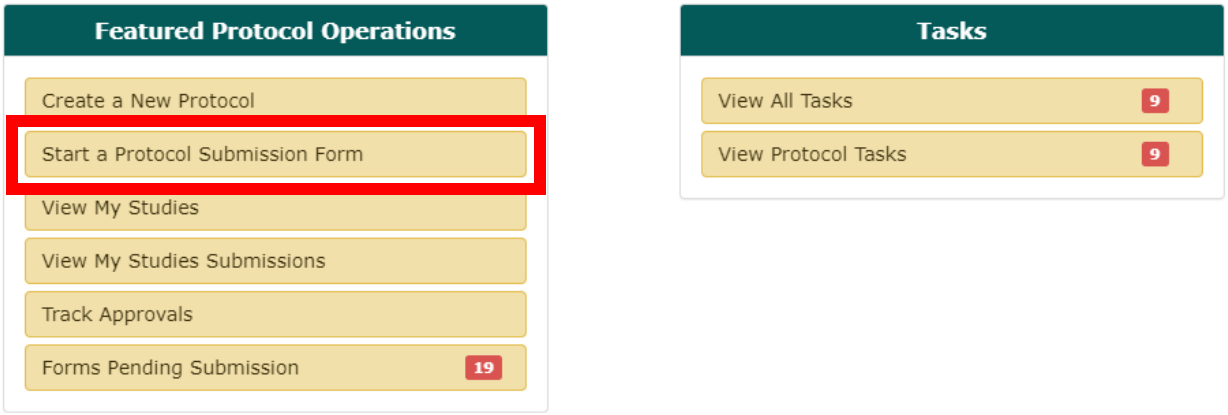
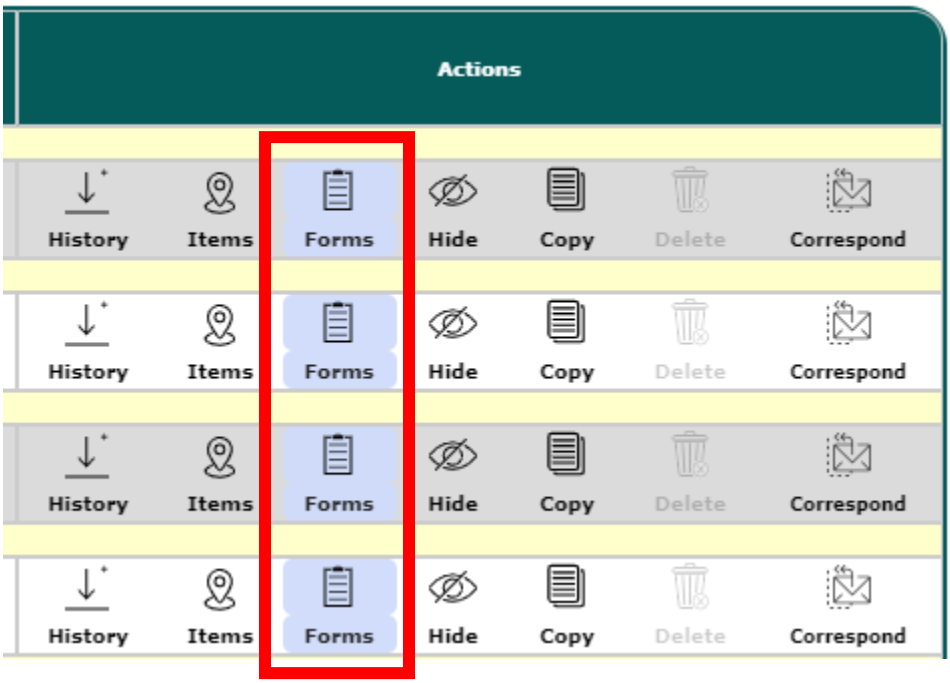
Submitting a Modification

At any point during the life of your study you can create a Modification form to submit changes for approval. Certain changes to a study require you to submit the change to the IRB before that change can be applied to the study. Changing key study personnel, the study population, recruitment, and/or enrollment goal, and a change in Conflict of Interest (COI) are just some of the items that must be submitted in the form.

To begin a Modification form, select the yellow Start a Protocol Submission Form button on your iRIS home screen.

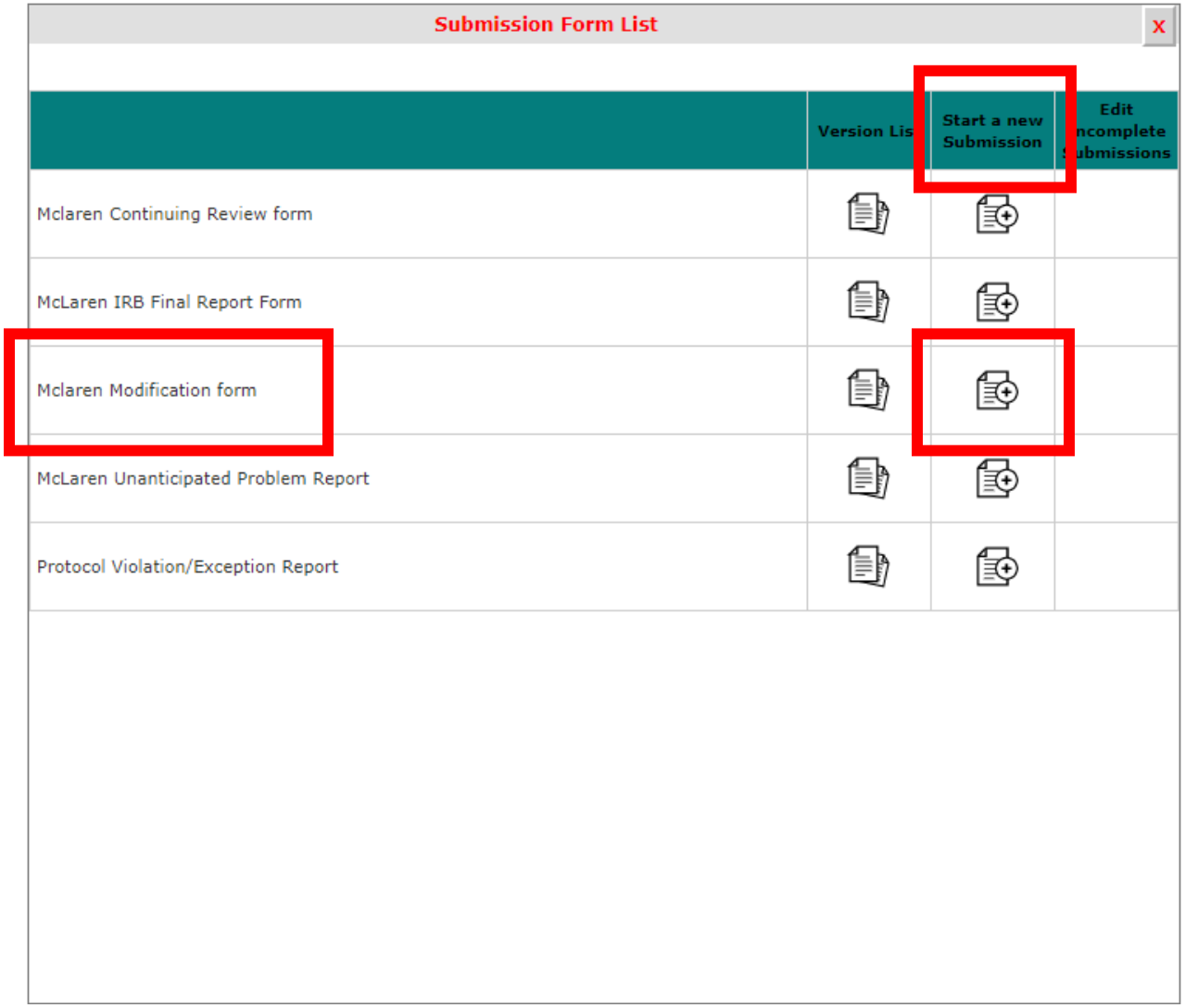


You will be automatically directed to your All Studies section tab. The Forms icons next to each of your studies will flash light blue for a few seconds. Click on the Forms icon next to the study you would like to submit a Modification form for.



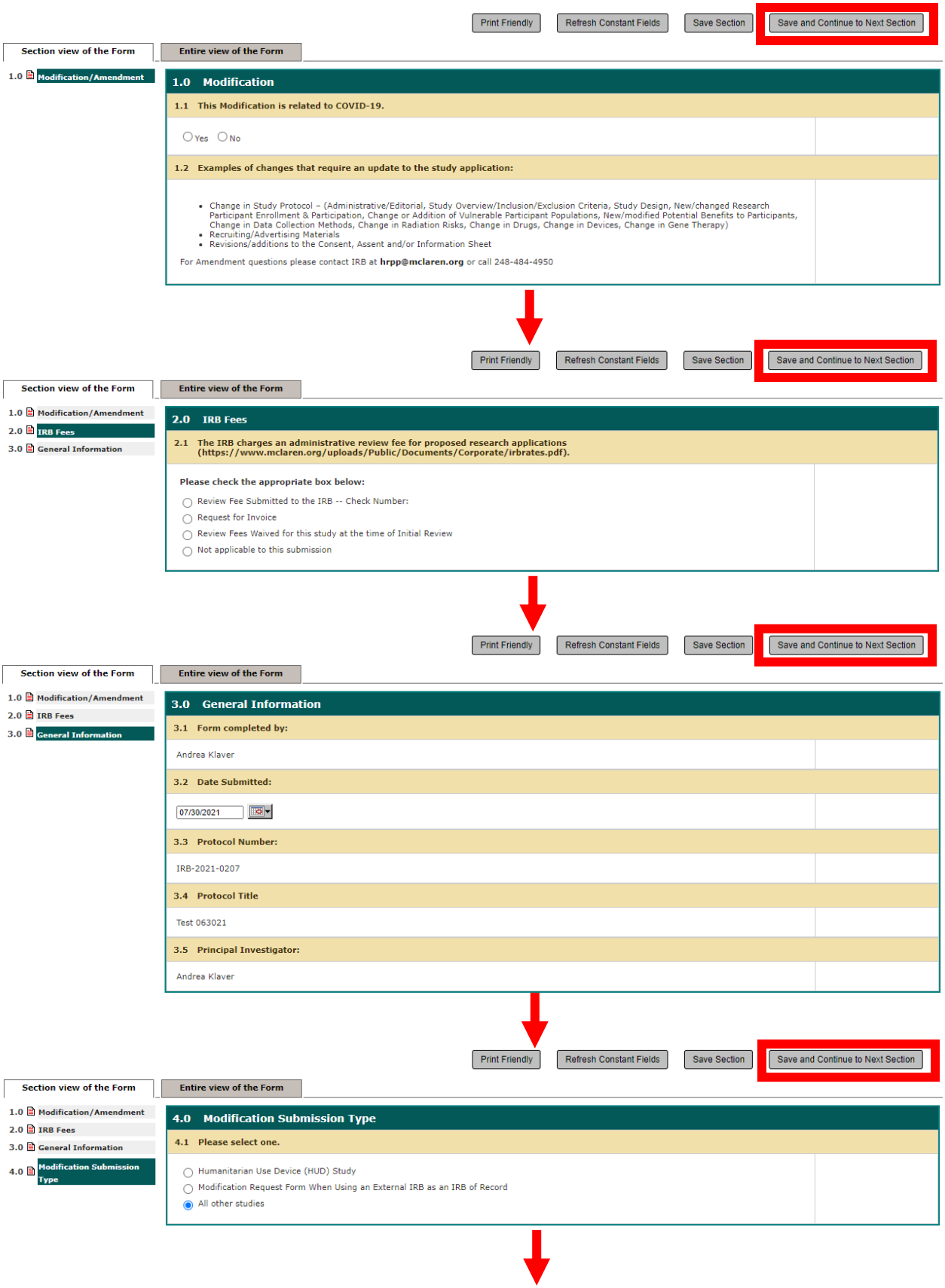
A new screen will display in a pop-up within your window showing the different types of forms you may submit in iRIS for your study.

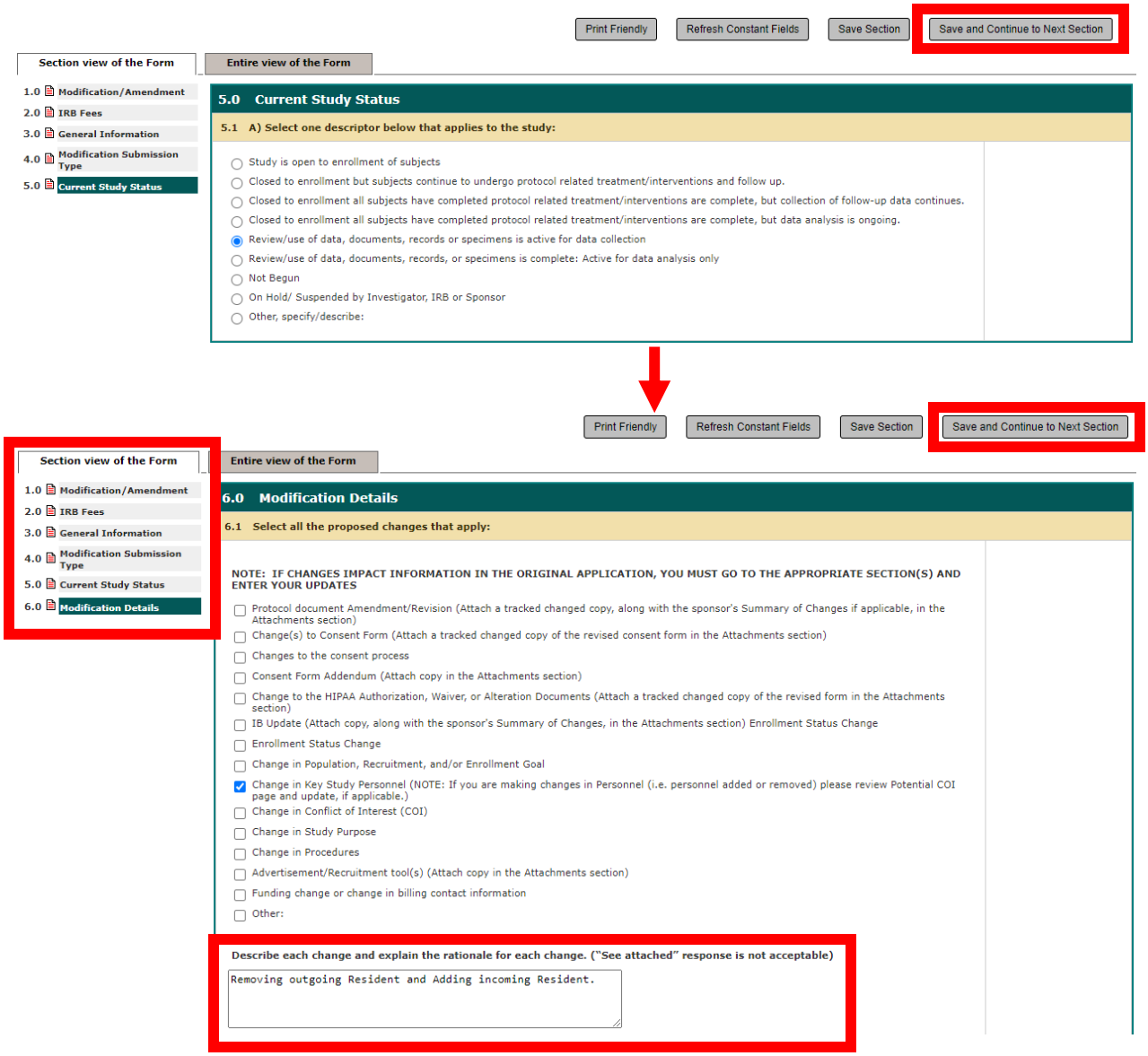
Find the McLaren Modification Form and click the icon underneath the Start a new Submission column.



Within this form, you will be presented with progressive questions. Based on the answers you provide to the questions you see on the screen, you will be able to request changes to certain areas of your study.

Complete the sections of the Modification form using the gray Save and Continue button in the upper right of each screen to navigate through the sections.


Print Friendly
Refresh Constant Fields
Save Section
Save and Continue to Next Section
Section view of the Form
Entire view of the Form
1.0 Modification/Amendment
1.0 Modification
1.1 This Modification is related to COVID-19.
Yes No
1.2 Examples of changes that require an update to the study application:
Change in Study Protocol – (Administrative/Editorial, Study Overview/Inclusion/Exclusion Criteria, Study Design, New/changed Research Participant Enrollment & Participation, Change or Addition of Vulnerable Participant Populations, New/modified Potential Benefits to Participants, Change in Data Collection Methods, Change in Radiation Risks, Change in Drugs, Change in Devices, Change in Gene Therapy)
Recruiting/Advertising Materials
Revisions/additions to the Consent, Assent and/or Information Sheet
For Amendment questions please contact IRB at hrpp@mclaren.org or call 248-484-4950
Print Friendly
Refresh Constant Fields
Save Section
Save and Continue to Next Section
Section view of the Form
Entire view of the Form
1.0 Modification/Amendment
2.0 IRB Fees
3.0 General Information
2.0 IRB Fees
2.1 The IRB charges an administrative review fee for proposed research applications (https://www.mclaren.org/uploads/Public/Documents/Corporate/irbrates.pdf).
Please check the appropriate box below:
Review Fee Submitted to the IRB -- Check Number:
Request for Invoice
Review Fees Waived for this study at the time of Initial Review
Not applicable to this submission
Print Friendly
Refresh Constant Fields
Save Section
Save and Continue to Next Section
Section view of the Form
Entire view of the Form
1.0 Modification/Amendment
2.0 IRB Fees
3.0 General Information
3.0 General Information
3.1 Form completed by:
Andrea Klaver
3.2 Date Submitted:
07/30/2021
3.3 Protocol Number:
IRB-2021-0207
3.4 Protocol Title
Test 063021
3.5 Principal Investigator:
Andrea Klaver
Print Friendly
Refresh Constant Fields
Save Section
Save and Continue to Next Section
Section view of the Form
Entire view of the Form
1.0 Modification/Amendment
2.0 IRB Fees
3.0 General Information
4.0 Modification Submission Type
4.0 Modification Submission Type
4.1 Please select one.
Humanitarian Use Device (HUD) Study
Modification Request Form When Using an External IRB as an IRB of Record
All other studies



In Section 6.0 Modification Details, you will have the opportunity to select which type(s) of Modifications you would like to make to your study.

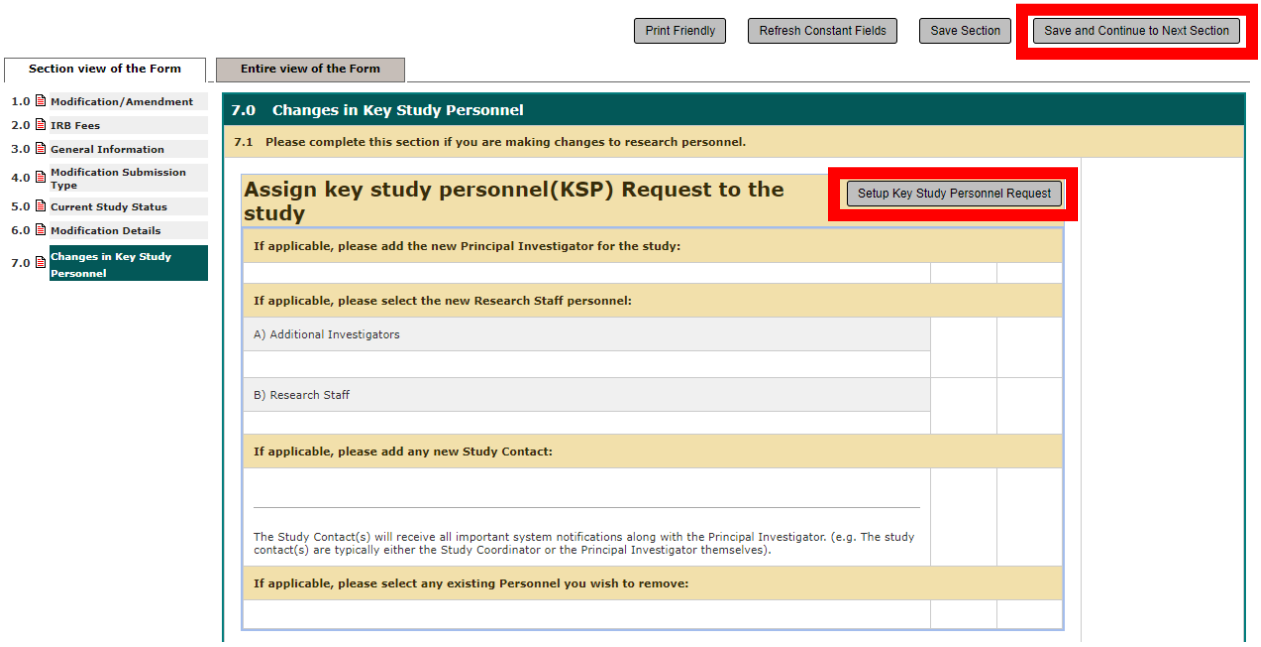
This section asks you to briefly describe the proposed changes in a free text box.

Further down the screen in this section, you are also asked if there are changes to the consent form, and if the Modification will affect the risks and/or benefits to subjects.

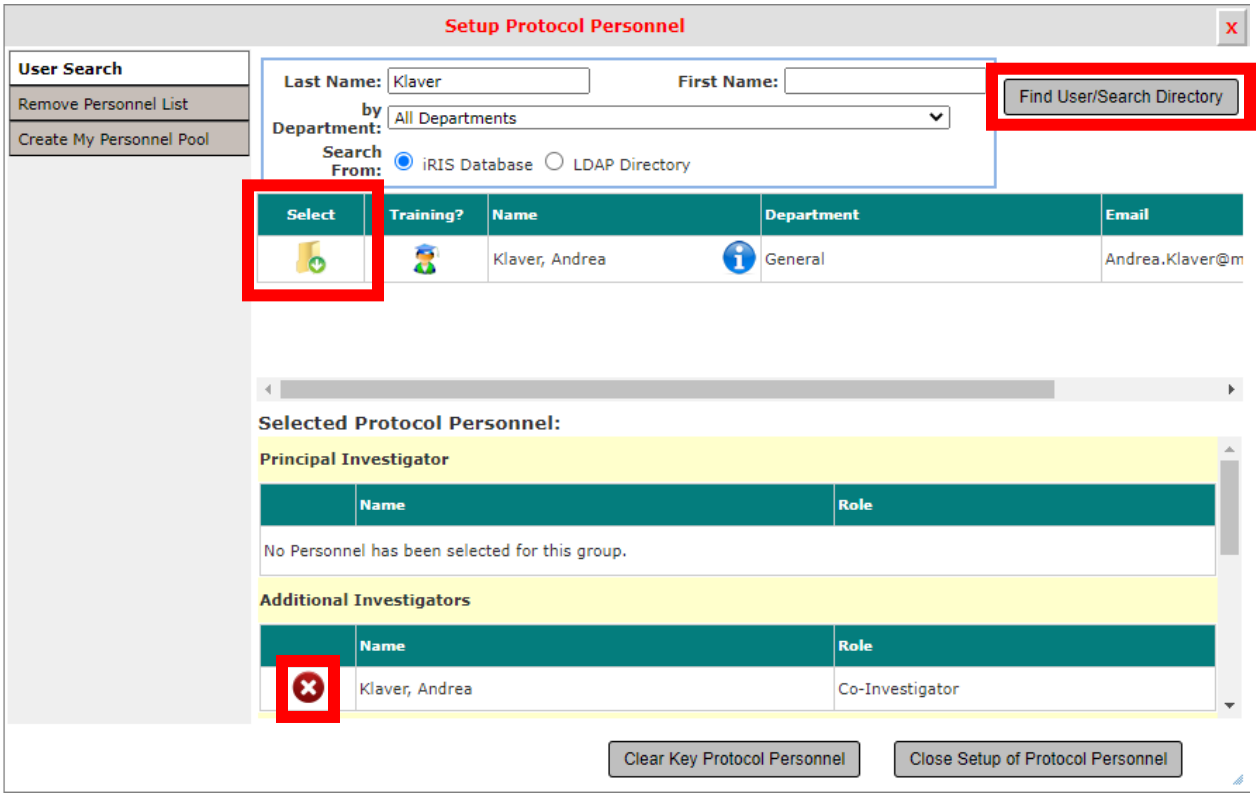
In this example, I would like to add and remove key study personnel.

Section 7.0 Changes in Key Study Personnel gives you the opportunity to amend the list of approved key study personnel through addition or removal.

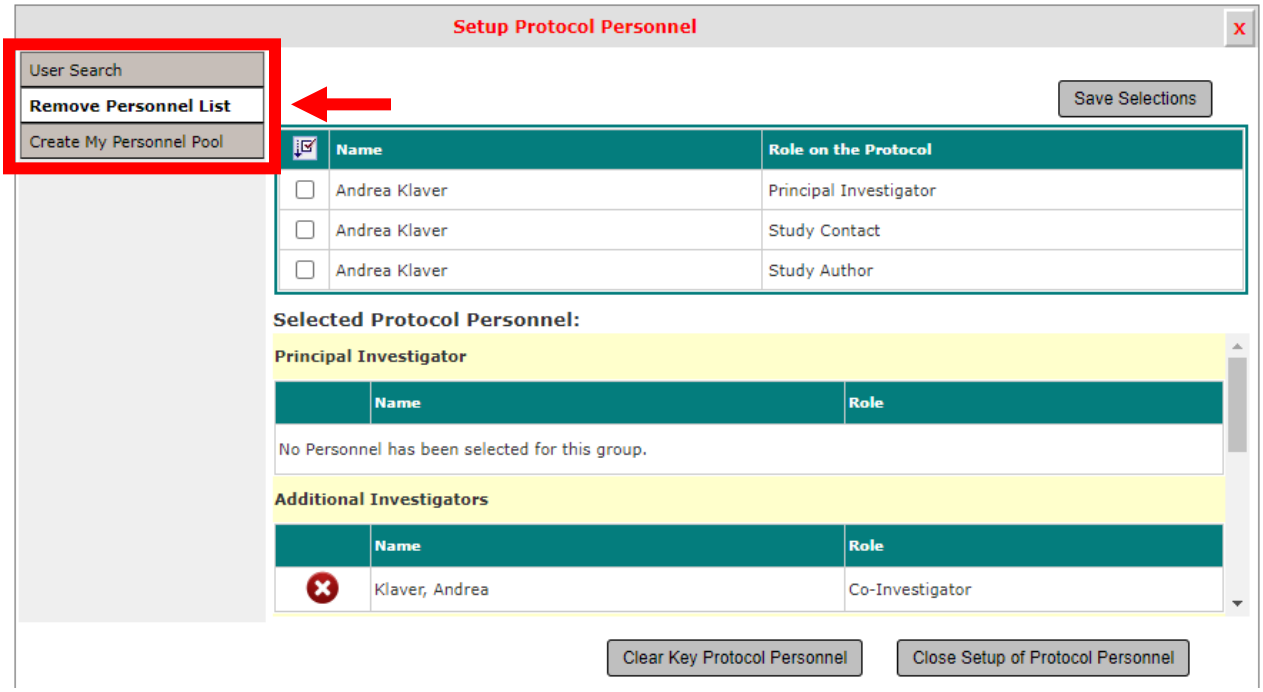
Click on the **Setup Key Study Personnel Request** button.



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 list of Key Study Personnel. Select the User and their Role (in a 2nd pop-up; not pictured). To undo an addition, click the icon.



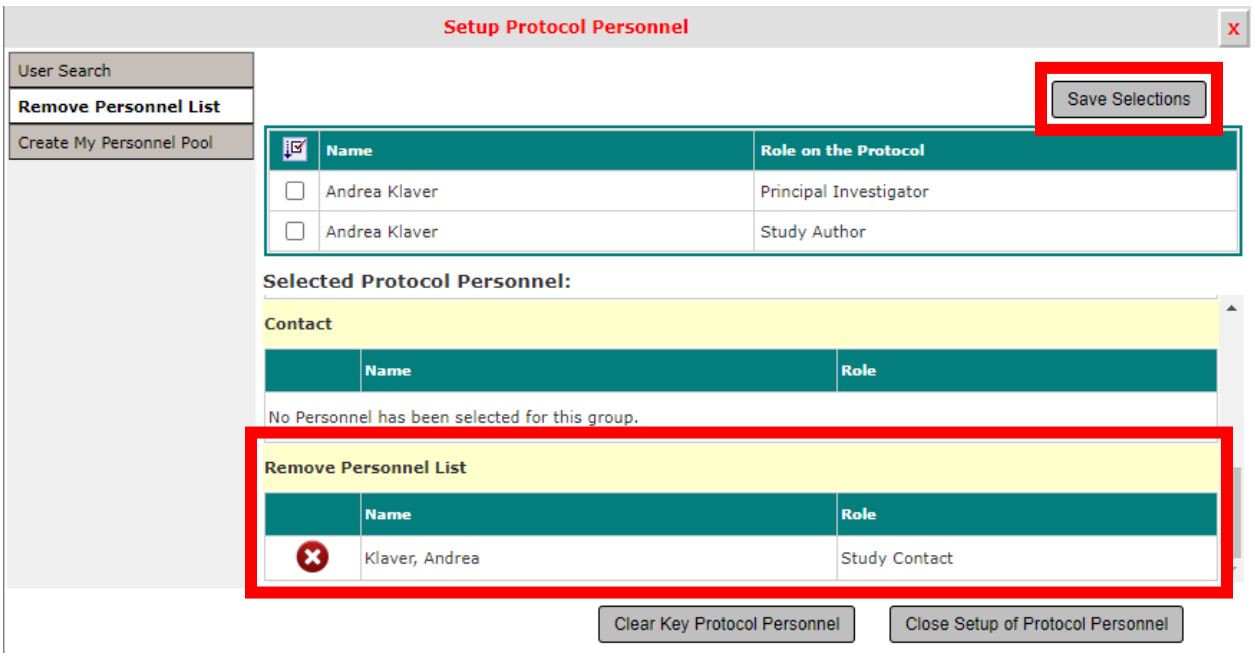
To remove Key Study Personnel, navigate to the Remove Key Personnel section by clicking on the link on the left side of the window.



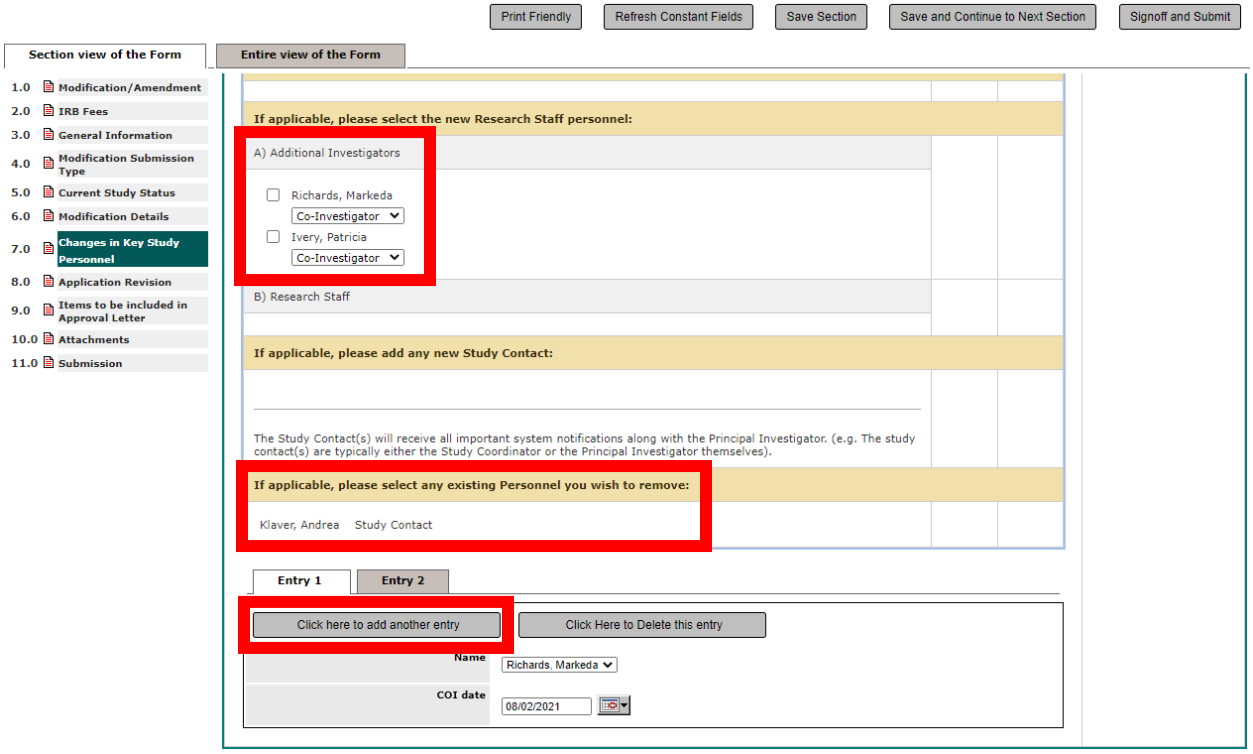
In the top section, find the Key Study Personnel and their Role on the Protocol that you would like to remove. Check the box to the left of their name/Role.

Their name/Role will be moved down to the Remove Personnel List section of the window.

Click Save Selections and Close Setup of Protocol Personnel to apply your changes.



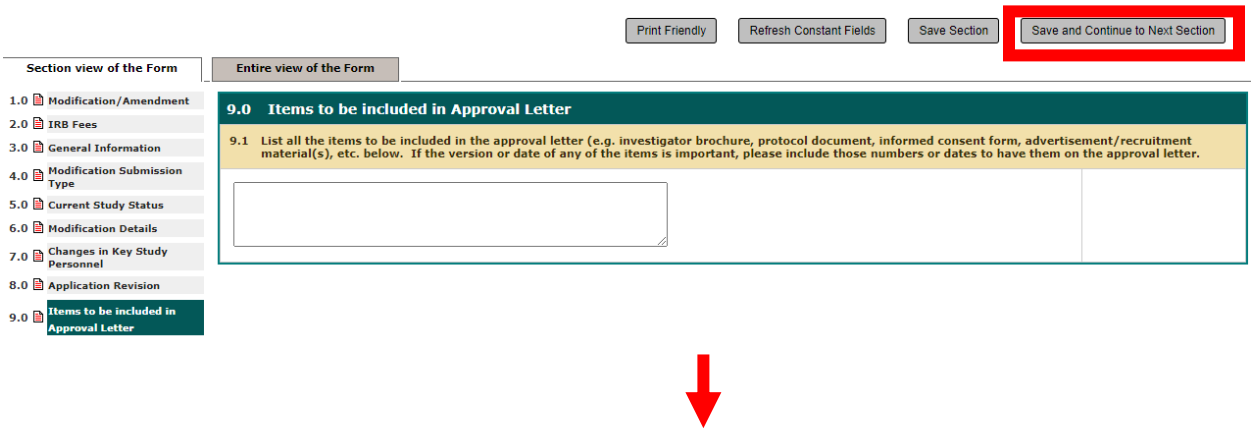
After you **Save Selections**, you will be taken back to **Section 7.0 Changes in Key Study Personnel** of the Modification form. You should now see any added personnel and any existing personnel for removal, along with their Roles.

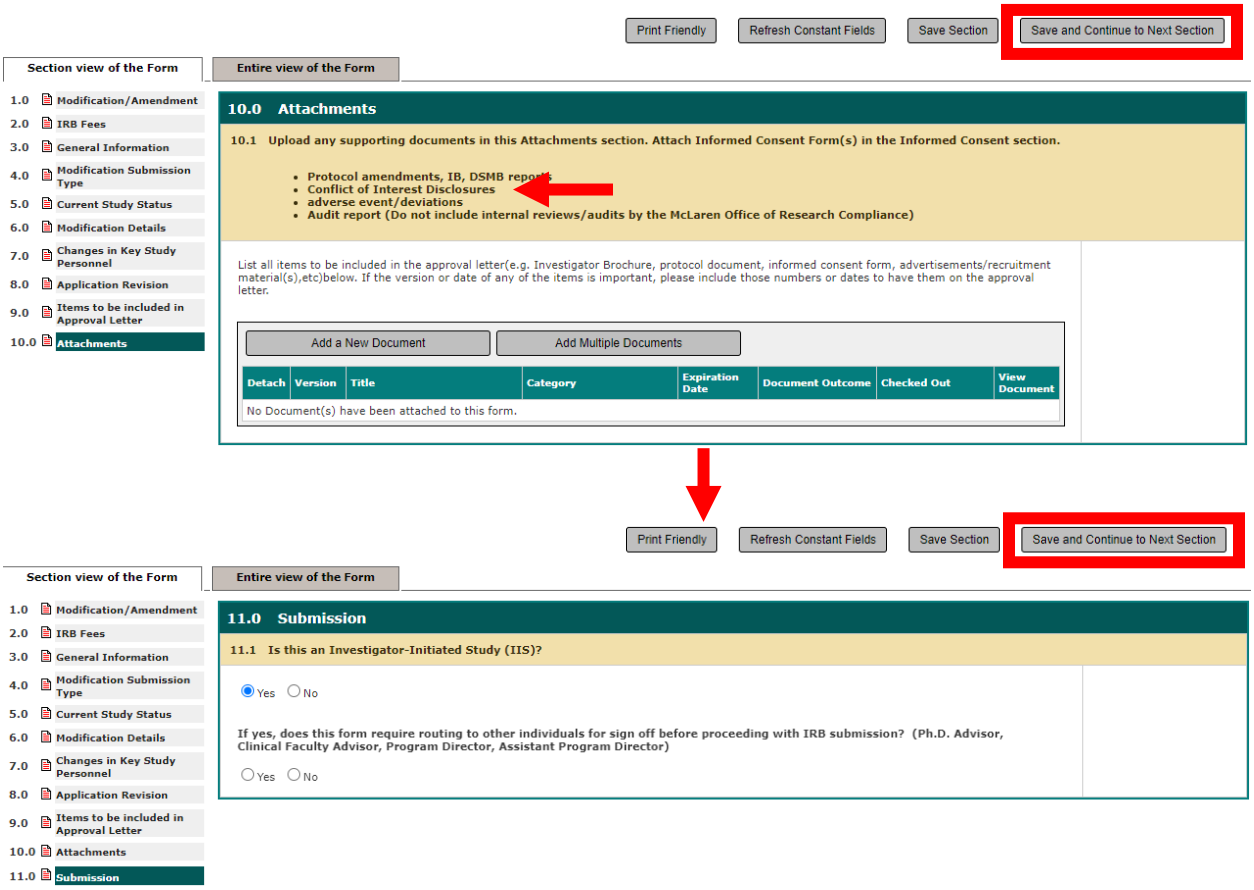


Below the personnel changes, you will be prompted to enter Conflict of Interest (COI) information for Key Study Personnel to be added in the Modification (Investigators only).

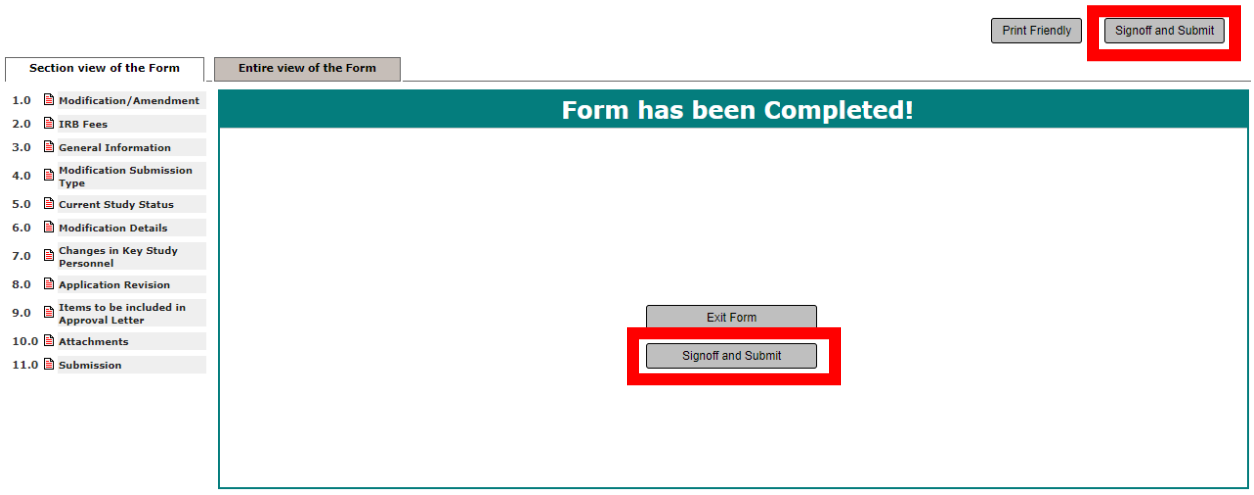
Use the drop-down menu to select the name of the new personnel. Use the calendar to select the date. To ensure there is an entry for each new personnel to be added, select the **Click here to add another entry** button.

Continue completing the sections of the Modification form using the gray **Save and Continue** button in the upper right of each screen as before.





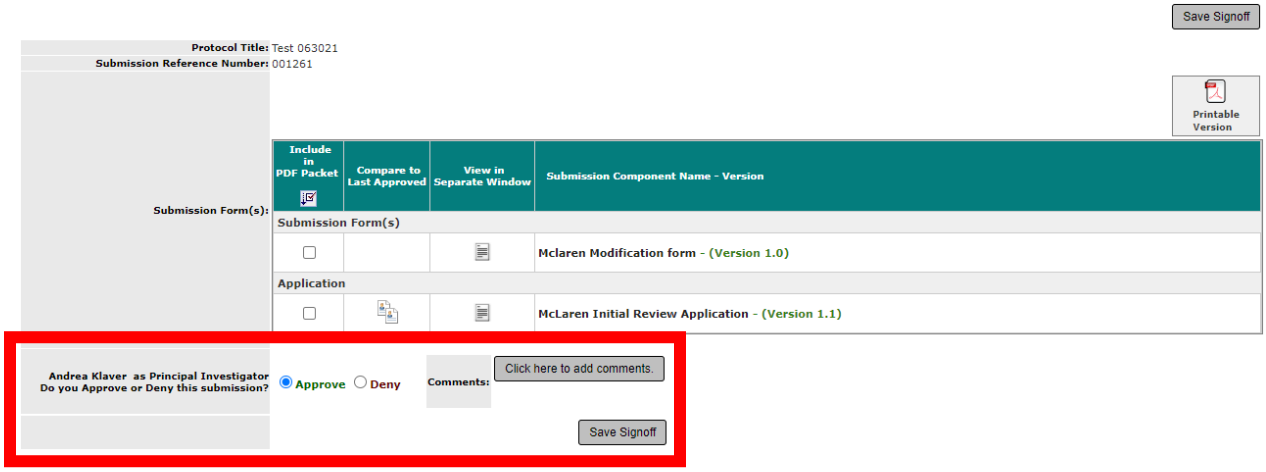
When you have completed all sections of the Modification form, you will be presented with a screen notifying you that the form is complete, as shown below.



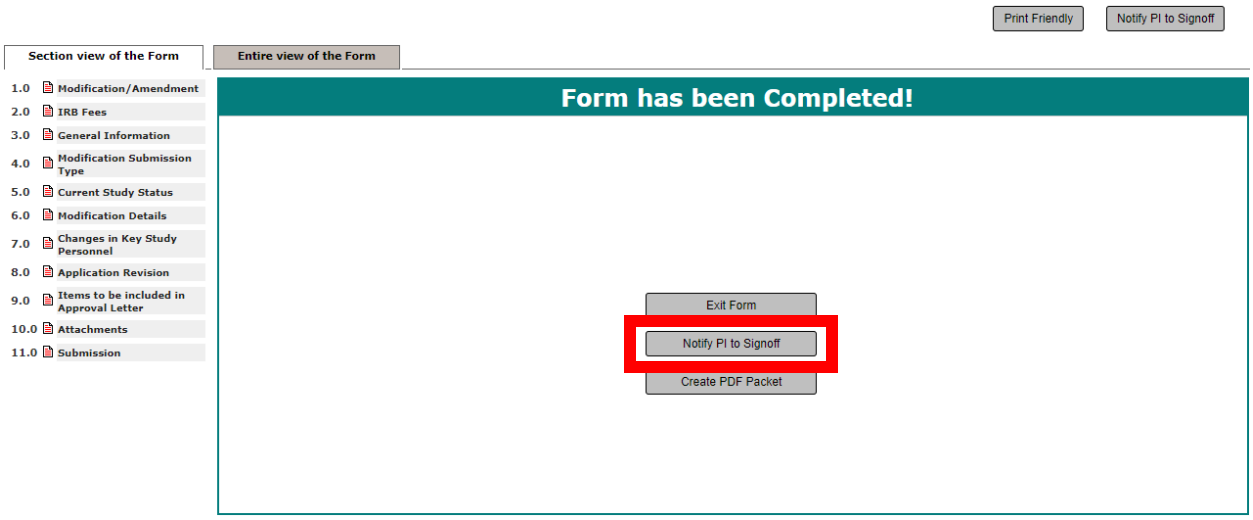
If you are the PI of this study: You will be directed to electronically signoff when you reach the end of the Modification form. Select the Signoff and Submit button.

The Modification form and the Initial Study Application are available for review.

Approve the submission and save your signoff by clicking the Save Signoff button.



If you are NOT the PI: The PI will be notified that there is a Modification awaiting their electronic signoff in iRIS. When you reach the end of the Modification form, select the Notify PI to Signoff button.



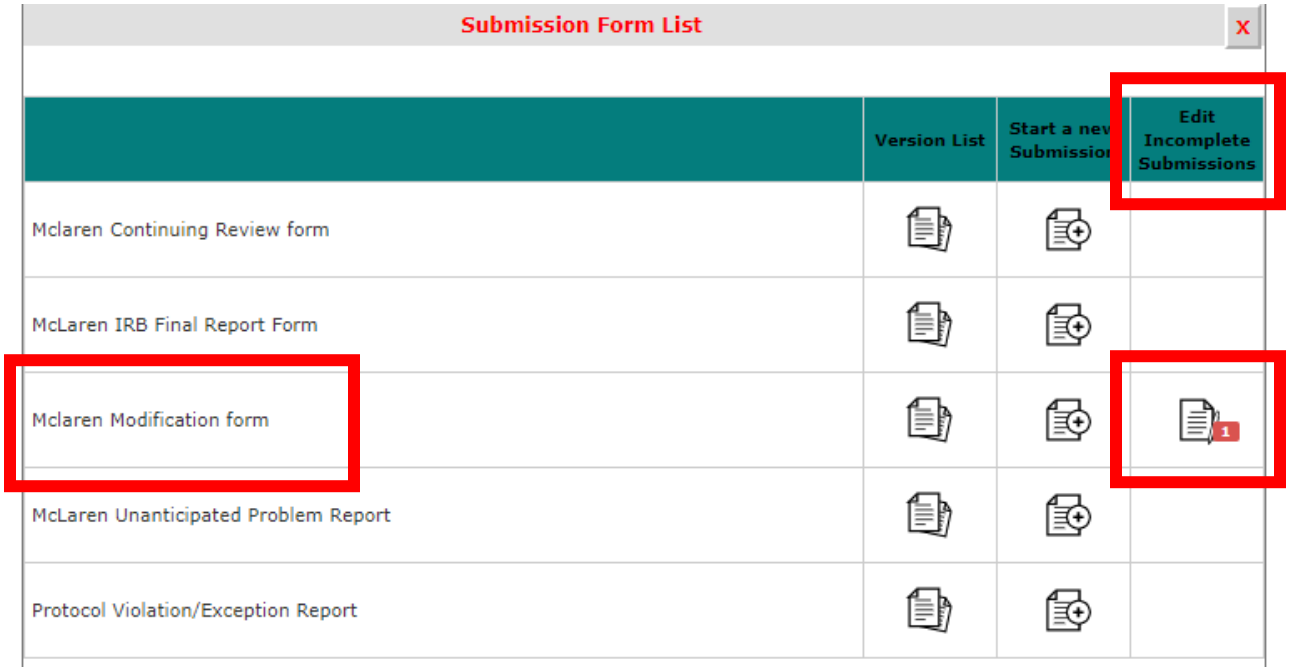
At any time while working through the Modification form submission, you may select the gray Save Section button that appears on most screens in the upper right corner. This will save your progress if you need to leave the form and continue another time.

When you return to iRIS to complete your Modification form submission, begin the process the same way as before: select the yellow Start a Protocol Submission Form button on your iRIS home screen and click on the Forms icon next to the study you would like to continue your Modification form for.

When the pop-up opens within your window showing the different types of forms you may submit in iRIS for your study, find the McLaren Modification Form.

Instead of clicking the  icon underneath the Start a new Submission column, click the  icon underneath the Edit Incomplete Submissions column.

You will be taken back into your Modification form.



To open your Modification form to complete and submit, click on the  icon underneath the Edit/View column.