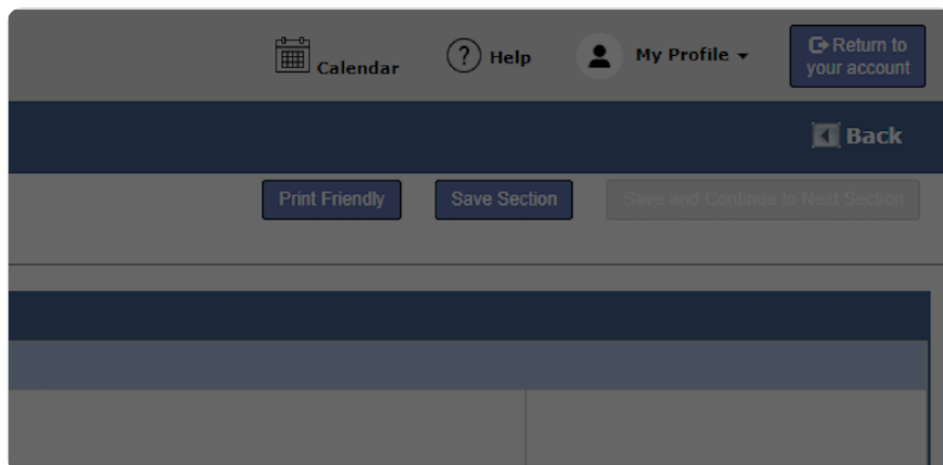

Step 25: Click *Save and Continue to Next Section*

Step 26: In section 9.0, answer the questions regarding data collection and PHI Waiver requests (formerly OHR-3/4).

Step 27: Click *Save and Continue to Next Section*

Step 28: You have completed the application, but it has NOT been submitted to the IRB yet.

Step 29: Click *Save and Continue to Next Section*

Step 30: A pop up will appear notifying you that you have completed the application. At this time, you will have the opportunity to attach additional documents.

You have completed the Application.

The System has transitioned to the New Study Application and your application has been attached.

Please complete the New Study Application and attach any supporting documents with your submission.

OK

Step 31:Enter a lay summary of the research.

Step 32: Click *Save and Continue to Next Section*

Step 33: Attach additional documents. This may include consent forms, surveys, questionnaires, protocols, etc..

Step 34: Click *Save and Continue to Next Section*

Step 35: Review directions in step 4.0.

4.0 Signatures

4.1 Obtaining Signatures

You can use the following options to obtain required signatures for this application:

1. On this screen click 'Signoff and Submit' to advance to the 'Submission Routing and Signoff' page. On the Submission Routing and Signoff page, assign any signatories to sign the application at this time by checking the box next to the signatory name. You can also select additional signatories at this time. Then click "Save – Signoff Routing List." On the next page click "Save – Start Signoff Routing." To do this, you must click yes to the statement:

   Please verify the list above represents the finalized Personnel for review and signoff?

2. If you know that some or all of your signatories are currently unable to sign the application, and you would like to submit the application now, **do not designate them as signatories on "Submission Routing and Signoff" page.**

   Later in the review process, you will receive a stipulation task from an IRB analyst that will instruct you to obtain the missing signatures. **At that time, all required signatures must be obtained before your approval letter will be issued.**

   For the second option, there are three ways you can obtain signatures:

   I. Assign signatories in the Routing section as described in item 1, above.

   II. Use the signature document to collect signatures. This document must be uploaded to the submission packet in the Study Documents section of this application.

   III. Use a combination of routing function and signature document to obtain signatures.

Step 36: Click *Save and Continue to Next Section*

Step 37: Click *Signoff and Submit*

ire ready to send for signoff, click Signoff and Submit. Clicking Exit Form will send this back t

Signoff and Submit

Exit Form

Step 38: Ensure all appropriate personnel have been included in signoff.

RISID-2022-0791   Study   New Study Application - (Version 1.0)

Calendar   ? He

Setup for Submission Routing and Signoff   X

ew of the Form

ⓘ This screen enables the collection of Key Personnel and Additional Personnel for Review and Signoff. The Check box "Checked" indicates the person is included in the signoff process. The Check box "Unchecked" indicates the person is not included in the signoff process. The Add Additional Personnel button is used to search from the user database and add them to the routing list. The order of the Additional Personnel is to create a review order for the assigned personnel. If personnel have 1, 2(sequential)

Select the Key Personnel for Submission Routing and Signoff:

If your application is co   is back to your study workspace

Include in signoff	Approved	Name	Role
☑		Steven Muller	Principal Investigator
☐		Steven Muller	Study Author

Select Additional Personnel for Submission Routing and Signoff: Add Additional Personnel to the Routing List

Include in signoff	Order	Approved	Name	Role

No additional personnel have been added to the signoff routing list.

Step 39: Click on *Save - Signoff Routing List*

Cancel - Finalize later   Save - Signoff Routing List

Step 40: Please verify the list above represents the finalized Personnel for review and signoff. Then, click *Save - Start Signoff Routing.*

Steven Haller   Principal Investigator

Please verify the list above represents the finalized Personnel for review and signoff?   ◯ Yes   ⦿ No

Cancel - Finalize later   Go back to Make changes   Save - Start Signoff Routing