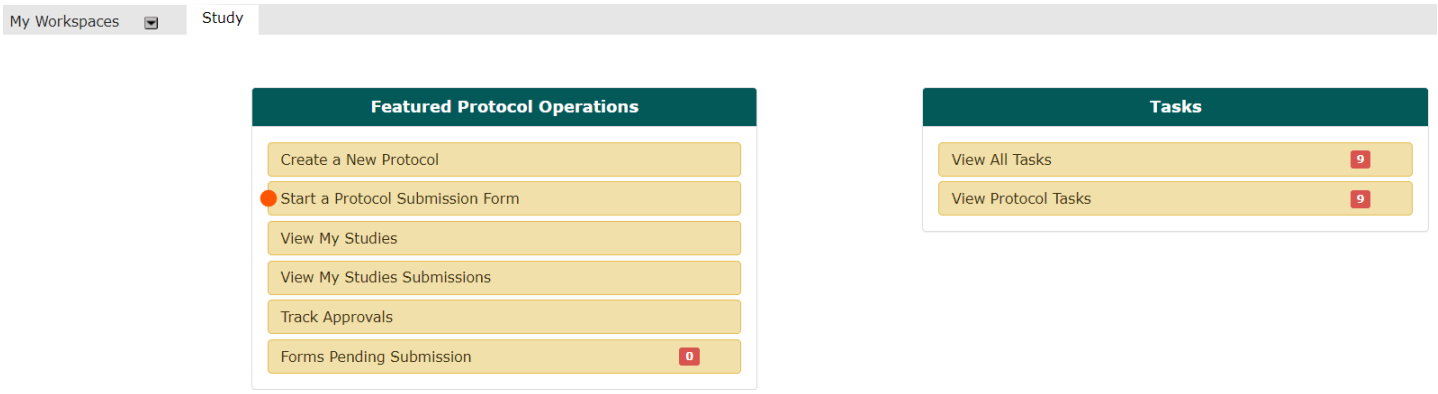
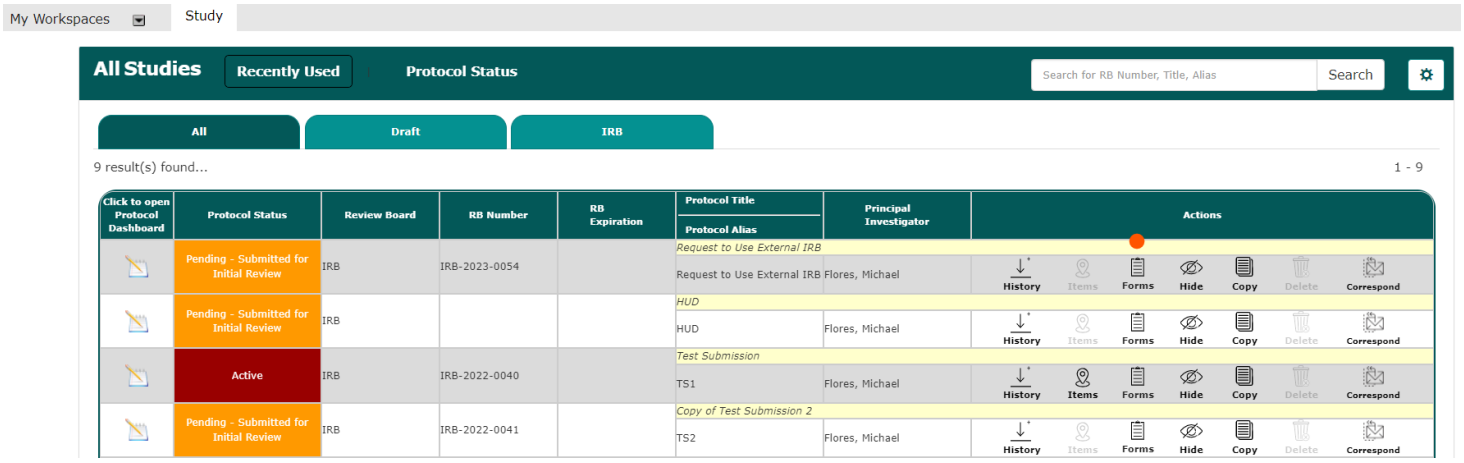
Modification - How to Add/Remove Key Study Personnel

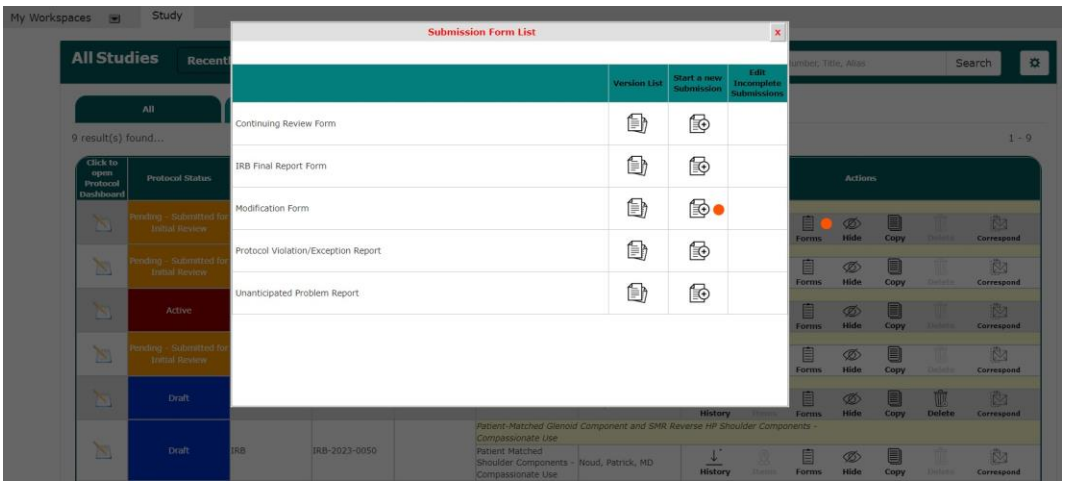
Step 1: After you login, iRIS will direct you to the Study Workspace. Under featured protocol operation, select "Start a Protocol Submission Form" to find the study protocol number for which you wish submit a Modification



Step 2: The "Start a Protocol Submission Form" command will direct you to the "All Studies" table (shown below), which lists all the studies associated with a particular PI. Locate the desired study IRB protocol number. Navigate to the right side of this row to the column titled "Actions". Select the "Forms" icon.

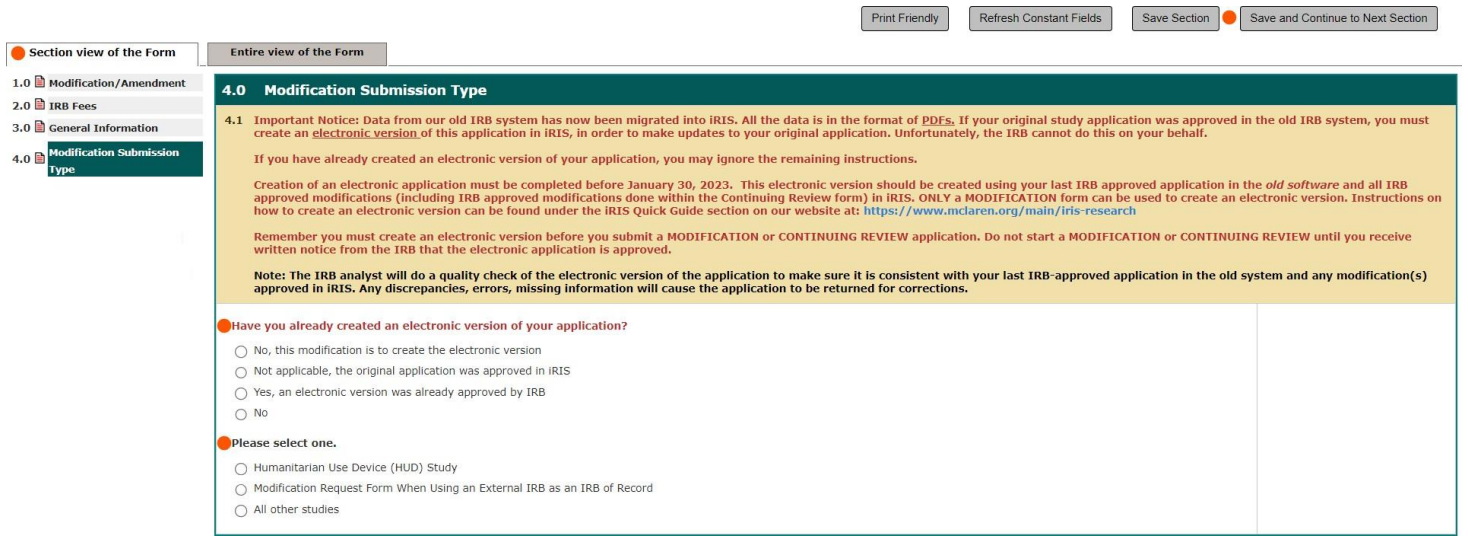


Step 3: Once you select the Forms icon, a pop-up box will display the submission form list. From the submission form list select the Modification form.



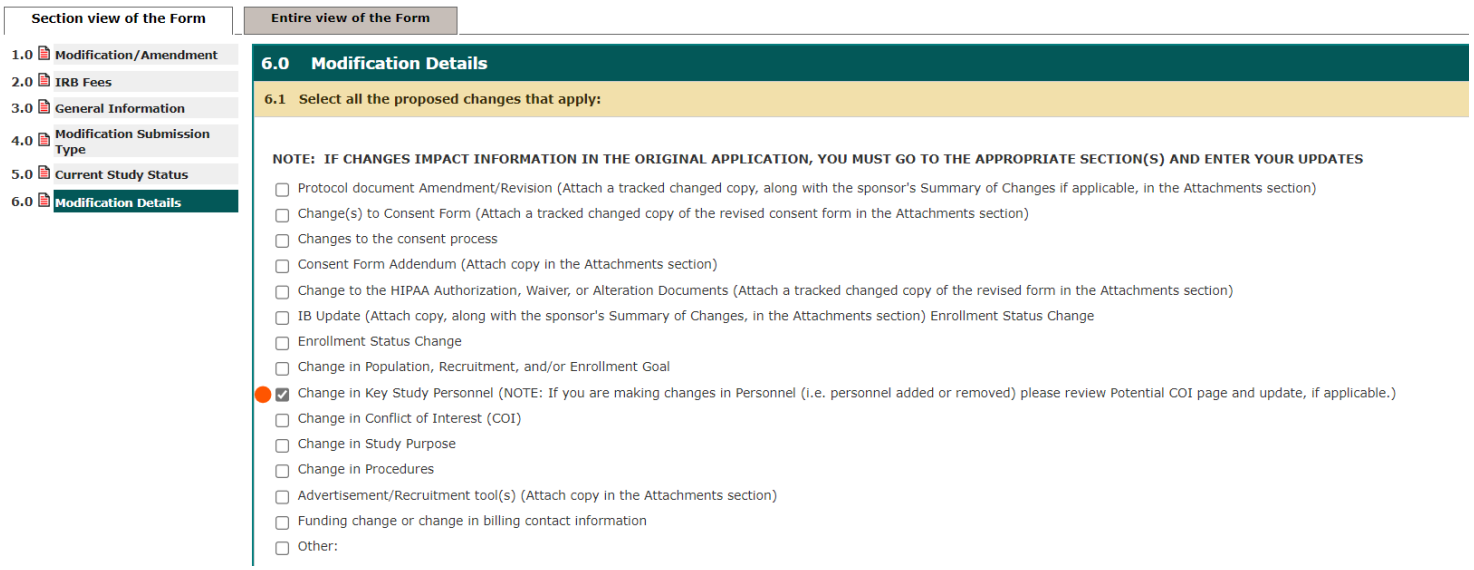
Step 4: Begin filling out the preliminary Modification form information. *The Section view of the Form window allows you to view the previous sections and toggle up or down if you need to check your work. The 'Save and Continue to Next Section' button allows you to move on to the next section.*

There are two questions under section 4.1 that will need to be answered to direct you to the correct Modification form you want to submit. Continue working through the sections of the form until you get to the Modification Details section.

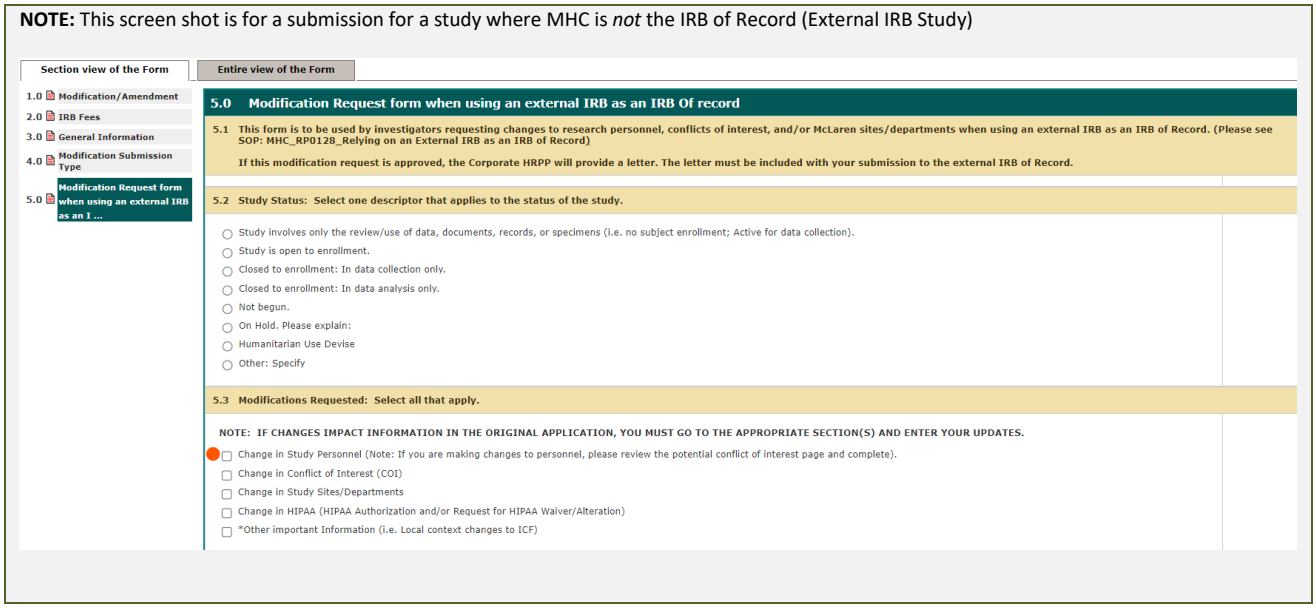


Step 5: Once you reach the Modification Details section, select "Change in Key Study Personnel".

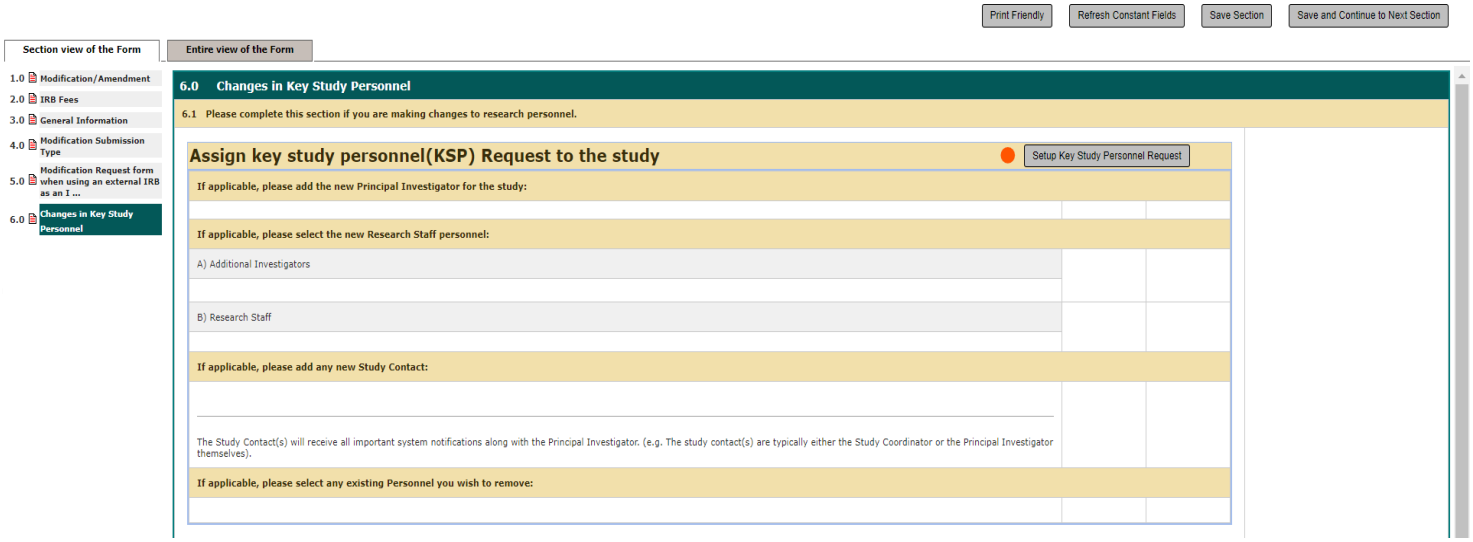
NOTE: This screen shot is for a submission for a study where MHC is the IRB of Record



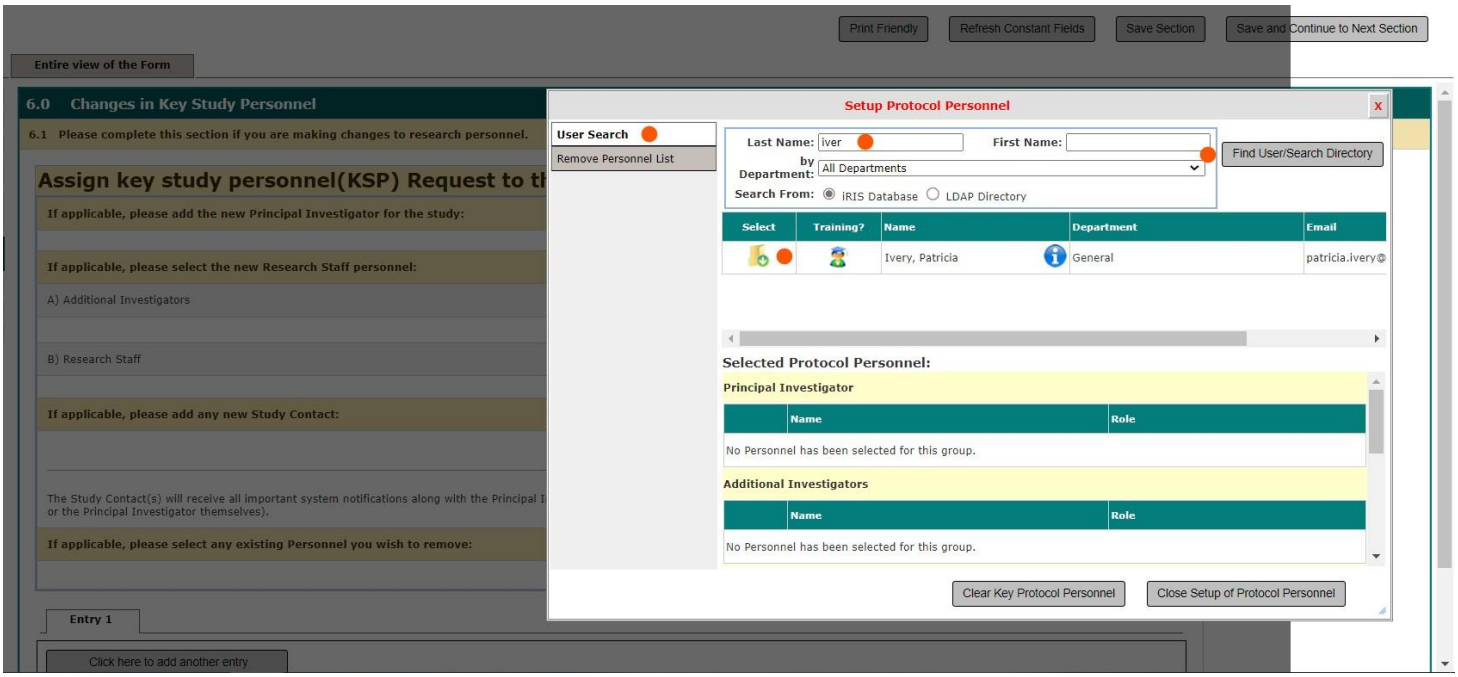
NOTE: This screen shot is for a submission for a study where MHC is *not* the IRB of Record (External IRB Study)



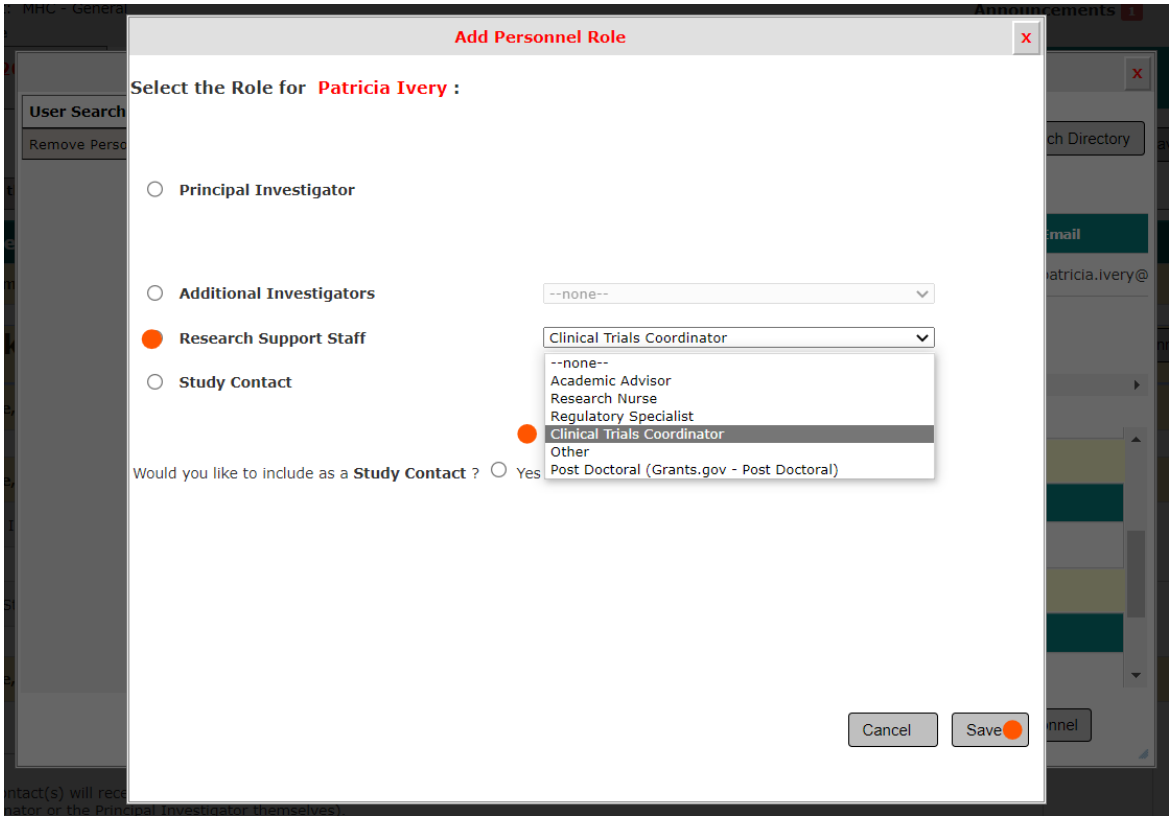
Step 6: Once you get to the section to make **Changes in Key Study Personnel**, you will see a table that allows you to complete the task. You have the option to <u>add or remove Study Personnel</u> (can do multiple personnel in one submission). <u>Select Setup Key Study Personnel Request</u>.



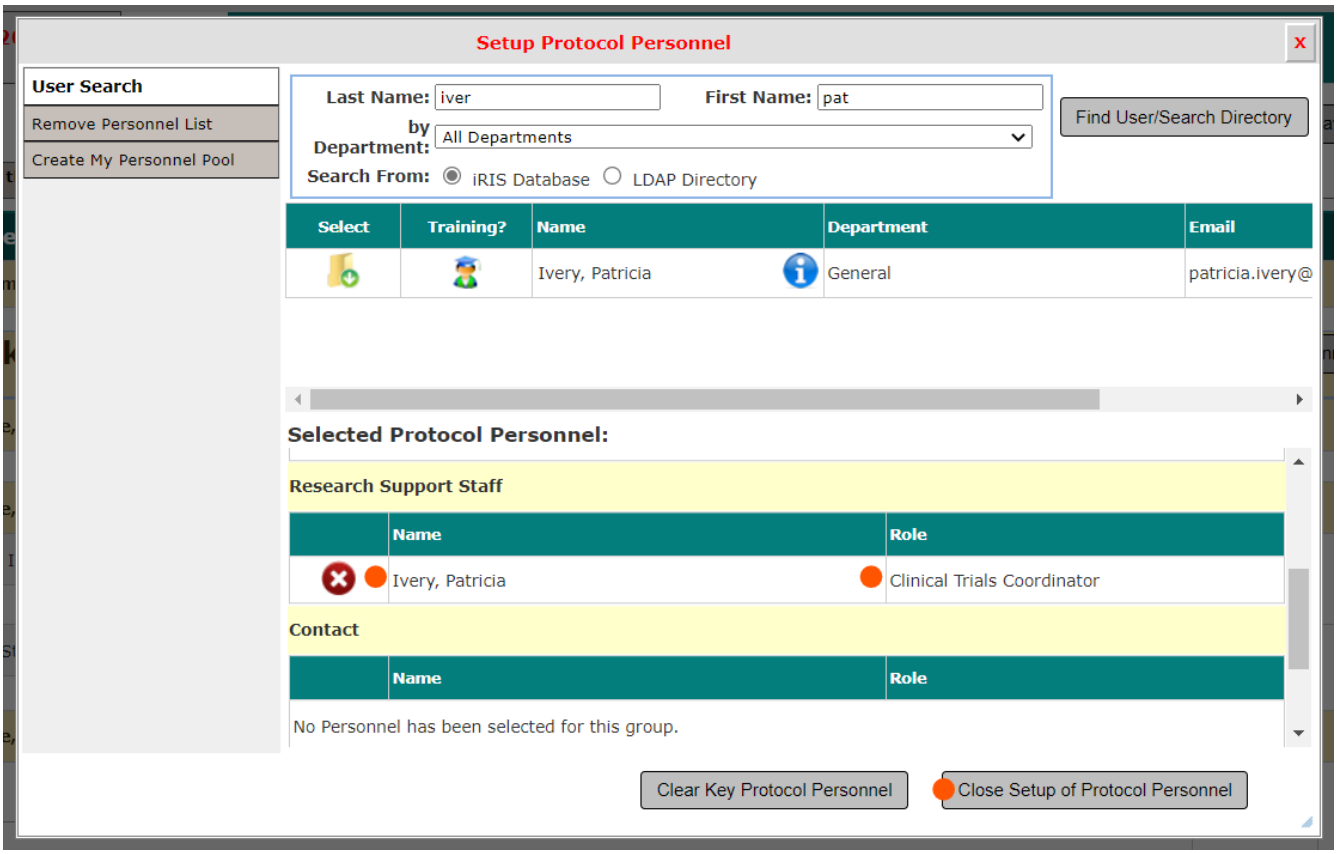
Step 7: <u>Adding Key Study Personnel</u> - Below is how the table (pop-up) looks like when you are "adding" KSP. Use the search fields to type in Last/First name (can be either one or both), then select Find User/Search Directory. The table below will display the user(s) that fit the name in the search fields. By selecting the green arrow facing down, this will allow you to request that user to be on the study.



When you select the green arrow, another pop-up window will appear where you can assign the new user a role on the study. Select the role then Save.

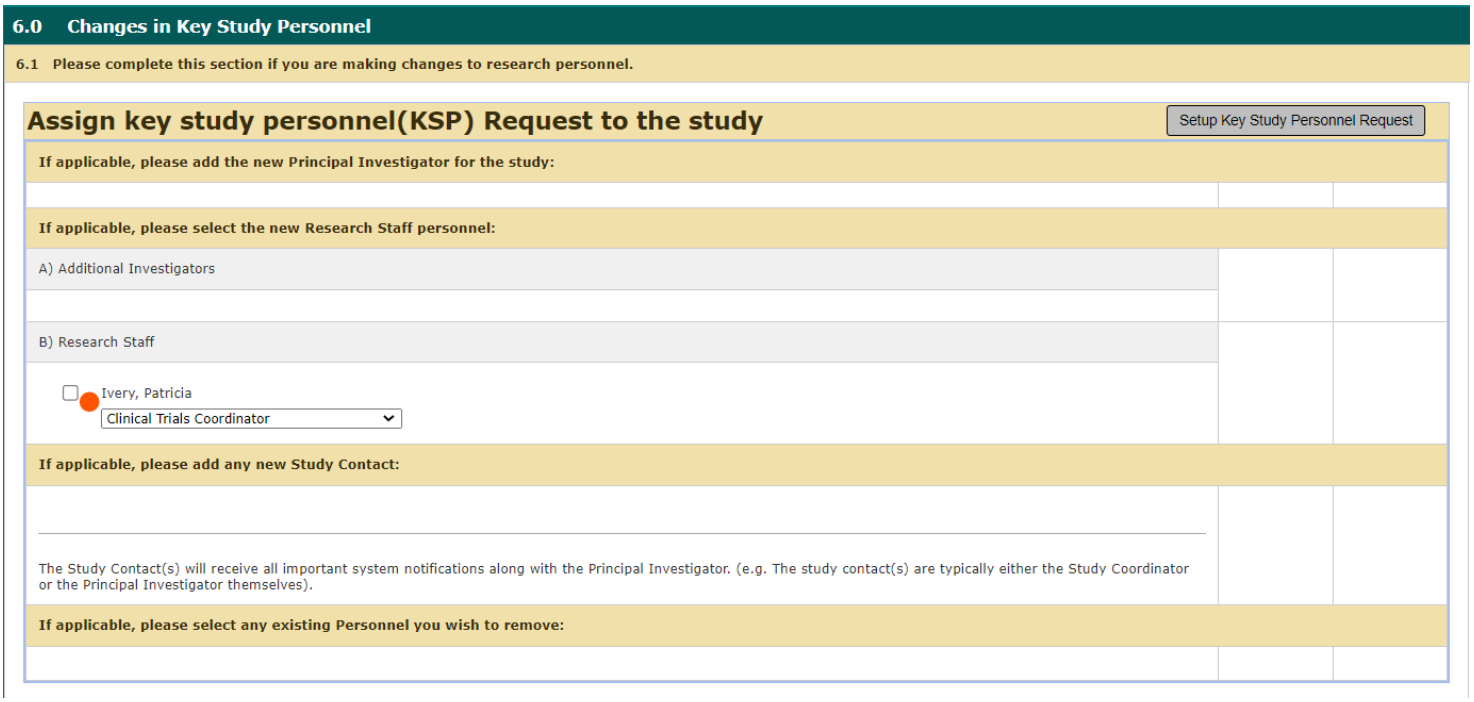


The table will register the user requested and their role will appear in the request. You can do another request to add or complete your request by selecting the Close Setup of Protocol Personnel button.

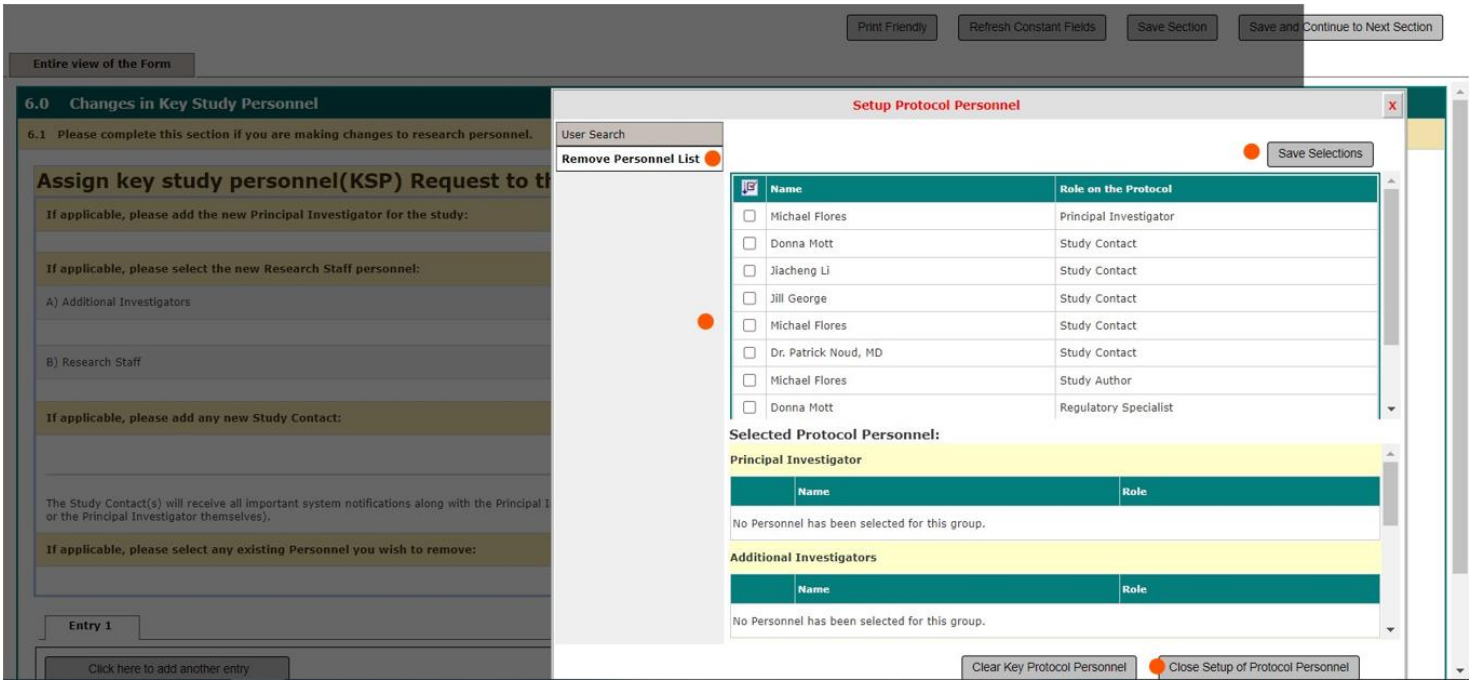


After you select Close Setup of Protocol Personnel button, the table in the Modification form is updated to reflect the request that was made.

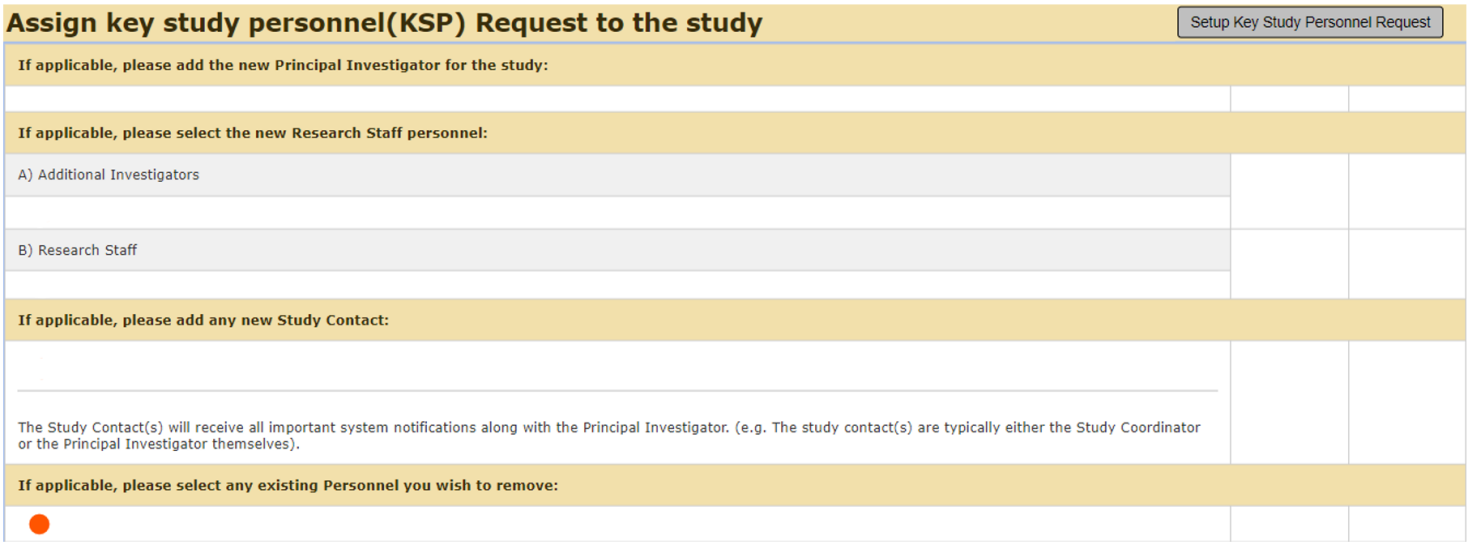
Note: IF added KSP does not automatically generate on the Entry table after you select the Close Setup of Protocol Personnel button, click the Save Section button on the top right of the screen, so iRIS can register that request and update the table and the name(s) on the drop-down selection.



Step 8: <u>Removing Key Study Personnel</u> - The table below looks like the one for adding KSP, however this time you select "Remove Personnel List", and the table displays current study personnel. Select the user(s) you want to remove then select "Close Setup of Protocol Personnel."

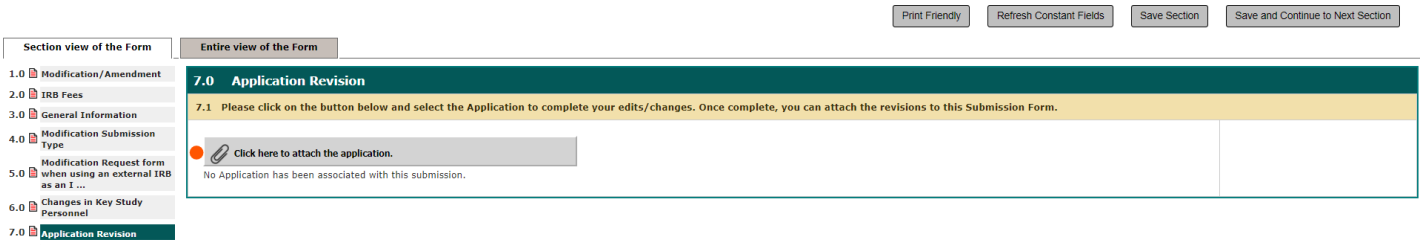


Step 9: After you select Close Setup of Protocol Personnel button, the table in the Modification form is updated to reflect the request that was made and the name(s) will appear under the header “If applicable, please select any existing Personnel you wish to remove:”

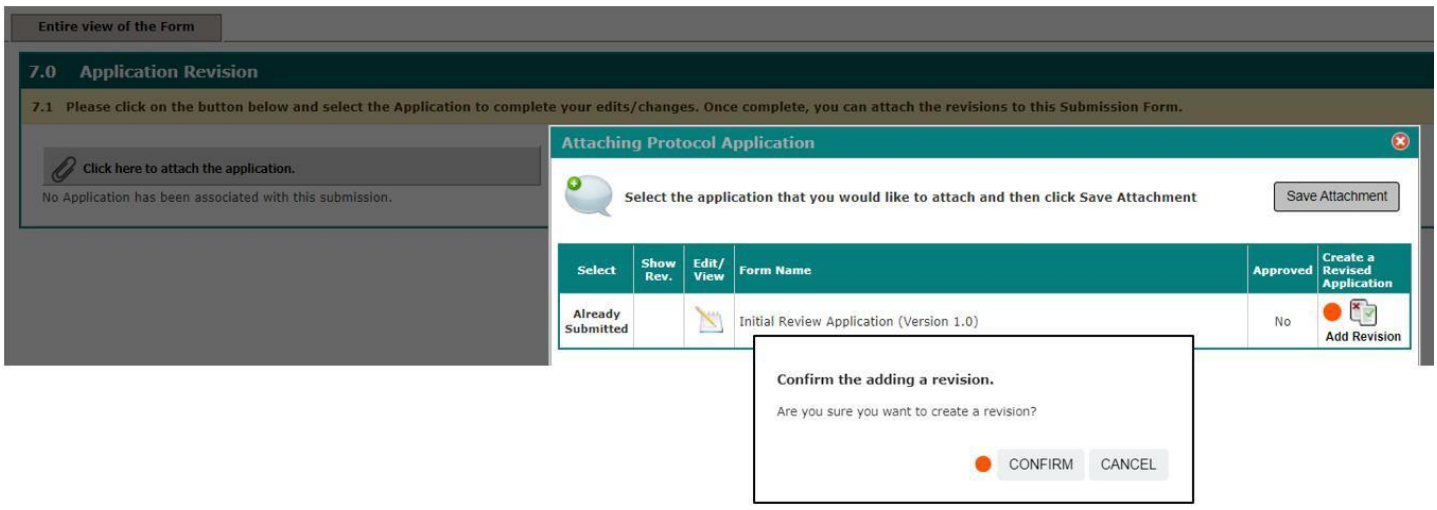


Step 10: Edit/Update Initial Application - This tool will allow you to update the original application before submitting to the IRB. Once you update the original application a new version will be created. Please follow this step anytime you update the original application. In this example you are going to add information for each KSP added to the original application or remove information for personnel that is taken off the study.

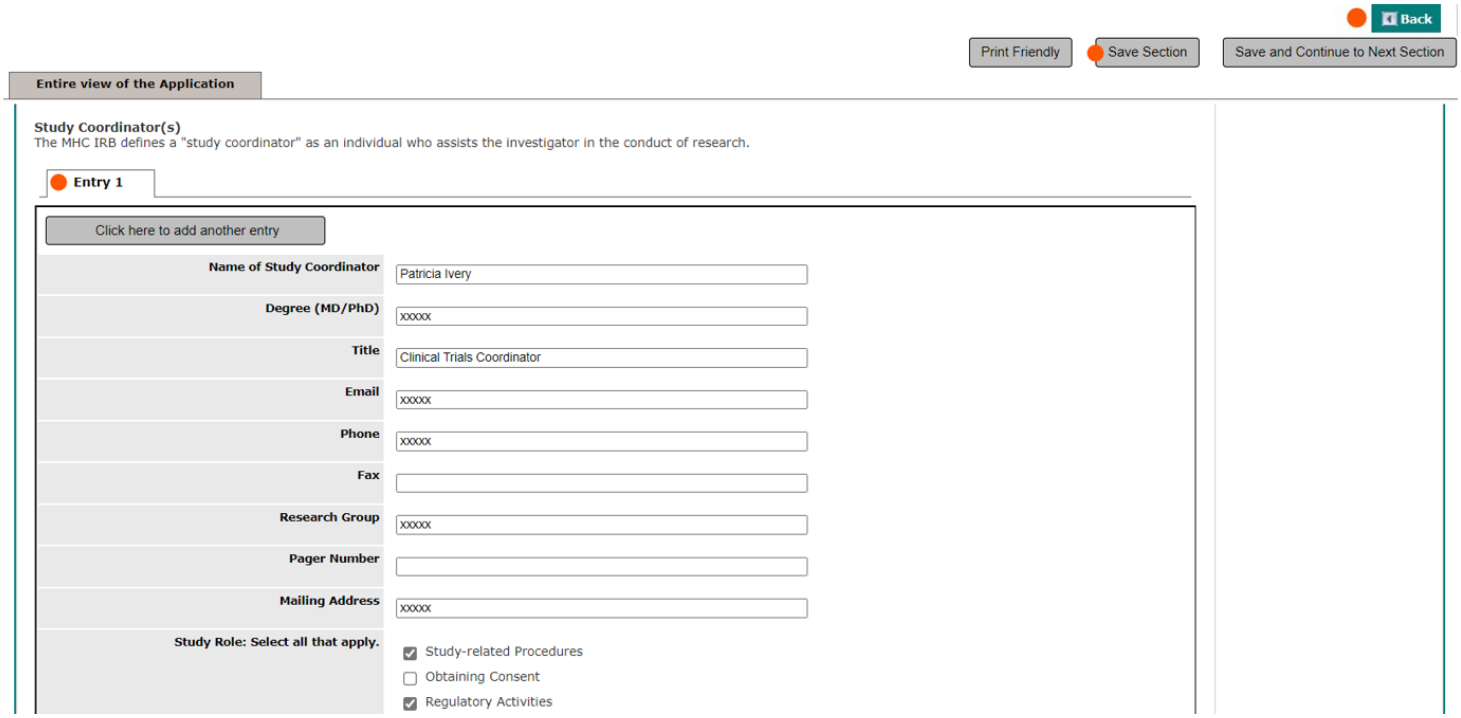
*** NOTE:** At the bottom of this document, there are instructions to guide the PI in submitting a Modification within a Continuing Review form.



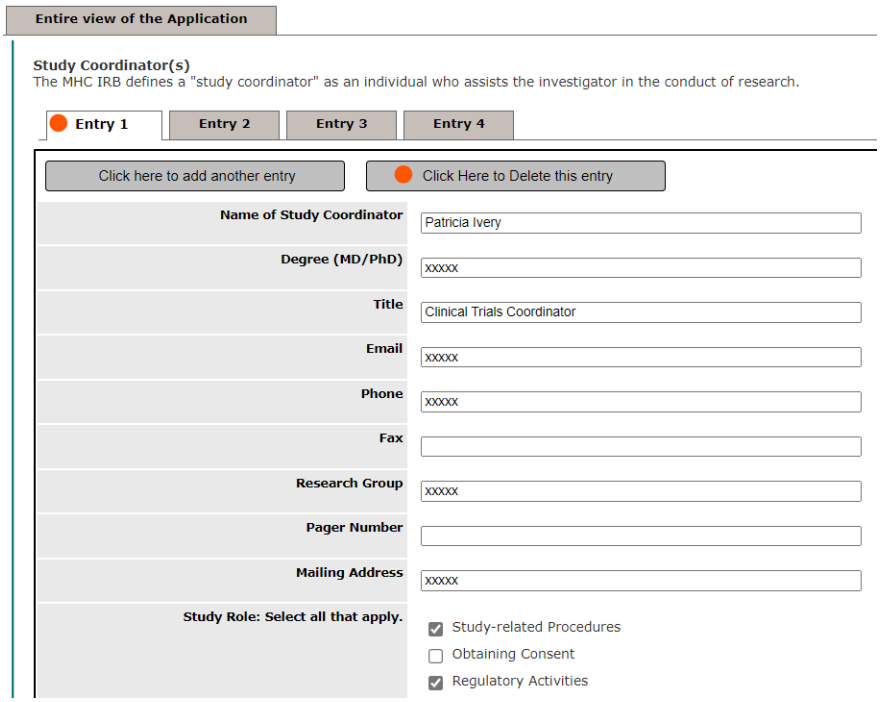
When you click on the button "Click here to attach the application" there will be a pop-box that allows you to Add Revision to the last approved Initial Review Application (currently Version 1.0). After you click on the Add Revision icon, another pop-up will display to Confirm action.



Step 11: To account for the added KSP, toggle down to the Personnel Information section of the Initial Review Application. There is a table where you can add entries for each added personnel and their respective information. Once you complete each added KSP information, click on the Save Section button then the Back button to return to the Modification Submission Form.

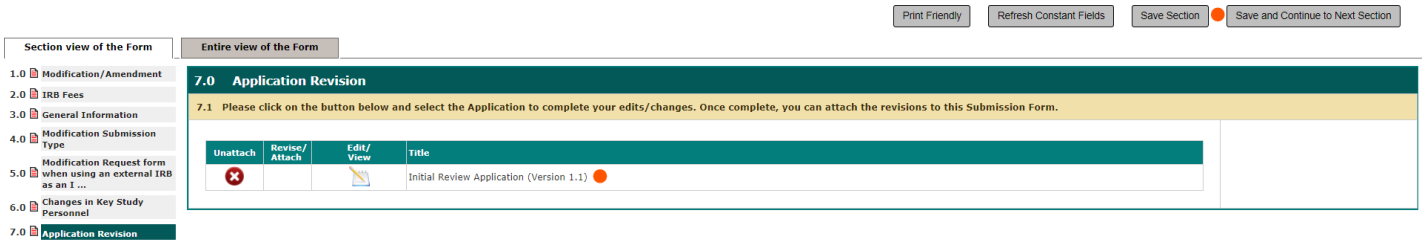


Step 12: If you are removing KSP, locate the panel of the person you are removing from the study and select the Click Here to Delete this entry button. Be sure you are on the right Entry before you delete. Save Section and select the Back button to return to the Modification form.

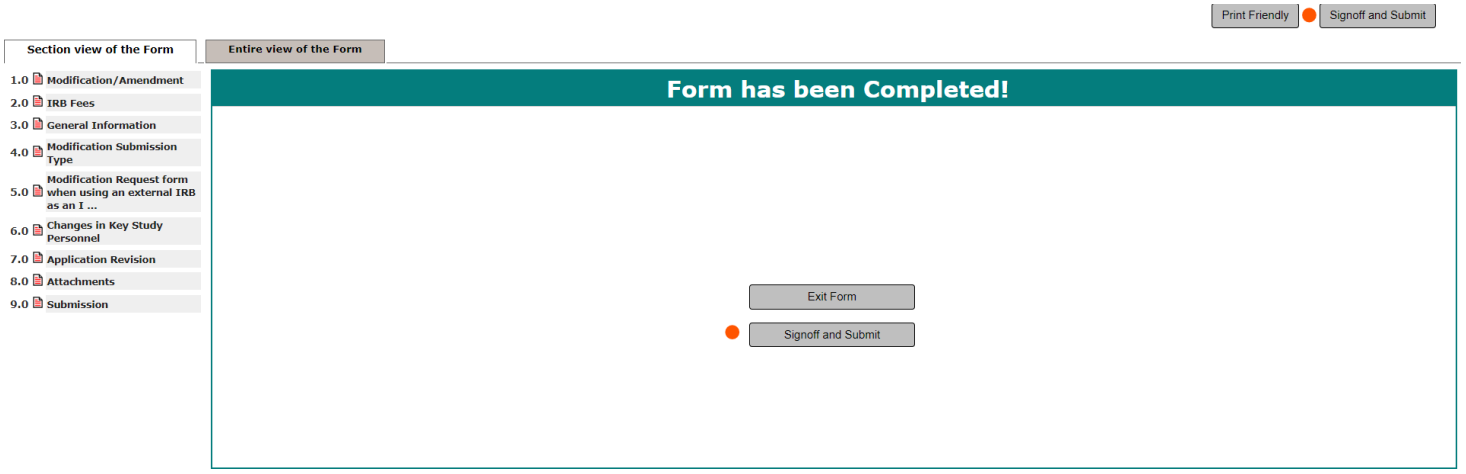


Important Note: You are not to make any changes to section 3.0 of the original application

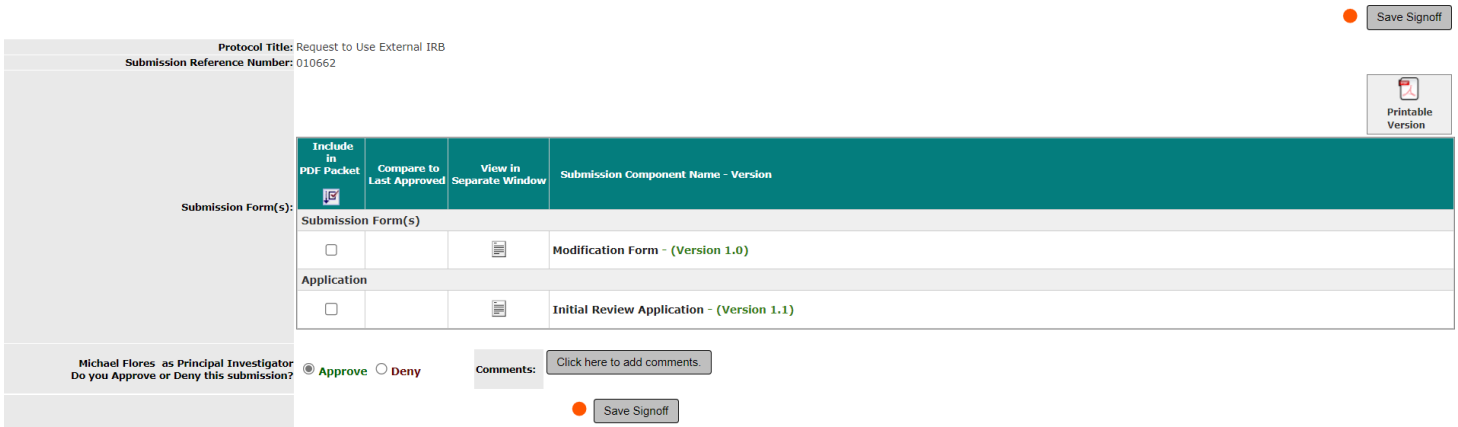
Step 13: You are now back in the Modification Submission form, and you will notice that after you revised the Initial Review Application, it is now Version 1.1 on the table.



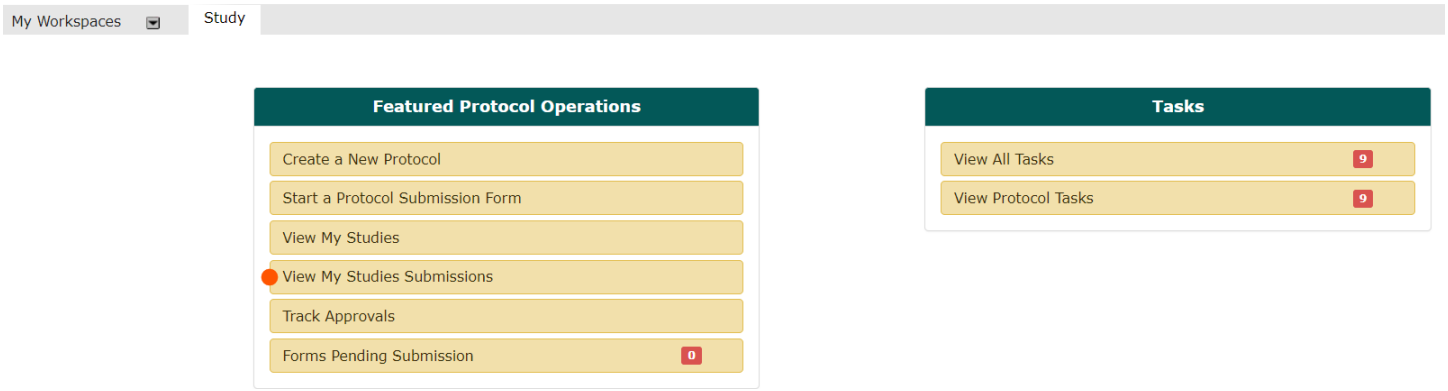
Step 14: You will Save and Continue to the next section and complete applicable questions. Once you are complete, you will see this screen where you can Signoff and Submit.



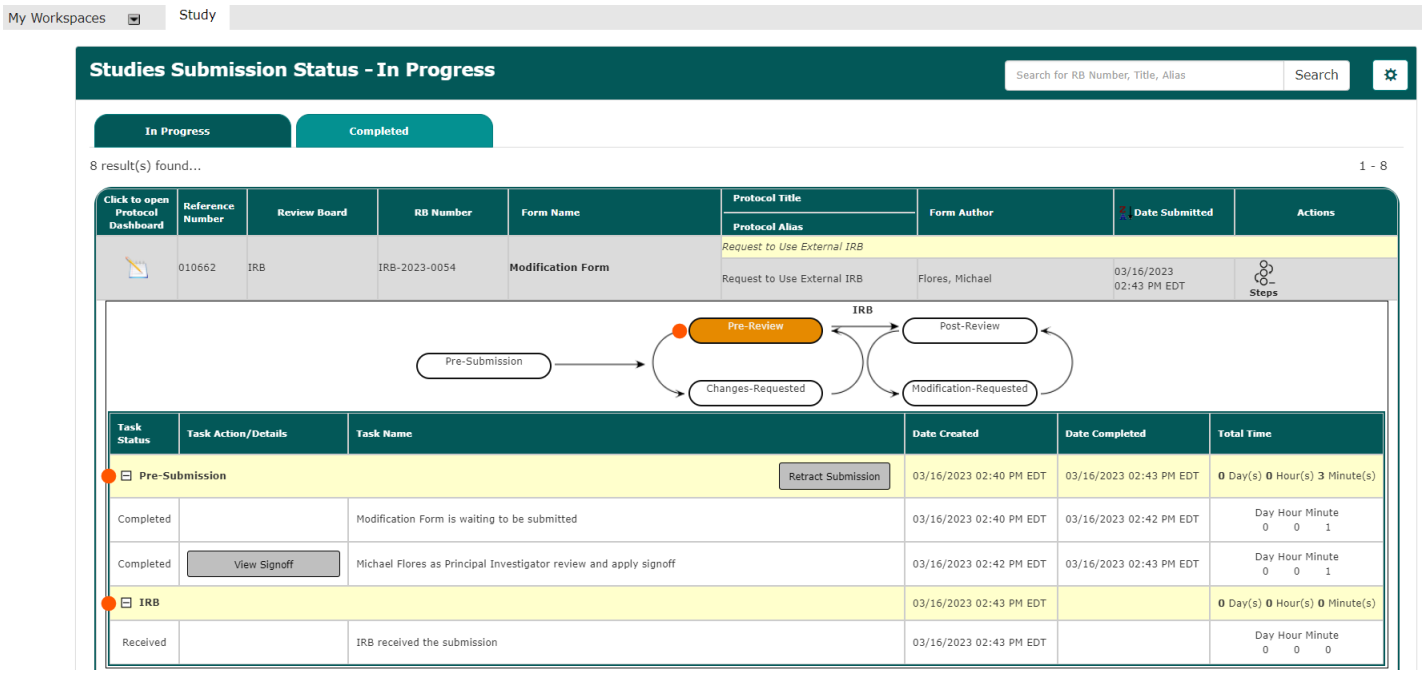
Step 15: After you click Signoff and Submit, iRIS will direct you to this page where you can approve the Submission and record your electronic signature. iRIS will automatically route the submission to the PI. The submission will not be submitted to the IRB until the PI has signed off.



Step 16: After you submitted the Modification Submission form, you can track the progress of your submission. In the Study Workspace, there is a table called Studies Submission Status – In Progress.



This is how the table looks like after iRIS toggles you down to the Studies Submission Status table.



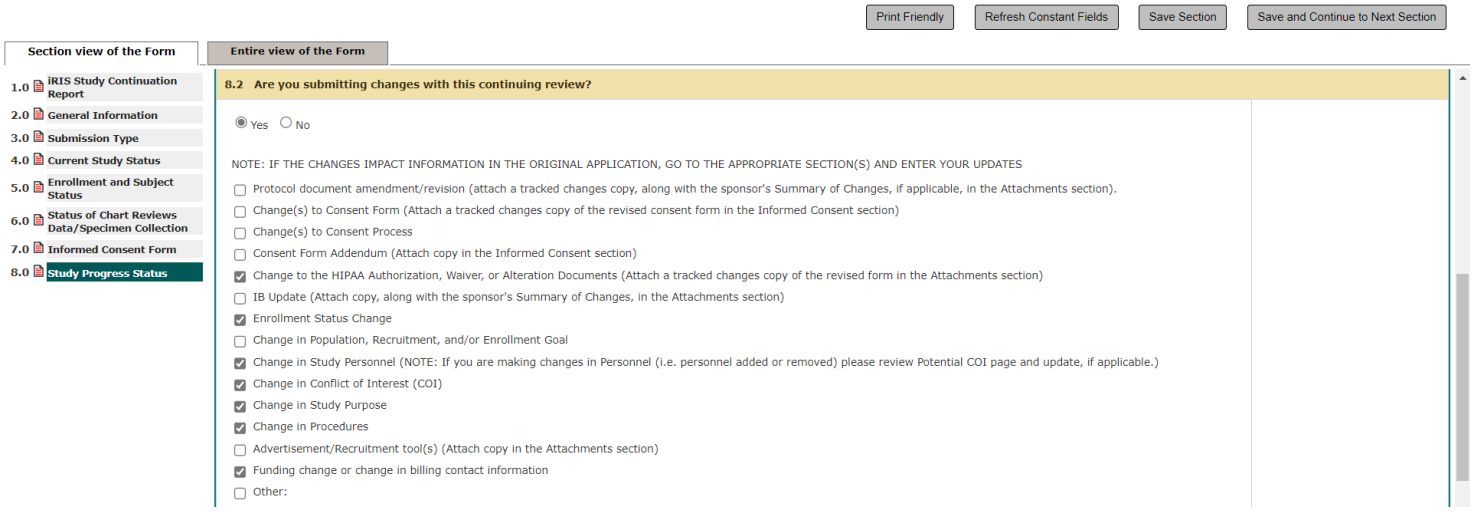
Please note the any Key Study Personnel changes submitted via the process above are not effective until IRB Review of the modification is complete.

Completing a Modification within the Continuing Review Form

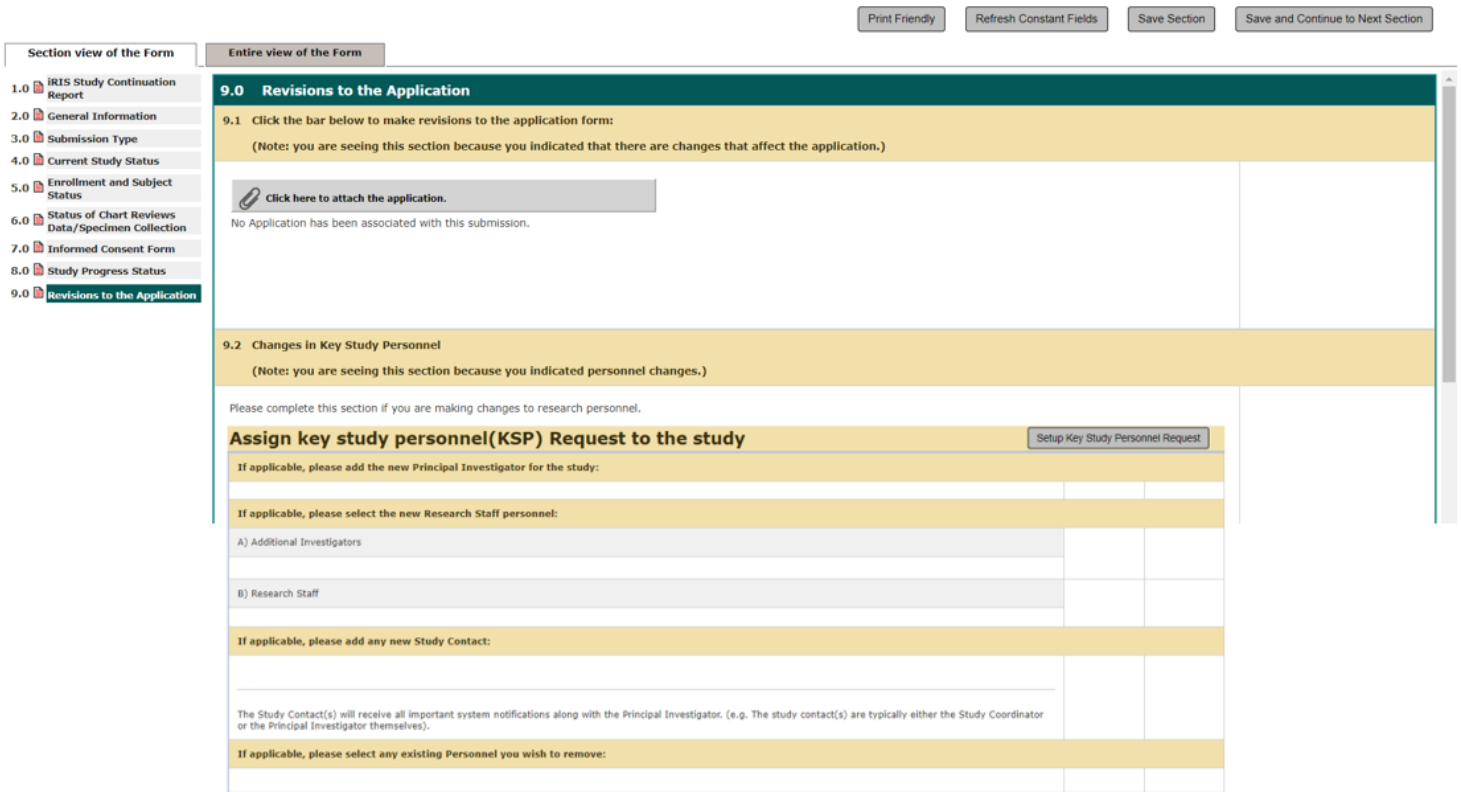
The process of completing a modification within the Continuing Review application is like a solo Modification submission. Below are a couple of screen shots that will guide you.

Step 1: Follow steps 1-3 in the Modification guide. When you get to number three, select Continuing Review and begin filling out the form.

Step 2: On the Study Progress Status section of the Continuing Review, you have the options to select what type of changes you are requesting. If any of the ones below are selected, Save and Continue to Next Section.



Step 3: iRIS will direct you to the next section, Revisions to the Application. The tool to change/edit the Initial Review Application and add/remove KSP will both be in this section. Both tools work the same way as in the Modification Submission form.



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