
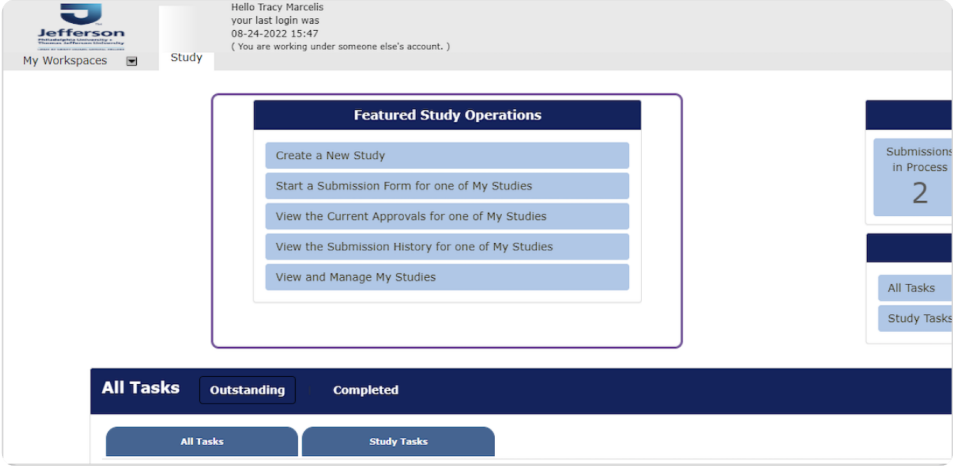


Submitting a New Study

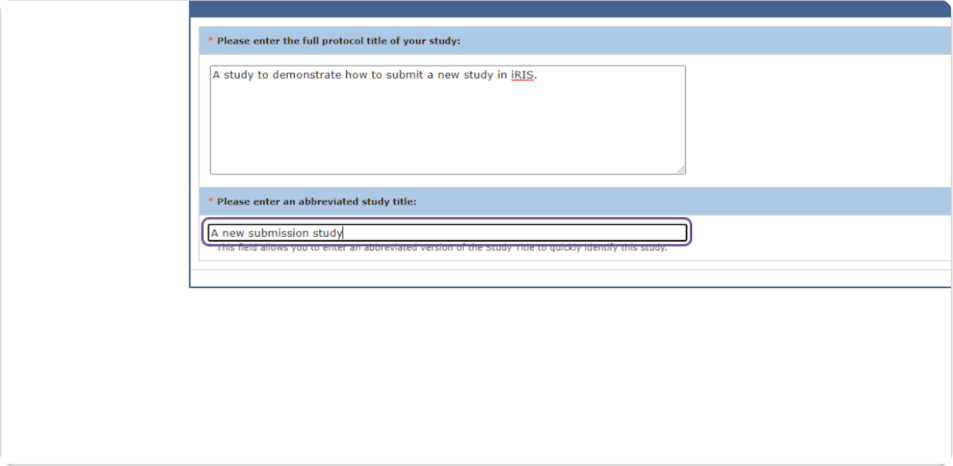
 The following workflow is intended to walk a user through submitting a New Study for review. Although this walks a user through an exempt study submission, the basics stay the same for all submissions.

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



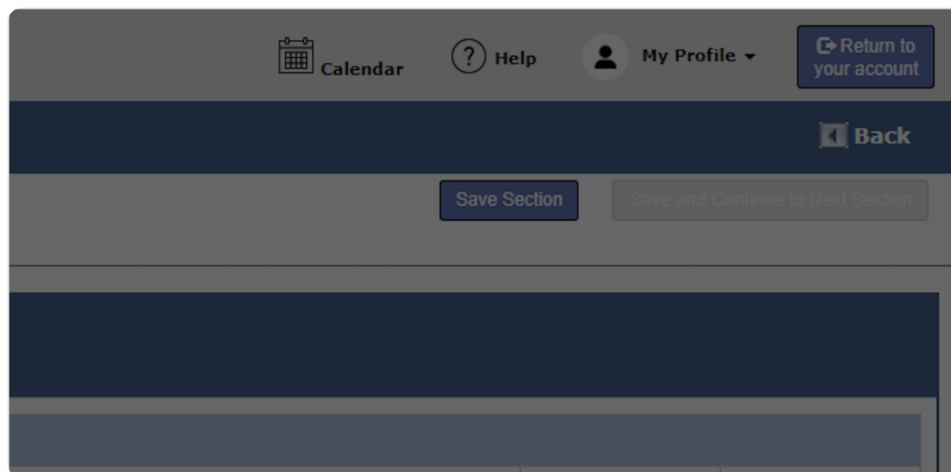
The screenshot shows the Jefferson IRIS homepage. At the top left is the Jefferson logo. To its right, a user greeting reads: "Hello Tracy Marcellis, your last login was 08-24-2022 15:47 (You are working under someone else's account.)". Below the logo is a "My Workspaces" tab with a dropdown arrow, and a "Study" tab. The main content area features a "Featured Study Operations" box with a purple border containing five buttons: "Create a New Study", "Start a Submission Form for one of My Studies", "View the Current Approvals for one of My Studies", "View the Submission History for one of My Studies", and "View and Manage My Studies". To the right of this box is a sidebar with "Submissions in Process" showing a count of "2", and buttons for "All Tasks" and "Study Tasks". At the bottom, there is a navigation bar with "All Tasks", "Outstanding", and "Completed" tabs, and below that, "All Tasks" and "Study Tasks" buttons.

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

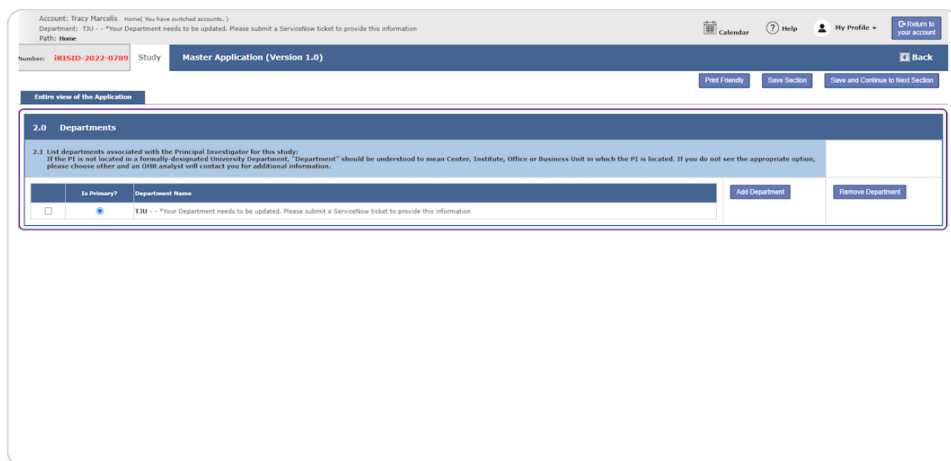


The screenshot shows a form for entering study details. It has two main sections. The first section is titled "Please enter the full protocol title of your study:" and contains a large text input field with the text "A study to demonstrate how to submit a new study in IRIS." The second section is titled "Please enter an abbreviated study title:" and contains a smaller text input field with the text "A new submission study". Below this field is a small note: "This field allows you to enter an abbreviated version of the Study Title to quickly identify this study."

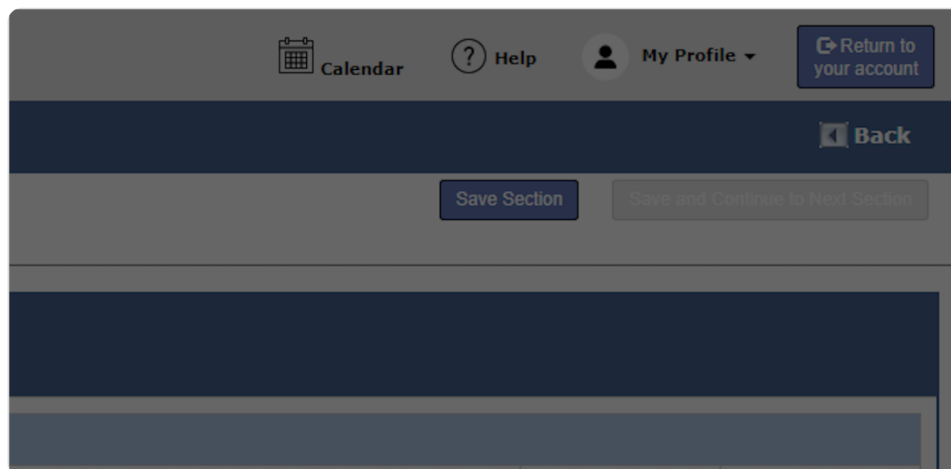
Step 3: Click on *Save and Continue to Next Section*.



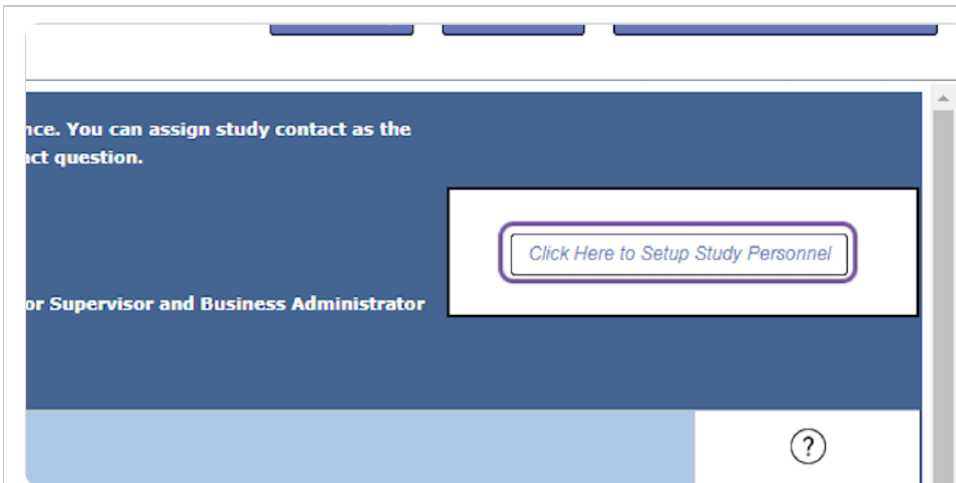
Step 4: Ensure the department displayed is correct. If you see the message that is displayed below, please Add Department and select the appropriate department.



Step 5: Click on *Save and Continue to Next Section*



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



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

(You have switched accounts.)

Setup Study Personnel

Last Name:

User Search by Study:

Select	Training	Name	Department
No results found			

Step 8: Click *Find User/Search Directory*

Email

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

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

Setup Study

Last Name: Muller

User Search by Study: All Departments

Select	Training	Name
		Muller, Steven

click to see the users training details

Step 10: Select the User

h by Study

is section is used to build the list of personnel on the study. User Search Study allows you to search for a user and associated them to a role on the study.

Last Name: Muller

User Search by Study: All Departments

Select	Training	Name
		Muller, Steven

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

used to build the list of the study. User search allows you to search for a user and associated them to the study.

Last Name: Muller

User Search by Study: All Departments

First Name:

Find User/Search

Select	Training	Name	Department	Email
				ym55@person.edu

Add Personnel Role

Select the Role for Steven Muller :

☒ Principal Investigator
 ☐ Key Study Personnel:
☐ Study Contact(s):
☐ Signatories:

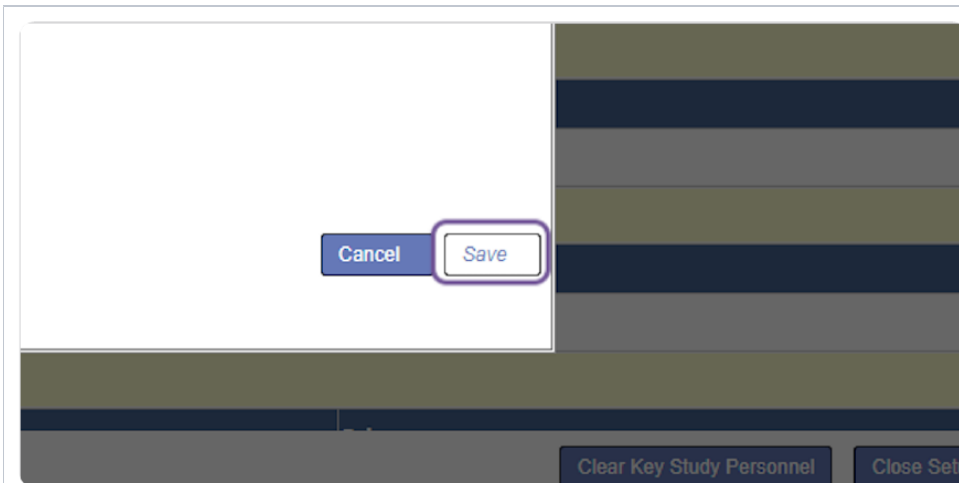
Refer to Signatory Requirements in 3.0

Would you like to include as a Study Contact ? ☒ Yes ☐ No

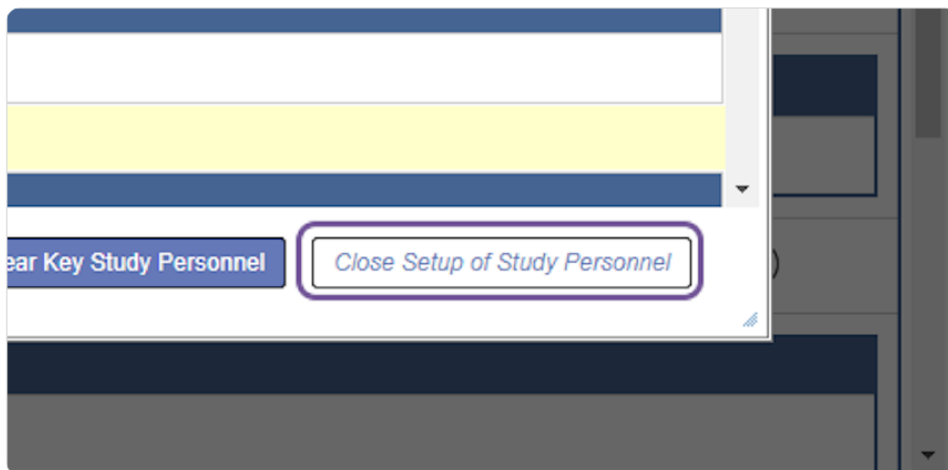
Cancel

Save

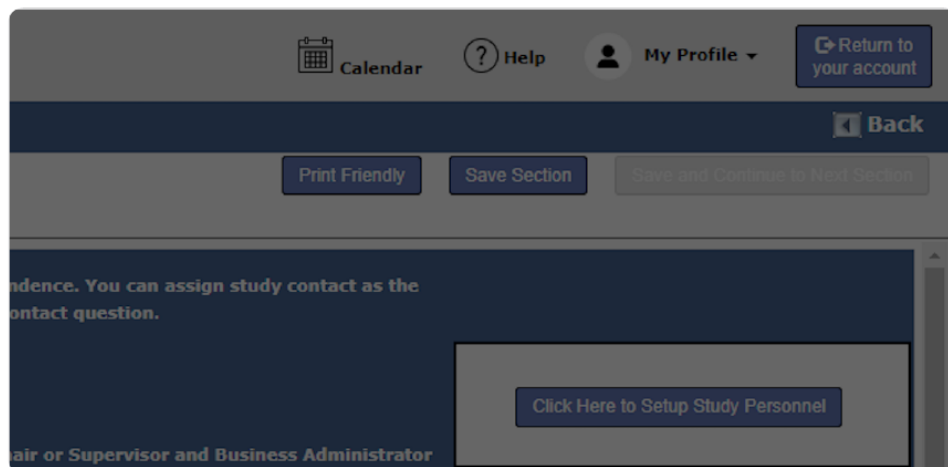
Step 12: Click Save



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



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



Step 15: Answer the questions in Section 4.0.

Account: Tracy Martelli (new! You have unlinked accounts.)

Department: T32 - "Your Department needs to be updated. Please submit a ServiceNow ticket to provide this information."

Path: Home

Calendar

Help

My Profile

Return to your account

IRB Number: IRB510-2022-0709

Study: Master Application (Version 1.0)

Print Friendly

Save Section

Save and Continue to Next Section

Entire view of the Application

4.0

Determination Section

4.1

Is your study's objectives, aims, eligibility, or outcomes pre-cancer or cancer-related?

☐ Yes
☐ No

4.2

Does your study include written, verbal and/or implied consent process?

☐ Yes
☐ No

4.3

Was approved or authorized by Jefferson IRB and issued a Jefferson IRB number prior to the IRB Go Live date of 09/30/2022, and was not migrated to IRB (i.e., you cannot find the study in IRB)? enter the Jefferson IRB number here. This will ensure that the Jefferson IRB number is assigned to this study in IRB.

☐ Yes
☐ No

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

Calendar

Help

My Profile

Return to your account

Back

Print Friendly

Save Section

Save and Continue to Next Section

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

Account: Tracy Martelli (new! You have unlinked accounts.)

Department: T32 - "Your Department needs to be updated. Please submit a ServiceNow ticket to provide this information."

Path: Home

Calendar

Help

My Profile

Return to your account

IRB Number: IRB510-2022-0709

Study: Master Application (Version 1.0)

Print Friendly

Save Section

Save and Continue to Next Section

Entire view of the Application

5.0

Selecting IRB of Record

5.1

Is this a study site study that is or is intended to be under single IRB oversight (i.e., study involves non-Jefferson/Hofstra sites. Contact OIRB with questions.)

☐ Yes
☐ No

5.2

Select IRB of Record:

☐ Jefferson
☐ NCI CRB
☐ Commercial IRB (e.g. NORS, Advarra, etc.)
☐ Academic or other external IRB

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

Calendar

Help

My Profile

Return to your account

Back

Print Friendly

Save Section

Save and Continue to Next Section

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

Entire view of the Application

Print Feedback Save Feedback Save and Continue to Next Section

6.0 General Information (OHR-1)

6.1 Funding sponsor names

Add a New Sponsor to the Study

Details	Edit	View Details	Sponsor Name	Project Number	Parent Number
No sponsor has been added to this Study.					

6.2 Demographics

Non-enrollment

Yes No

6.3 Does this study involve only data collection with no interactions with participants?

Yes No

6.4 Does this study involve only collection of stored or discarded biospecimens, with or without data collection, and with no interactions with participants?

Yes No

6.5 Are you applying for consent research?

Yes No

6.6 Authorizations

EMERGENCY DEPARTMENT APPROVAL: If your study involves human subjects from the Emergency Department (ED), please certify that the ED has been notified, and attach a copy of the ED letter of acknowledgment. YOU MAY NOT SUBMIT TO THE IRB UNTIL YOU HAVE THIS LETTER. Contact the ED at 315-595-4066 or Anna.M.Chang@jefferson.edu for more information.

Yes No

ECG/CARDIOGRAPHY APPROVAL: If your study involves electrocardiography, please certify that the protocol has been reviewed by the ECG/CARDIOGRAPHY LAB and include the approval letter with your submission. YOU MAY NOT SUBMIT TO THE IRB UNTIL YOU HAVE THIS LETTER. Contact the Director of the ECG/CARDIOGRAPHY LAB at 215-595-4348 for more information.

Yes No

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

My Workspace PI: Muller, Steven

Section view of Application Entire view of the Application

1.0 Study Title
2.0 Departments
3.0 Study Personnel
4.0 Determination Section
5.0 Selecting IRB of Record
6.0 General Information

☐ Research and demonstration projects conducted or supported by a Federal department or agency, or otherwise subject to the approval of examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible change payment for benefits or services under those program

6.7 Description of Exempt research:

Please provide a brief summary (in lay language) of your research, and a justification for why it fits the exemption criteria you

A brief summary.

Will the research involve interaction with participants?

Yes No

Does the research involve:

Pregnant women, Human fetuses and/or Neonates?

Yes No

Prisoners?

Yes No

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

Account: Tracy Marcels Home You have switched accounts.
Department: 131 - Your Department needs to be updated. Please submit a ServiceNow ticket to provide this information
Info Here

Numbers IRB ID: 2022-0700 Study Master Application (Version 1.0)
Rules: Steven

Print Feedback Save Feedback Save and Continue to Next Section

Entire view of the Application

Yes No
Children?
Yes No

6.8 Authorizations:

EMERGENCY DEPARTMENT APPROVAL: If your study involves human subjects from the Emergency Department (ED), please certify that the ED has been notified, and attach a copy of the ED letter of acknowledgment. YOU MAY NOT SUBMIT TO THE IRB UNTIL YOU HAVE THIS LETTER. Contact the ED at 315-595-4066 or Anna.M.Chang@jefferson.edu for more information.

Yes No

ECG/CARDIOGRAPHY APPROVAL: If your study involves electrocardiography, please certify that the protocol has been reviewed by the ECG/CARDIOGRAPHY LAB and include the approval letter with your submission. YOU MAY NOT SUBMIT TO THE IRB UNTIL YOU HAVE THIS LETTER. Contact the Director of the ECG/CARDIOGRAPHY LAB at 215-595-4348 for more information.

Yes No

RADIOLOGY APPROVAL: If your study involves radiology imaging through the Department of Radiology for research purposes, or if your study will require data management services of the Radiology department for data extraction from archives, de-identification of patient imaging studies, additional post processing of images and/or exporting of images from the radiology PACS, please certify that the protocol has been reviewed and approved by the Radiology Dept. and include the approval letter with your IRB submission. YOU MAY NOT SUBMIT TO THE IRB UNTIL YOU HAVE THIS APPROVAL. Submit your request at: <https://www.jefferson.edu/academics/collaborative-scholarship-institute/health-department/radiology/research/radiology-research-irb-approval.html>

Yes No

RADIATION SAFETY COMMITTEE APPROVAL: If your study involves ionizing radiation exposure to research subjects, submit Form OHR-32 to the Radiation Safety Officer (RSO) at catherine.andrich@jefferson.edu (phone 215-545-1050 or 215-595-7812).

Yes No

INSTITUTIONAL BIOSPECIMEN COMMITTEE AND IRB REVIEW AND APPROVAL: If your study is interventional and involves recombinant DNA technology (gene therapy or gene transfer) please contact Sue Gatta in Environmental Health and Safety at 215-7627 or Susan.Gatta@jefferson.edu AND the IRB prior to study submission.

Yes No

QUESTIONS DEPARTMENT APPROVAL: If your study involves Blumling Department personnel in any role or requires nurses to add to or alter their patient care and/or documentation practices, please certify that the project has been reviewed by the Department of Nursing's Office of Nursing Research and attach a letter of acknowledgment. YOU MAY NOT SUBMIT TO THE IRB UNTIL YOU HAVE THIS LETTER. Contact the Office of Nursing Research at 215-552-0679 or Sherry.McIntyre@jefferson.edu for more information.

Yes No

IRB BUILDING DEPARTMENT APPROVAL: If your study involves IRB Building Department personnel in any role or requires nurses to add to or alter their patient care and/or documentation practices, please certify that the project has been reviewed by the Research and IRB Council and attach a letter of preliminary approval. YOU MAY NOT SUBMIT TO THE IRB UNTIL YOU HAVE THIS LETTER. Contact the Research Steering Committee at 215.595.4348. Research@jefferson.edu for more information.

Yes No

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-Investigator. 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 ownership

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

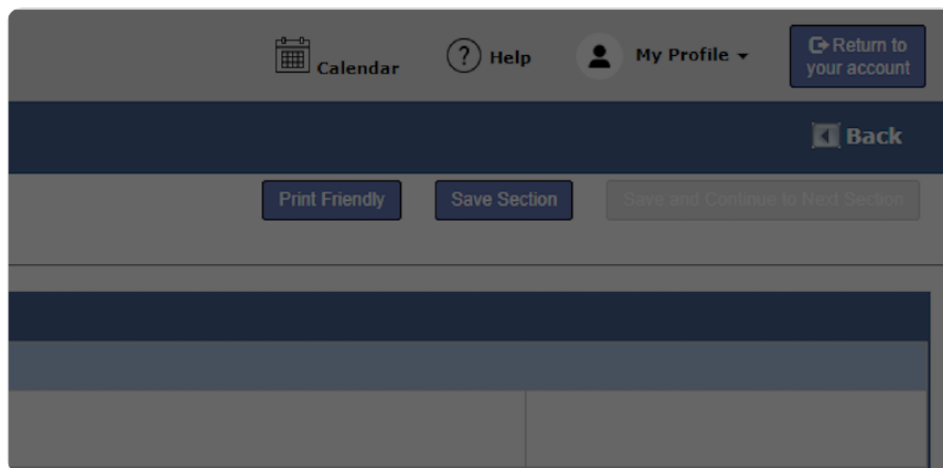
Step 23: Click **Save and Continue to Next Section**

The screenshot shows a dark-themed navigation bar at the top with icons for Calendar, Help, My Profile, and a 'Return to your account' button. Below this is a 'Back' button. In the center, there are three buttons: 'Print Friendly', 'Save Section', and 'Save and Continue to Next Section'.

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

The screenshot shows the 'Location / Collaboration' section of the application. It includes a sidebar with a list of sections (7.0 Study Title, 7.1 Study Personnel, 7.2 Information Section, 7.3 Research Information, 7.4 Location / Collaboration) and a main content area. The main content area has a title 'Location / Collaboration' and a sub-header 'Study personnel research to be performed at the following site(s). Select all that apply.' Below this is a table with columns 'Location' and 'Personnel'. The table has 10 rows. The first row is for 'Infection Health Institute'. The second row is for 'Infection Health Center City'. The third row is for 'Infection Health Center City'. The fourth row is for 'Infection Health Center City'. The fifth row is for 'Infection Health Center City'. The sixth row is for 'Infection Health Center City'. The seventh row is for 'Infection Health Center City'. The eighth row is for 'Infection Health Center City'. The ninth row is for 'Infection Health Center City'. The tenth row is for 'Infection Health Center City'. Below the table is a checkbox for 'All research under Infection Health Institute is conducted in studies other than this one'.

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

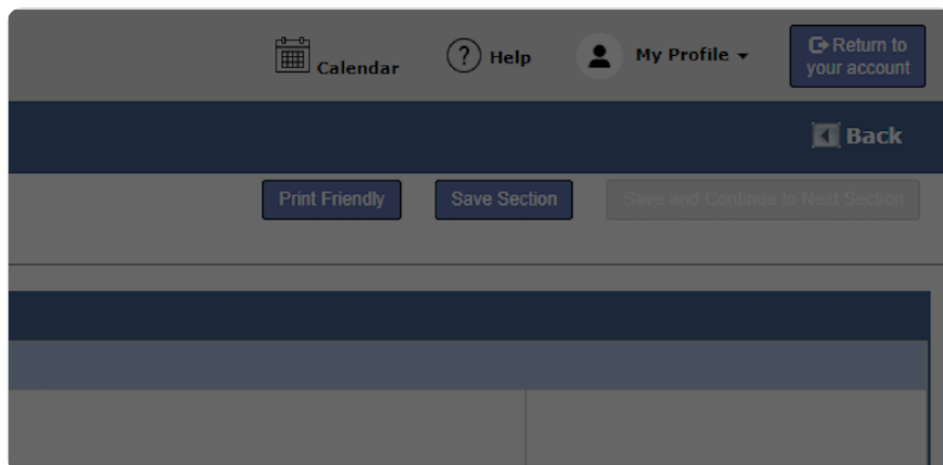


Step 26: In section 9.0, answer the questions regarding data collection and PHI Waiver requests (formerly OHR-3/4).


This screenshot shows the 'Data Collection & Waiver of Consent (OHR-3/4)' section of the Jefferson IRB application. The left sidebar lists various sections, with 'Data Collection & Waiver of Consent' selected. The main content area contains several questions and text boxes for input. Question 9.0 asks for a list of all data that will be collected for the study. Question 9.1 asks for the specific source of the data to be collected. Question 9.2 asks for a table of data collection methods, including chart/image/diagnostic review, survey/questionnaire (mail), and survey/questionnaire (phone), with options for retrospective or prospective collection.

The data will be collected by:	
Chart / image / diagnostic review?	<input type="checkbox"/> Retrospective <input type="checkbox"/> Prospective
Survey / questionnaire (mail)?	<input type="checkbox"/> Retrospective <input type="checkbox"/> Prospective
Survey / questionnaire (phone)?	<input type="checkbox"/> Retrospective <input type="checkbox"/> Prospective




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.




Account: Terry Marcella (view my own account details)
 Department: TOL - Your Department needs to be updated. Please submit a ServiceNow ticket to provide the information.
 Path: Home

 Calendar
  Help
  My Profile
 [Go to my own profile](#)

 My Workspaces


002 Tasklist: **RECID-3622-0799**
 Study

Master Application (Version 1.0)

 Track

Section view of Application

Enter view of the Application


3.0 Study Title
 3.0 Experiments
 3.0 Study Personnel
 4.0 Submission Status
 3.0 Submitting Site of Record
 3.0 General Information
 3.0 Location / Collaboration
 6.0  **Get Consent**


Application Complete


Application Complete


3.0 Click Save & Continue to proceed to the Initial Review Submission Packet.
 The Initial Review Submission Packet is a short form filled out after the protocol application has been completed. This is an area to attach protocol-related documents, consent forms, and review the application.


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

Calendar

Help

My Profile ▾

Return to your account

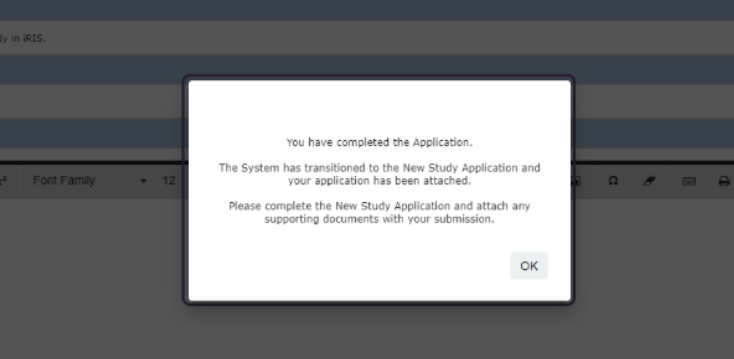
Back

Print Friendly

Save Section


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.





The screenshot shows a web application interface for submitting a study. At the top, a dark blue header contains the text "Submission Packet to the Review Board". Below this, a light blue banner displays the text "submit a new study in IRIS." followed by a large, faint "IRIS" logo. The main content area is a light gray rectangle. In the center of this area, a white modal dialog box with a dark gray border is open. The dialog contains the following text: "You have completed the Application." followed by "The System has transitioned to the New Study Application and your application has been attached." Below this, it says "Please complete the New Study Application and attach any supporting documents with your submission." At the bottom right of the dialog is a gray button labeled "OK". The background of the page is dark gray and features a horizontal navigation bar with several icons: a magnifying glass, a list icon, a document icon, a folder icon, a mail icon, a car icon, a person icon, and a gear icon. The bottom of the page shows a dark gray footer with the text "Font Family" and "12".


Step 31: Enter a lay summary of the research.

Calendar

Help

My Profile ▾

Return to your account

Back

Print Friendly

Save Section

Save and Continue to Next Section

Step 35: Review directions in step 4.0.

Accession Number: 2022-0709

Department: TSS - TSS Department needs to be updated. Please submit a Service Request ticket to provide this information.

Path: Home > study request

Number: 2022-0709

Policy Branch

Study

New Study Application - (Version 1.0)

[Print Friendly](#) [Refresh Content Fields](#) [Sign Section](#) [Save and Continue to Next Section](#)

Enter some of the steps:

4.0 Signatures

4.1 Obtaining signatures


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


- On the 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 the time by checking the box next to the signatory name. You can also add additional signatories At this time. Then click "Save + Signoff Routing List" on the main page click "Sign + Start Signoff Routing". It is do this, you must click yes to the statement
Please verify the list above represents the Required Personnel for review and signoff?
- 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" pages.**
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:


- Assign signatories in the Routing section as described in item 1, above.
- Use the signature document to collect signatures. This document will be uploaded to the submission packet in the Study Documents section of this application.
- Use a combination of routing function and signature document to obtain signatures.


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

Calendar

Help

My Profile ▾

Return to your account

Back

Print Friendly

Save Section

Save and Continue to Next Section

Step 37: Click *Signoff and Submit*

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

Signoff and Submit

Exit Form

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

Account: Steven Muller
Department: TJU - Office of Human Research
Path: Home > study mgmt.

IRISID-2022-0791

New Study Application - (Version 1.0)

Setup for Submission Routing and Signoff

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, 2f sequential 1

Select the Key Personnel for Submission Routing and Signoff:

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Steven Muller	Principal Investigator
<input type="checkbox"/>	<input type="checkbox"/>	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.

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