Determination of Human Subject Research
Setting up Submission Routing and Signoff

Begin on the Study Assistant Workspace home screen. Select "Create a New Study."
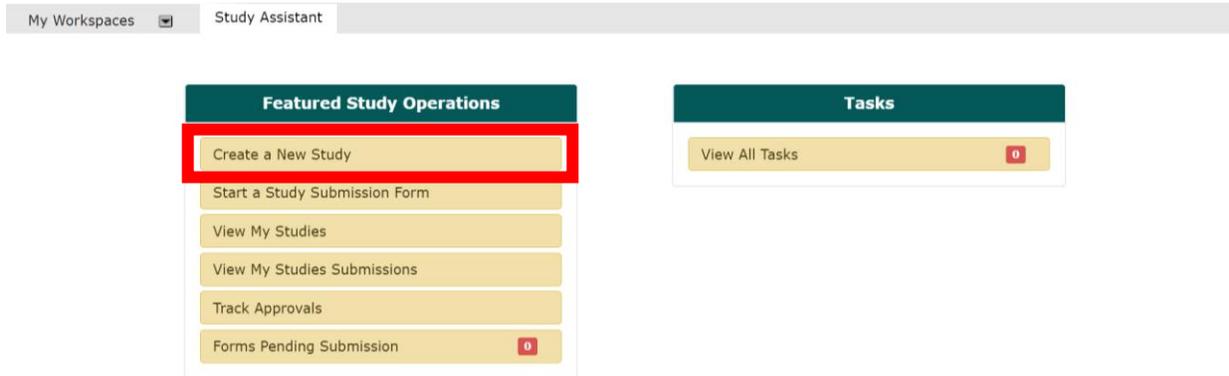
You are taken to the first of three sections of the application, known as the Study Shell. After the first three initial screens of this application are complete, a new study record is created in the system. Begin filling in the information.

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.
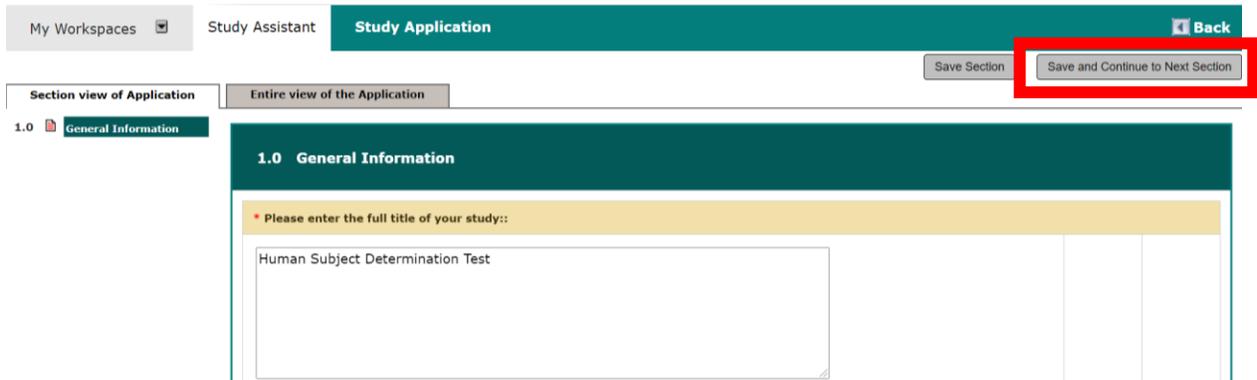
The next section of the Study Shell is where you will Setup Department(s) Access. Add or Remove Departments using the gray buttons.
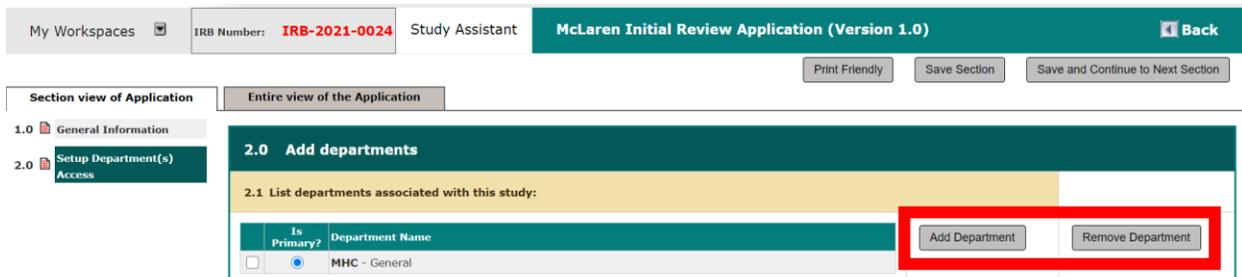
Next, you will Grant Key Personnel access to the study. Any user added to the study will have the ability to access the study in iRIS. To add any user to any role, click the Setup Study Personnel button.
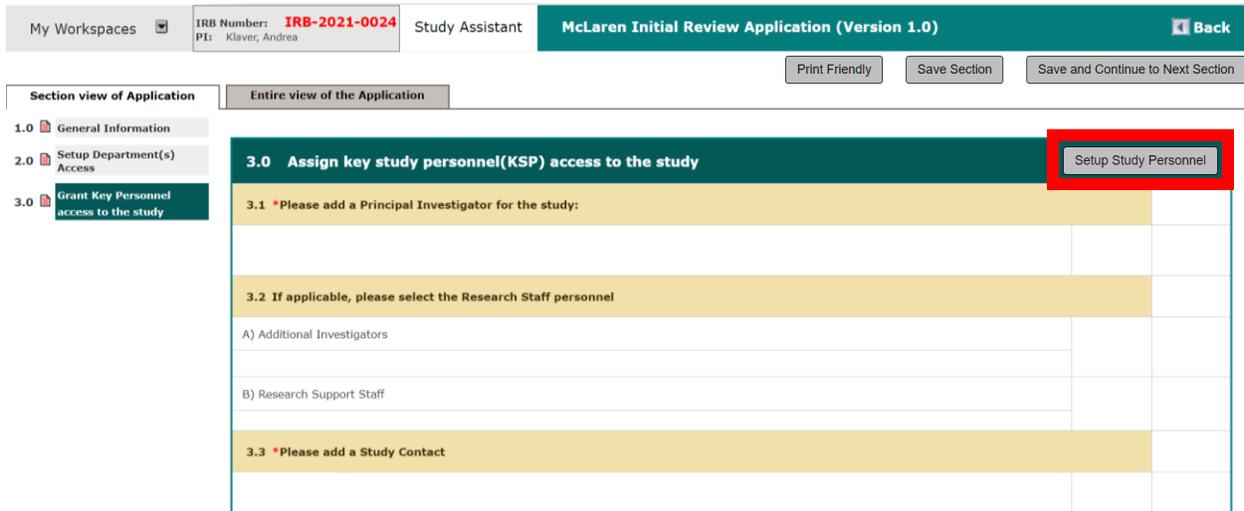
Another screen will display in a pop-up within your window showing the study personnel list and their roles, as it is populated.

For example, let's search by Last Name. Click on the gray Find User/Search Directory button at the top right of the window.
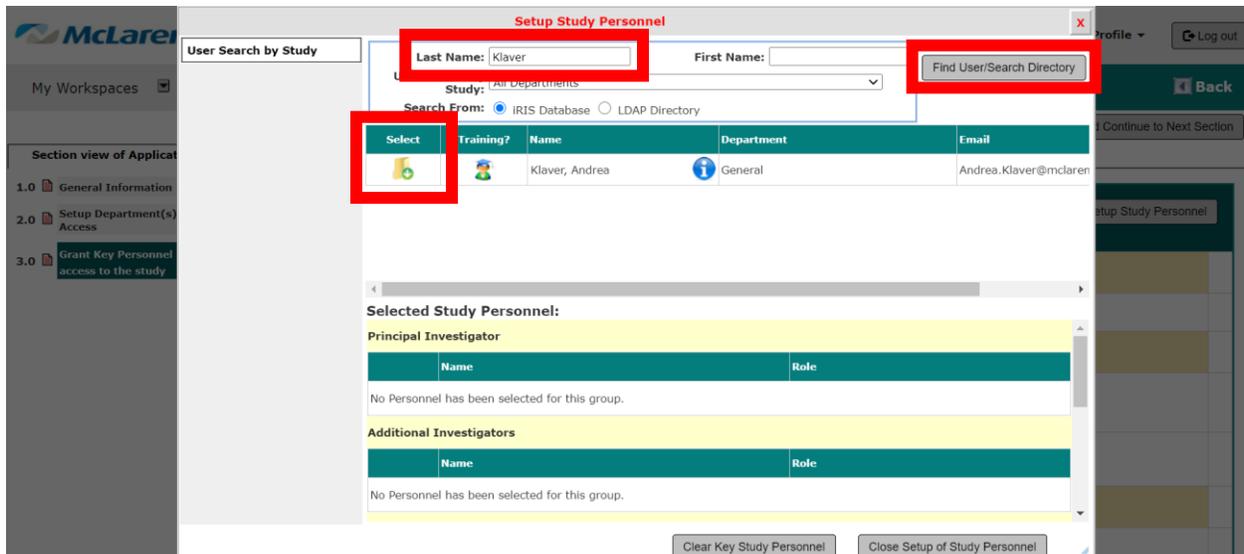
Click the Select icon to select the user. Another screen will display in a new pop-up asking you to Select the Role the user will have on the study.

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.
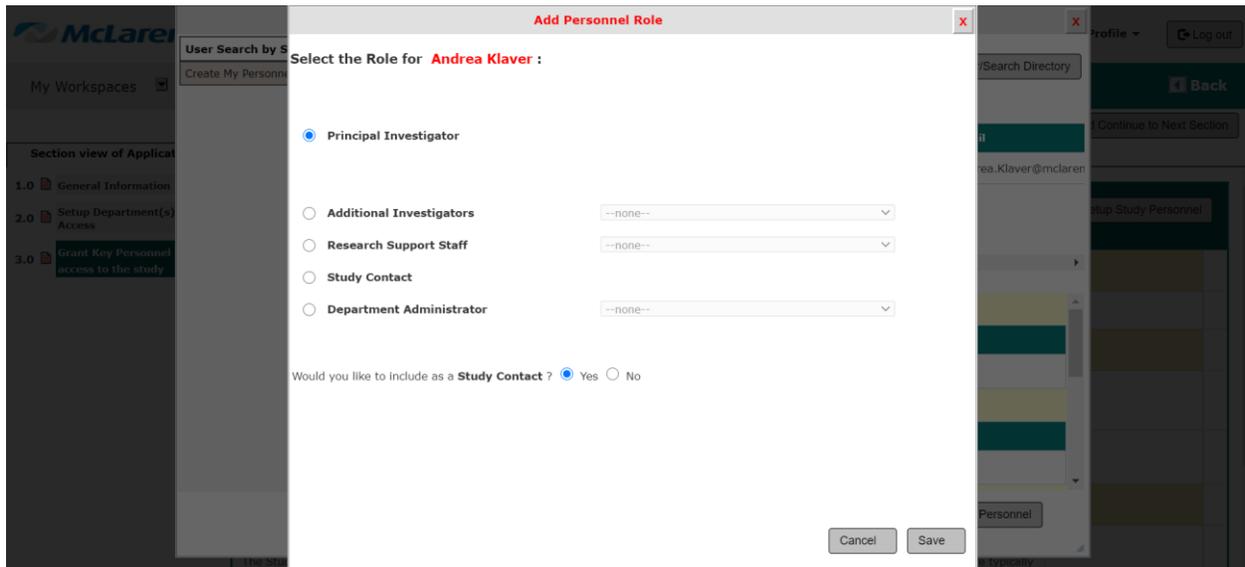
Next, you will be asked to enter General Information about your study submission. This includes whether medical residents, medical students, nursing students, etc. are participating in the study. Continue filling in the information.
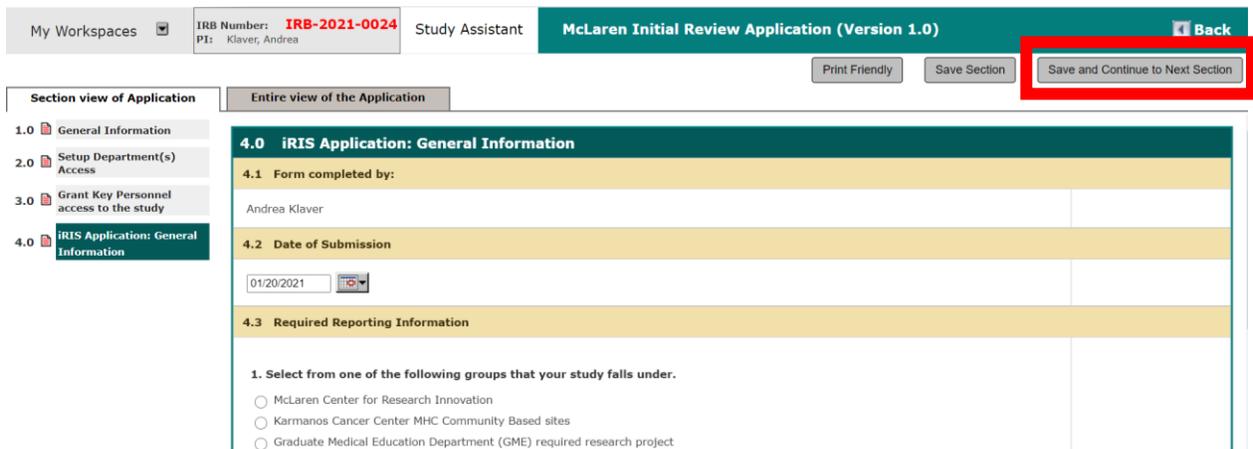
Indicate your Request for Determination of Human Subject Research in the next section.
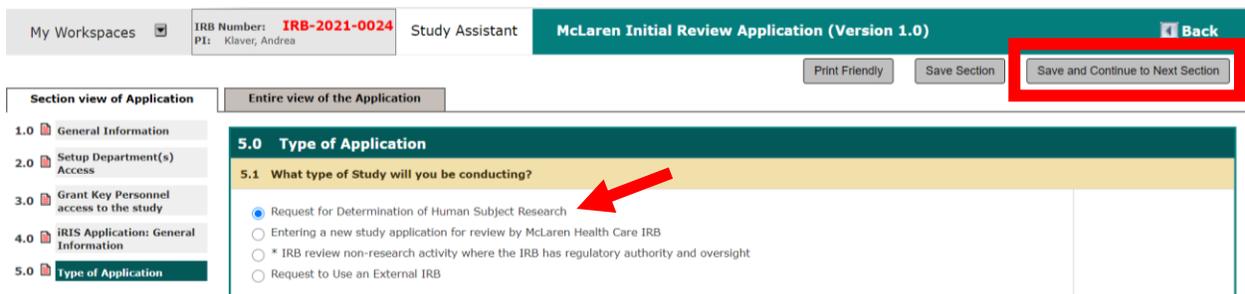
Information to complete in this section includes:

- 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.

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 **mcri@mclaren.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.
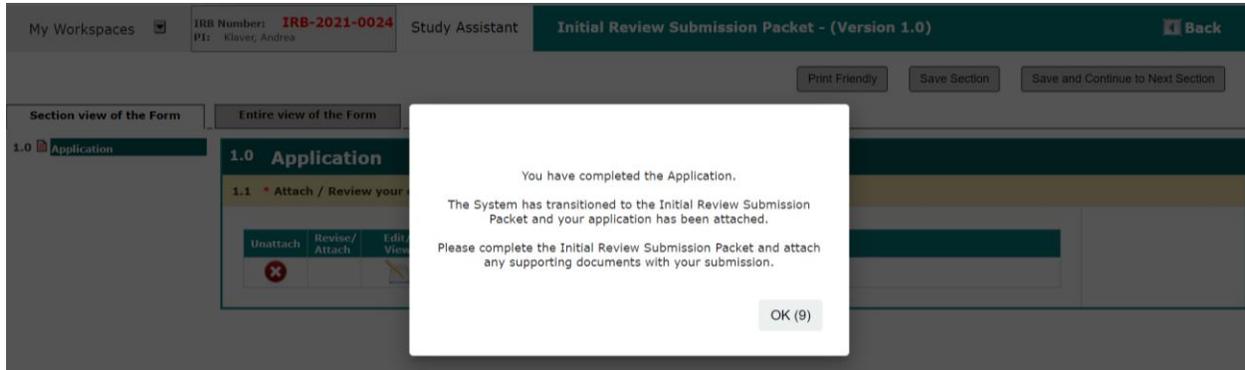
The Submission Packet functions the same way as the Study Application, regarding navigating and completing sections by adding information into the fields within each section. Complete this form by completing each section, attaching the necessary documentation, and clicking the Save and Continue button 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.
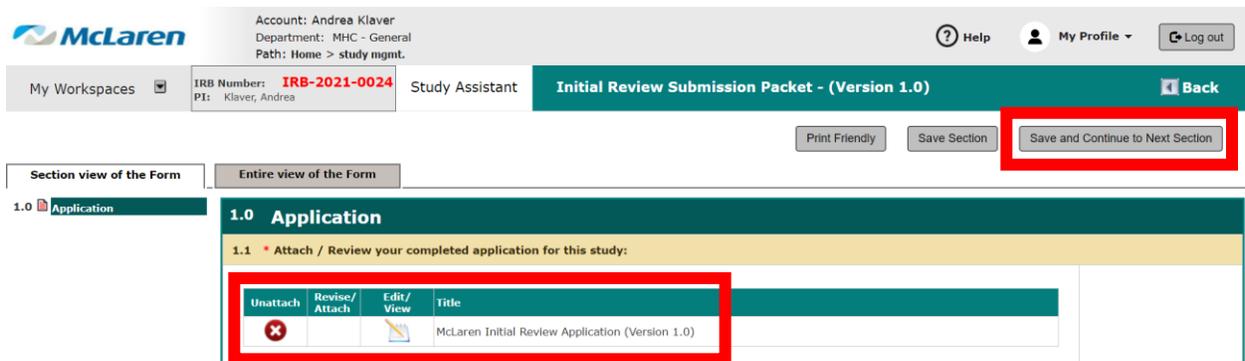
Upload all study documents in this section. A numbered list has been included in this section for your convenience.
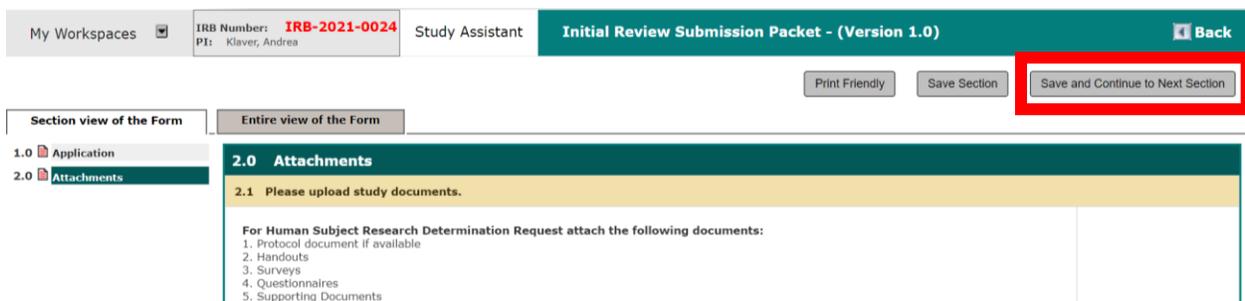
Once the Study Application and Submission Packet are complete and the required documents are attached, the form is ready to send to the IRB. You will be presented with a screen notifying you that the form is complete, as shown below.

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)].

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.

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

** 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.

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.

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.

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

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

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.

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).