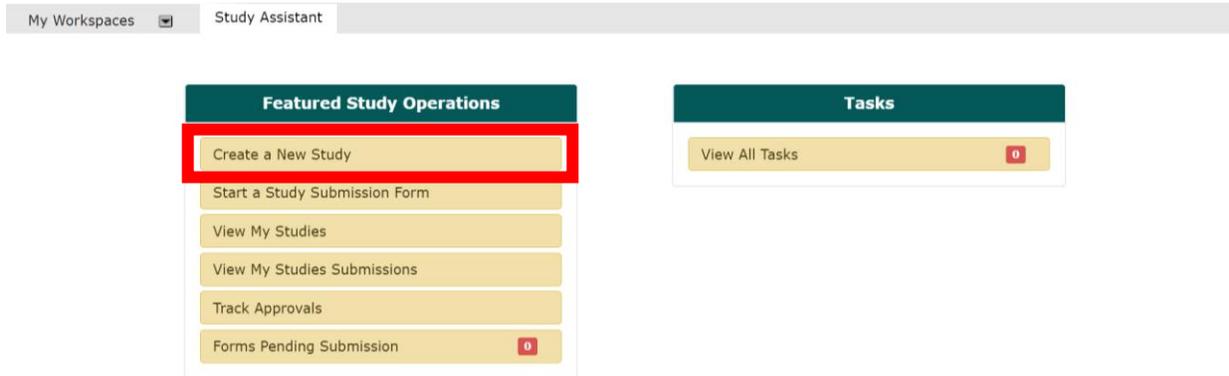


Determination of Human Subject Research

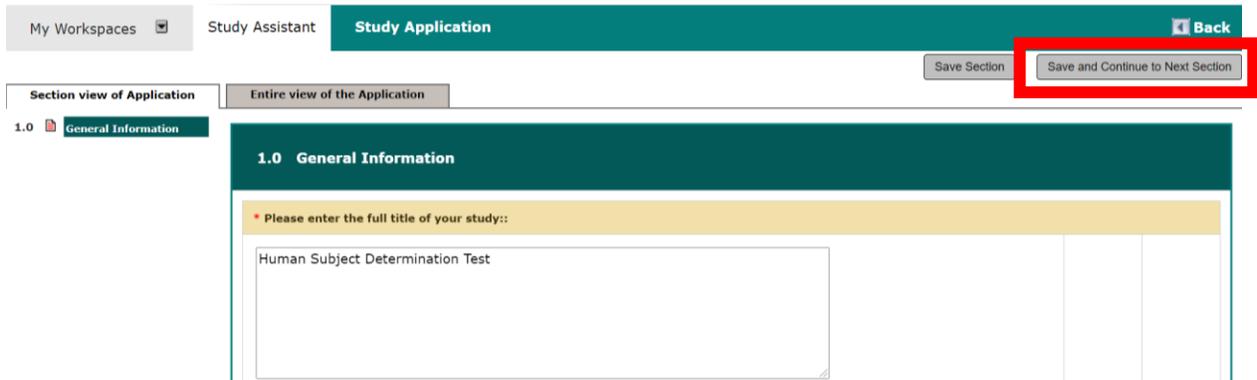
Setting up Submission Routing and Signoff

Begin on the Study Assistant Workspace home screen. Select "Create a New Study."

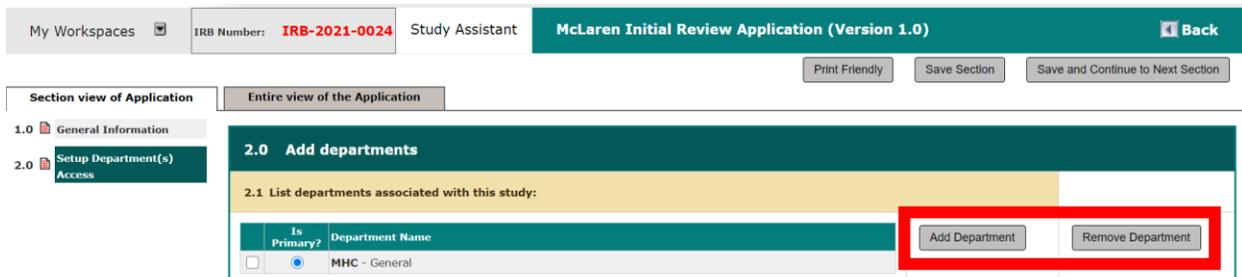


You are taken to the first of three sections of the application, known as the Study Shell. After the first three initial screens of this application are complete, a new study record is created in the system. Begin filling in the information.

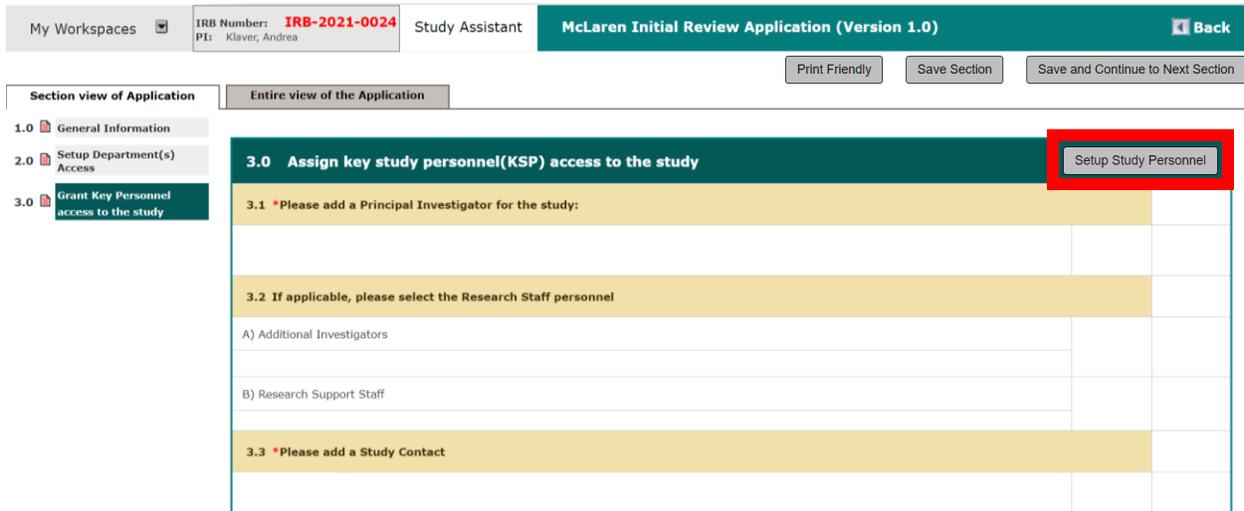
After this point, you can exit the application at any time and it will save a Draft. Navigate through the Sections using the gray "Save and Continue to Next Section" button.



The next section of the Study Shell is where you will Setup Department(s) Access. Add or Remove Departments using the gray buttons.

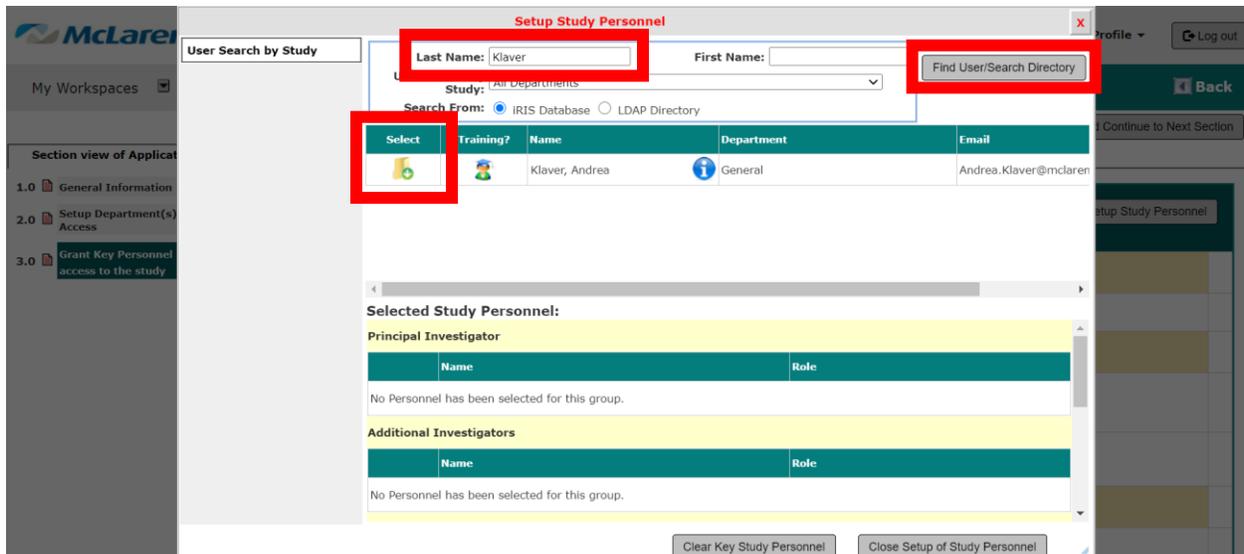


Next, you will Grant Key Personnel access to the study. Any user added to the study will have the ability to access the study in iRIS. To add any user to any role, click the Setup Study Personnel button.



Another screen will display in a pop-up within your window showing the study personnel list and their roles, as it is populated.

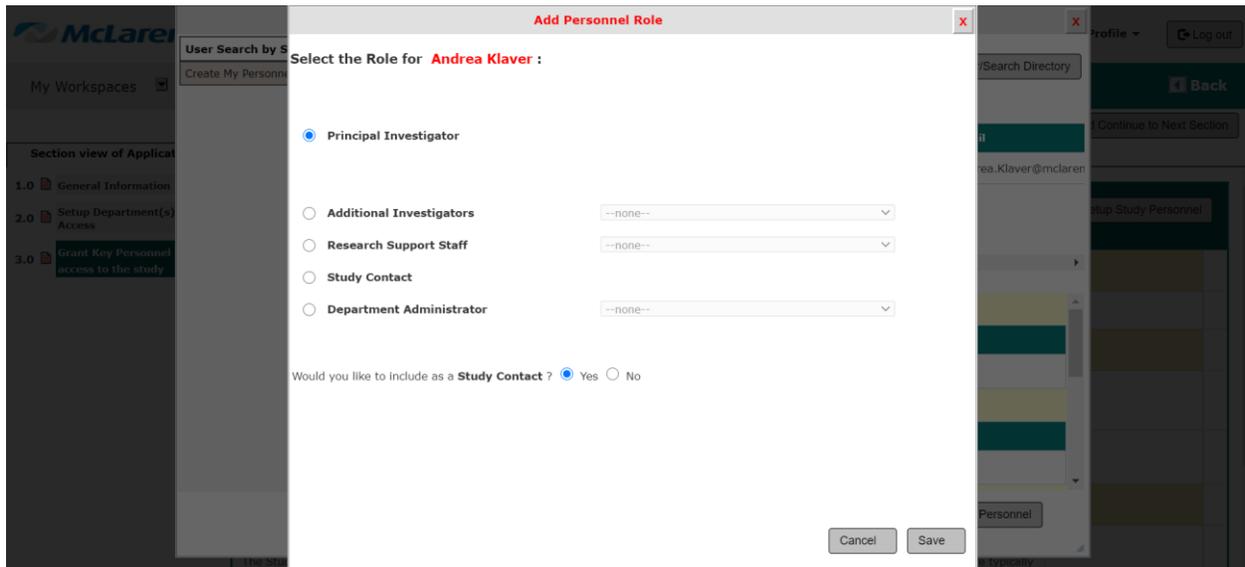
For example, let's search by Last Name. Click on the gray Find User/Search Directory button at the top right of the window.



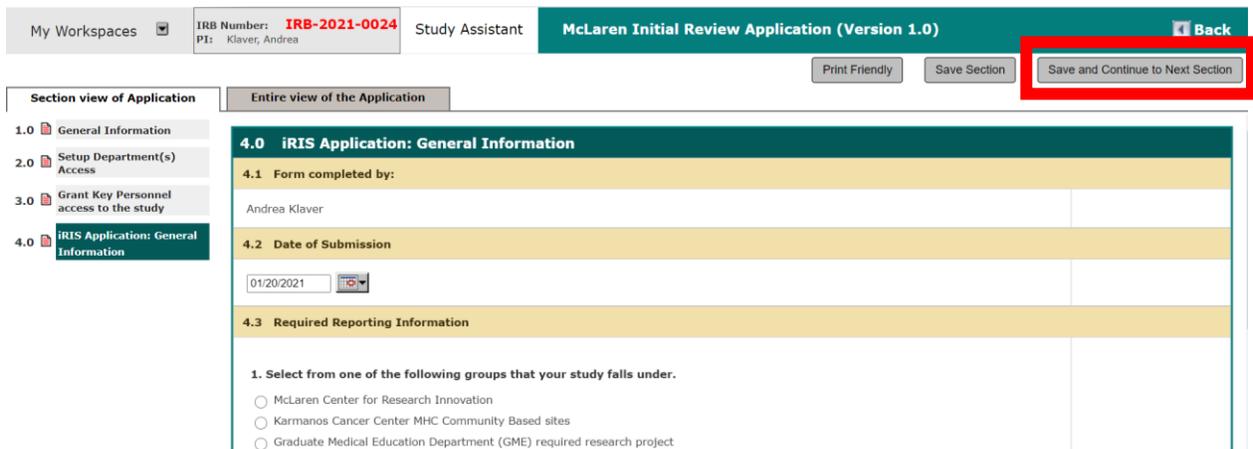
Click the Select icon to select the user. Another screen will display in a new pop-up asking you to Select the Role the user will have on the study.

The user you add as the Principal Investigator will default to the Study Contact. You may add additional Study Contacts as needed. A Study Contact is a user on the study who will

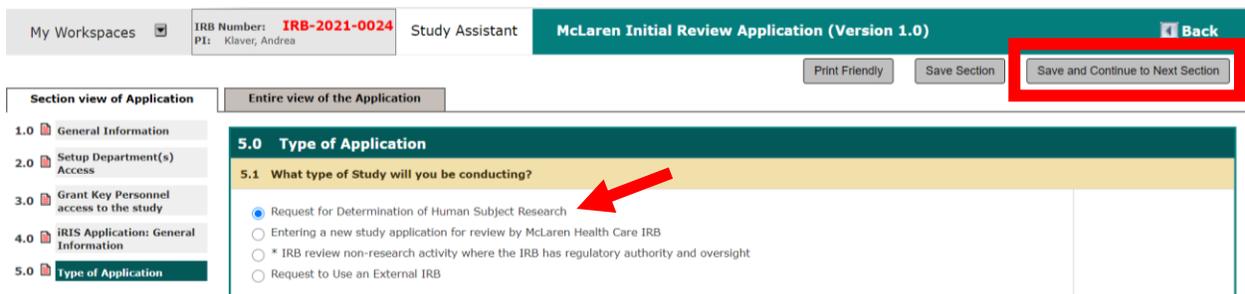
receive study related notifications from iRIS. A Study Contact is usually also another role on the study, like a Research Coordinator. Click Save to add more Key Personnel.



Next, you will be asked to enter General Information about your study submission. This includes whether medical residents, medical students, nursing students, etc. are participating in the study. Continue filling in the information.



Indicate your Request for Determination of Human Subject Research in the next section.



Information to complete in this section includes:

- INVESTIGATOR INFORMATION: Indicate Principal Investigator (PI) by selecting one of the boxes below.
- RESIDENT/FELLOW/STUDENT SUB-INVESTIGATOR (if applicable): The individual acting in role of co-investigator under the supervision of the PI.
- ACADEMIC ADVISOR (if applicable): Required for students who are McLaren employed and NOT a part of McLaren's GME program. This person is required to sign this form along with the PI.
- MORE SECTIONS: Project Information, Study Sites, Study Title, Primary Objective, and Secondary Objective (if applicable), Summary, Subject Population, Common Rule Determination, Explanation why you believe your activity does not require IRB review, etc.

Note regarding signatures:

1. If you are the PI of this study: You will be **required to electronically signoff** when you reach the end of this Submission.
2. For Medical Residents and Fellows that are part of MHC Graduate Medical Education Program: You are **required to route this application to the PI of the study and your Ph.D. Advisor for signature (sign-off)** prior to submitting to the IRB.
3. If you are other research personnel on this the study: At the end of this Submission, you will be allowed to route this Study to notify the individual(s) such as the Principal Investigator, Ph.D. Advisor, Academic Advisor etc. that there is a submission awaiting their signature.

My Workspaces ▼ IRB Number: **IRB-2021-0024** Study Assistant McLaren Initial Review Application (Version 1.0) Back

PI: Klaver, Andrea Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information

2.0 Setup Department(s) Access

3.0 Grant Key Personnel access to the study

4.0 IRIS Application: General Information

5.0 Type of Application

6.0 Request for Determination of Human Subject Research

7.0 **Confirmation of Scientific or Scholarly Review of Validity**

7.0 Confirmation of Scientific or Scholarly Review of Validity

7.1 A research plan must be scientifically sound and minimizes risk to the subjects and can reasonably be expected to answer the proposed question. Scientific or scholarly review can be performed by the members of the IRB reviewing the study and is based on the criteria required by federal regulations for IRB approval of a human research study. See Policy MHC-RP0109 Criteria for IRB approval. Although the IRB can review issues of scientific design and participant safety as needed, that role will be a secondary one.

This application should be used for scientific reviews that are not required to go through the McLaren Protocol Review Committee (PRC). See instructions below.

Instructions:

- **All Prospective Interventional Studies** scientific reviews will be done by the convened MHC Protocol Review Committee (PRC). Send request for review to mcric@mcclaren.org [Subject line in email should state "PRC Review"] Do not use this form.
- **Already have PRC approval:** Skip this form and upload PRC approval letter with application
- **For Non-Interventional Studies** If you are a researchers not associated with the Graduate Medical Education program, complete this form. Route this form for appropriate review and sign off: The Reviewer must be someone other than the PI.

If you are affiliated with the Graduate Medical Education program, complete this form. Route form for appropriate review and sign off: If the Program Director is the PI on the study, then review/signature is done by the Assistant Program Director. If the Assistant Program Director is the PI or if there is no Assistant Program Director, the review/signature is done by Chief Medical Officer (CMO).

In this section, it is noted that the **Scientific Reviewer's** signature confirms the soundness of the research design and the ability of the research to achieve its aims.

The **Scientific Reviewer** must be someone other than the PI.

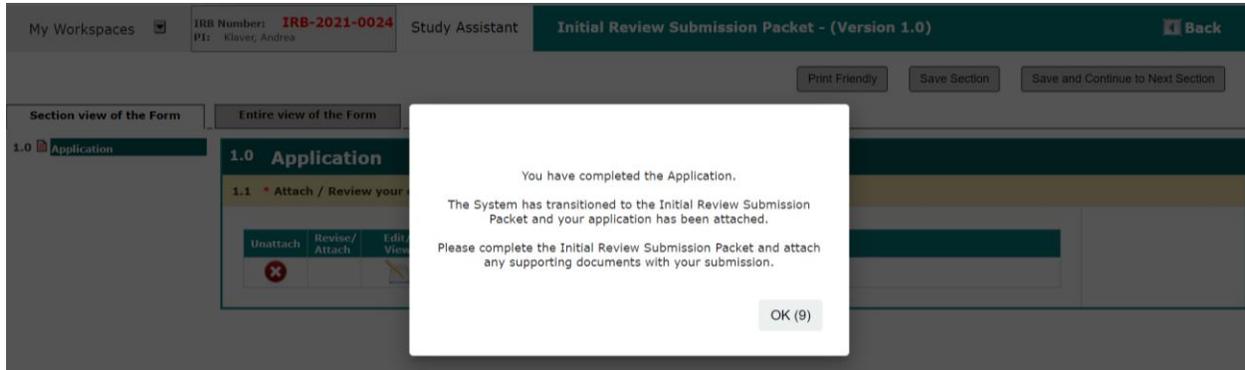
For Medical Resident and Fellows that are part of MHC Graduate Medical Education Program, the **Scientific Reviewer** must be:

- Program Director
- Assistant Program Director (if Program Director is the PI)
- Chief Medical Officer (if Assistant Program Director is the PI or if no Assistant Program Director)

Medical Residents and Fellows that are part of MHC Graduate Medical Education Program **must also obtain signature of Ph.D. Advisor.**

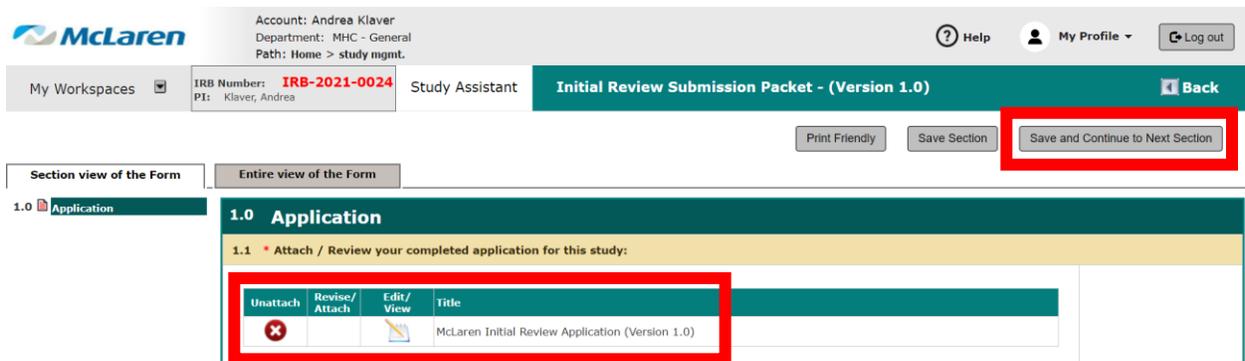
At the end of the Submission, you will be prompted to select individuals to route this Submission to for review (i.e. Ph.D. Advisor (if applicable)).

When you are finished filling out the form sections, iRIS will transition you into the Initial Review Submission Form/Packet. You will have transitioned to the next section when the screen appears that is shown below. An informative message between completing the Study Application and moving onto the Submission Packet has been added for clarity.

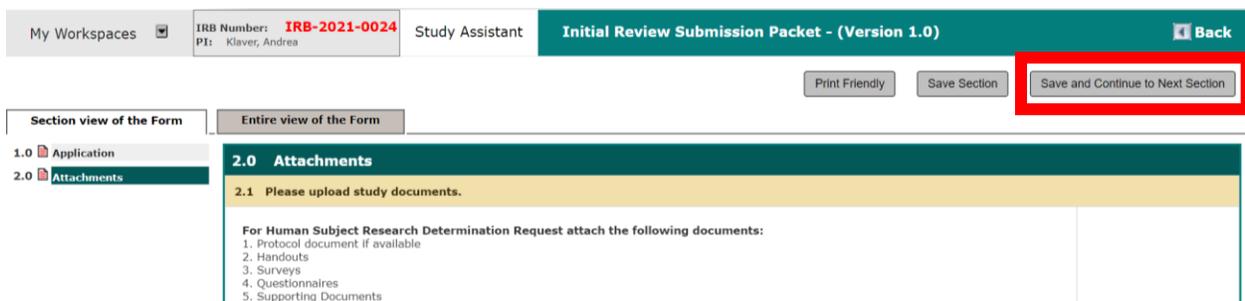


The Submission Packet functions the same way as the Study Application, regarding navigating and completing sections by adding information into the fields within each section. Complete this form by completing each section, attaching the necessary documentation, and clicking the Save and Continue button to proceed.

The Study Application will be attached to the Submission Form, along with any supporting study documents. Because the Study Application has already been completed and you transitioned to the Initial Review Submission Form, the Study Application will auto-attach.



Upload all study documents in this section. A numbered list has been included in this section for your convenience.



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.							

Once the Study Application and Submission Packet are complete and the required documents are attached, the form is ready to send to the IRB. You will be presented with a screen notifying you that the form is complete, as shown below.

My Workspaces	IRB Number: IRB-2021-0024 PI: Klaver, Andrea	Study Assistant	Initial Review Submission Packet - (Version 1.0)	Back
		Print Friendly Signoff and Submit		
Section view of the Form	Entire view of the Form			
1.0 Application	<div style="text-align: center;"> <p>Form has been Completed!</p> <p>Project Access and Assignments</p> </div> <div style="text-align: center; margin-top: 20px;"> <p>Exit Form</p> <p>Signoff and Submit</p> </div>			
2.0 Attachments				

If you are the PI of this study: You will be **directed to electronically signoff** when you reach the end of the Submission. Select the Signoff and Submit button.

For Medical Residents and Fellows that are part of MHC Graduate Medical Education Program: You are **required to route this application to the PI of the study and your Ph.D. Advisor for signature (sign-off)** prior to submitting to the IRB. (If you are NOT the PI on this study, the buttons on this page will be "Exit Form" and "Notify PI to Signoff." Select the Notify PI to Signoff button.)

If you are other research personnel on this the study: At the end of the Submission, you will be allowed to route this Study to notify the individual(s) such as the Principal Investigator, Ph.D. Advisor, Academic Advisor etc. that there is a submission awaiting their signature.

If your role on the study does not allow submission of forms, you will only have the Exit Form button. Exit the form and the PI and other Study Contact will be notified that a submission is waiting to be sent to the IRB.

Prior to initiating the signoff tasks, iRIS will ask you to define your Routing Signoff List.

Include the PI of the study, your Ph.D. Advisor, and a Scientific Reviewer [could be Program Director; Assistant Program Director (if Program Director is the PI); or Chief Medical Officer (if Assistant Program Director is the PI or if no Assistant Program Director)].

Setup for Submission Routing and Signoff

Information: 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:

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Andrea Klaver	Principal Investigator

Select Additional Personnel for Submission Routing and Signoff:

Include in signoff	Order	Approved	Name	Role
No additional personnel have been added to the signoff routing list.				

A screen will display in a pop-up within your window showing the Routing Signoff List, their Role, and their Order, as it is populated by you. (As the PI signature is required, that user will be pre-selected, and you will NOT be able to de-select the PI from the signoff process.)

To generate your Routing Signoff List, select the Add Additional Personnel to the Routing List button.

Another screen will display in a new pop-up where you can search for and find users in the iRIS Directory to add to your Routing Signoff List (below). Select the user and their Role.

Add Additional Key personnel to the Routing Signoff List

Last Name: First Name:

by Department:

Search From: iRIS Database LDAP Directory

Select	Name	Department	Email
<input checked="" type="checkbox"/>	Richards, Markeda	General	Markeda.Richards@mclaren.org

The Additional Personnel will be added to the signoff routing list upon clicking the "Save - Add to Routing List" button.

Remove	Name	Role
<input checked="" type="checkbox"/>	Markeda Richards	<input type="text" value="PhD Advisor"/>

Continue adding users to your Routing Signoff List in the same manner.

Add Additional Key personnel to the Routing Signoff List

Last Name: Waris First Name: Mahjabeen
by Department: All Departments
Search From: IRIS Database LDAP Directory

Find User/Search Directory

Select	Name	Department	Email
	Waris, Mahjabeen	General	Mahjabeen.Waris@mclaren.org

The Additional Personnel will to be added to the signoff routing list upon clicking the "Save - Add to Routing List" button

Remove	Name	Role
	Markeda Richards	PhD Advisor
	Mahjabeen Waris	Faculty/Advisor PI

**** Please note! The following step is not required! Ordering your signoffs is optional. ****

After you have saved your Routing Signoff List, iRIS allows you to list the users in the order you'd like them to receive the routing for signoff *if you wish to do so*.

The order of the Additional Personnel is to create a review order for the assigned personnel. If personnel have 1, 2 (sequential) respectively, the first personnel applies signoff before the second personnel receives it. If personnel have 1, 1 (parallel) respectively, the first and second personnel receive it at the same time.

If a personnel denies the signoff, then the submission must be revised and resubmitted with the routing starting from the beginning.

You have two options at this point:

1. **Order your signoffs:** iRIS will send signoff notifications in the order you choose. Signoff notifications will not be sent to the next user until the previous user has signed off. See screenshot below.

Setup for Submission Routing and Signoff

i 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

Select the Key Personnel for Submission Routing and Signoff:

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>		Andrea Klaver	Principal Investigator

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

Include in signoff	Order	Approved	Name	Role
<input checked="" type="checkbox"/>	<input type="text" value="1"/>		Markeda Richards	PhD Advisor
<input checked="" type="checkbox"/>	<input type="text" value="2"/>		Mahjabeen Waris	Faculty/Advisor PI

Cancel - Finalize later
Save - Signoff Routing List

2. **Do not order your signoffs:** If you do not want any signoff notifications withheld (i.e. you would like all signoff notifications sent out simultaneously), do not order your signoffs. Make sure that the number in each Order box is "1." See screenshot below.

Setup for Submission Routing and Signoff

i The order of the Additional Personnel is to create a review order for the assigned personnel. If personnel have 1, 2(sequential) respectively, the first personnel applies signoff before the second personnel receives it. If personnel have 1, 1(parallel) respectively, the first and second personnel receive it at the same time. If a personnel denies the signoff, then the submission must be revised and resubmitted with the routing starting from the beginning.

Select the Key Personnel for Submission Routing and Signoff:

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>		Andrea Klaver	Principal Investigator

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

Include in signoff	Order	Approved	Name	Role
<input checked="" type="checkbox"/>	<input type="text" value="1"/>		Markeda Richards	PhD Advisor
<input checked="" type="checkbox"/>	<input type="text" value="1"/>		Mahjabeen Waris	Faculty/Advisor PI

Cancel - Finalize later
Save - Signoff Routing List

When you have verified your Routing Signoff List and Order, select the Save – Start Signoff Routing button (below). This will initiate the process of notifying the users that they have been assigned a signature task. System-generated emails will be sent.

Setup for Submission Routing and Signoff

This screen is for reviewing the signoff routing list. You must answer "Yes" or "No" to the finalization of the Personnel. Once the "Yes" selection is made the button "Save - Start Signoff Routing" becomes enabled to be clicked. Clicking the "Save - Start Signoff Routing" will start the routing list and then the submission board review(s). Clicking the "Go back to Make Changes" will place you back to editing the routing list. Clicking the "Cancel -

Finalize List of Personnel for Submission Routing and Signoff:

Order	Approved	Name	Role
		Andrea Klaver	Principal Investigator
1		Markeda Richards	PhD Advisor
2		Mahjabeen Waris	Faculty/Advisor PI

Please verify the list above represents the finalize Personnel for review and signoff? Yes No

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

Users also receive a corresponding Submission Routing Signoff task on their homepage.

All Tasks Outstanding Completed

All Tasks Study Tasks Task List : All

2 result(s) found... 1 - 2

Click to open	Task Type	Date Received	Description
	Submission Routing Signoff	01/20/2021 12:53 PM EST	Andrea Klaver as Principal Investigator review and apply signoff

When the user opens the task to complete the signoff, this screen will appear:

My Workspaces ▾ Study Assistant **Submission Routing Signoff** Back

Save Signoff

Study Title: Human Subject Determination Test
Submission Reference Number: 000940

Printable Version

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name - Version
Submission Form(s)			
<input type="checkbox"/>			Initial Review Submission Packet - (Version 1.0)
Application			
<input type="checkbox"/>			McLaren Initial Review Application - (Version 1.0)

Andrea Klaver as Principal Investigator
Do you Approve or Deny this submission? Approve Deny

Comments
I approve this test study.

The Submission Packet and the Study Application are available for review.

The user may add comments by clicking the Click here to add comments button.

The user may Approve or Deny the submission and save their sign off by clicking the Save Signoff button.

You can track the status of your study submission on your iRIS home screen (Study Assistant Workspace) under the Studies Submission Status – In Progress section header.

Studies Submission Status - In Progress

In Progress **Completed**

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

Click to open Study Dashboard	Reference Number	Review Board	RB Number	Form Name	Study Title Study Alias	Form Author	Date Submitted	Actions
	000940	IRB	IRB-2021-0024	Initial Review Submission Packet	Human Subject Determination Test HSD Test	Klaver, Andrea	01/20/2021 12:45 PM EST	Incomplete Tasks Open Steps to Complete

Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
<input type="checkbox"/>	Pre-Submission				0 Day(s) 0 Hour(s) 10 Minute(s)
Completed		Initial Review Submission Packet is waiting to be submitted	01/20/2021 12:44 PM EST	01/20/2021 12:45 PM EST	Day Hour Minute 0 0 0
Received	<input type="button" value="Modify Signoff Routing List"/>	Assign Department Personnel for Signoff	01/20/2021 12:45 PM EST	01/20/2021 12:45 PM EST	Day Hour Minute 0 0 0
Received	<input type="button" value="Pending Signoff"/>	Andrea Klaver as Principal Investigator review and apply signoff	01/20/2021 12:53 PM EST		Day Hour Minute 0 0 1
Received	<input type="button" value="Pending Signoff"/>	Andrea Klaver as Principal Investigator review and apply signoff	01/20/2021 12:53 PM EST		Day Hour Minute 0 0 1

To modify your Routing Signoff List, you may select the Modify Signoff Routing List button. **This button only appears PRIOR to IRB submission (Pre-Submission) while signoffs are still pending.**

Once the signoffs have all been completed, this button will change to the View Signoff Routing List button (read-only).