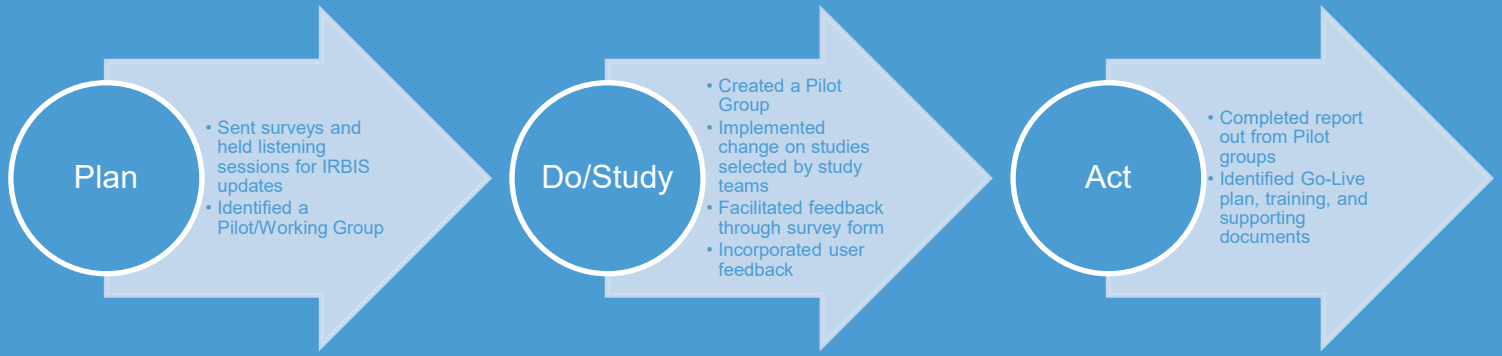
New IRBIS Personnel Modification Application

Celeste Cantrell, Senior IRB Analyst, Office of Human Research Ethics
Mike Matamoros, OHRE Associate Director of Operations and Education
Cassandra Myers, OHRE Director

THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

IRBIS Feedback/PDSA Process



Results

83 Pilot Surveys Received

- Process was quick and Easy

96% Rated Very Easy to Use

- Requested Confirmation Email- Implemented

97% Rated as Very Satisfied

- Improved Turnaround Time

Thank you !

Radiology
Lineberger CCC
Global Health-ID
Surgery
Dermatology
ORIS-Team

On May 6, 2021 OHRE is planning to implement a streamlined application that will allow for study personnel changes outside of the regular submission pipeline.

This means that you may submit a modification to add personnel while there is a study modification or renewal already submitted.

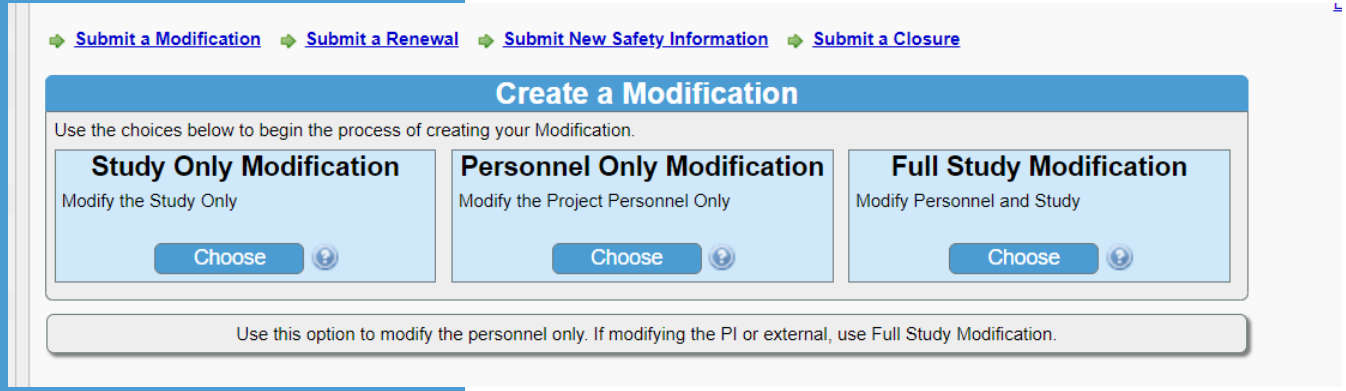
For studies that do not have a submission started (in draft, routing or under review), this action will be available on Thursday morning.

If you have an active submission, this action will be available after the current submission is finalized.

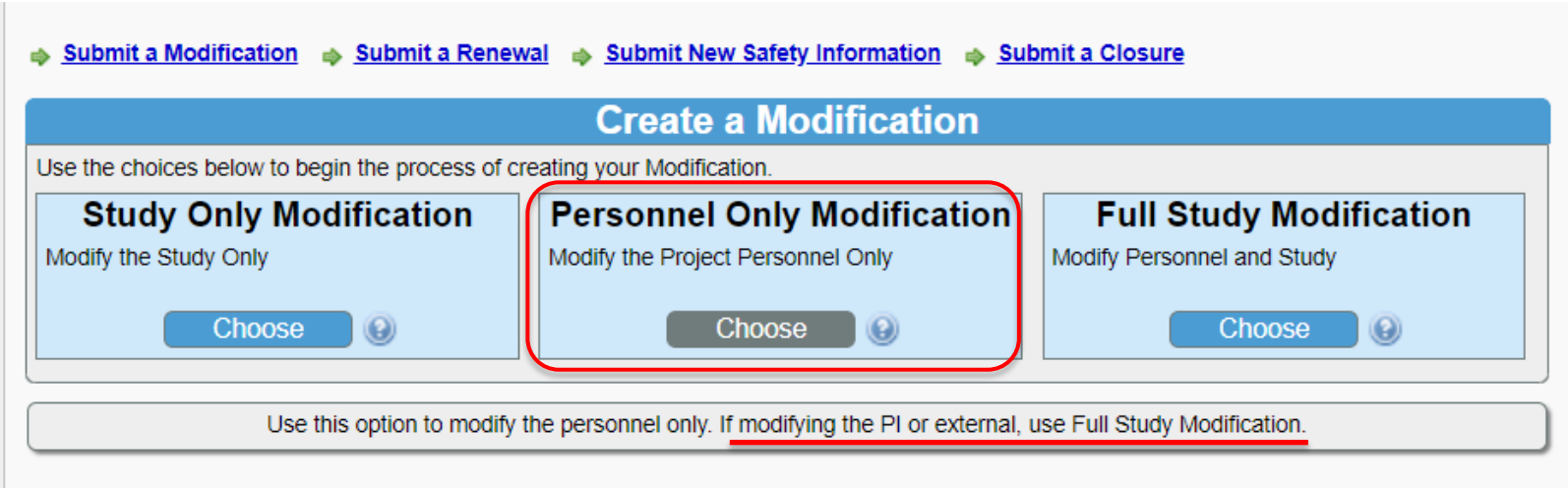
Changes to Modification Options

When you begin a modification, you will have the option to submit one of three types:

- Study only
- Personnel only
- Full Study (study changes + personnel changes)



Let’s draft a personnel only modification:



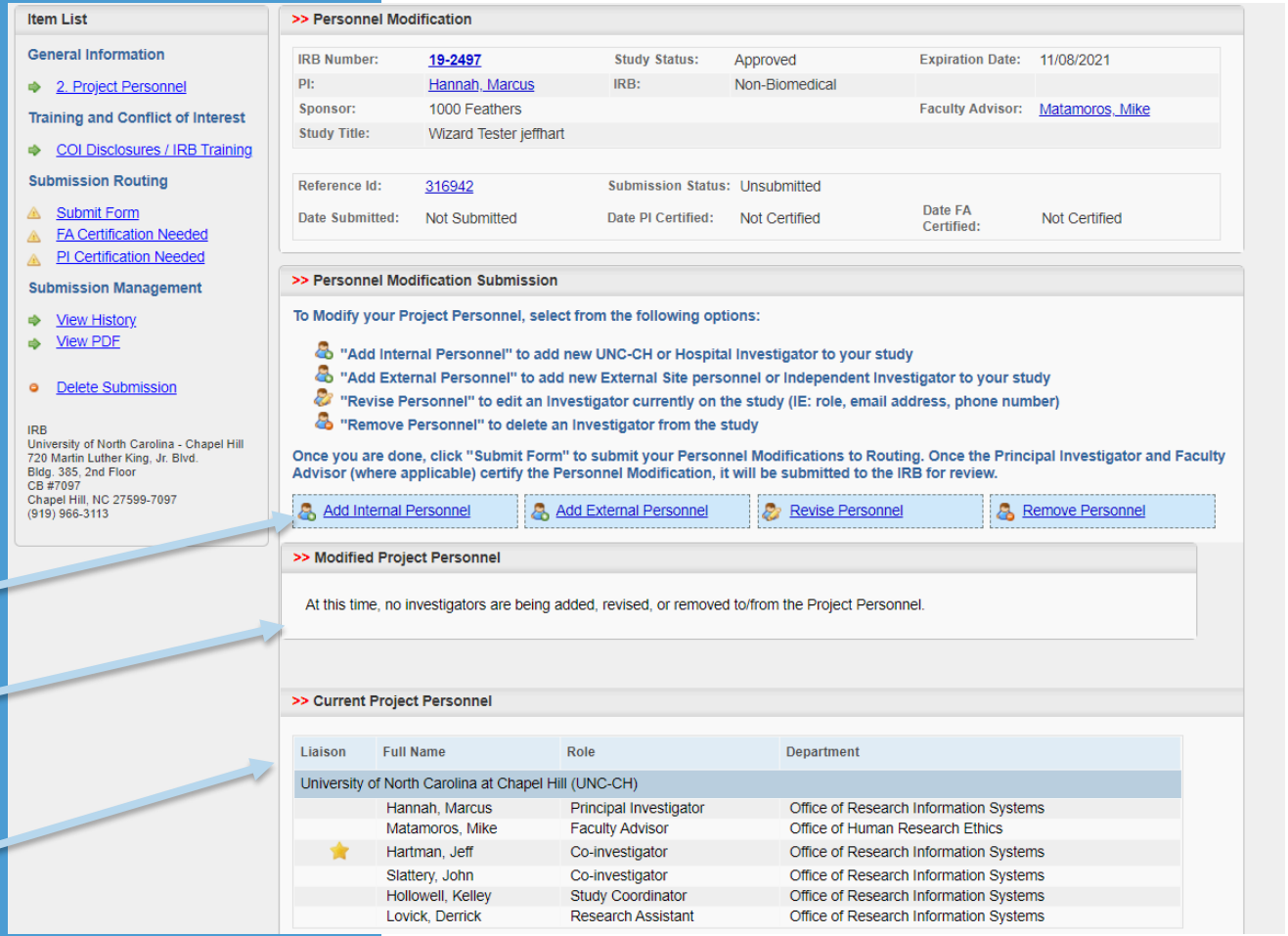
This modification type cannot be used to add/change the PI or Faculty Advisor, or to add external personnel.

The item list on the left is abbreviated to include only the sections and actions needed for personnel changes. Note that there is no modification summary. IRBIS will generate a summary of your changes for you.

Options for changes

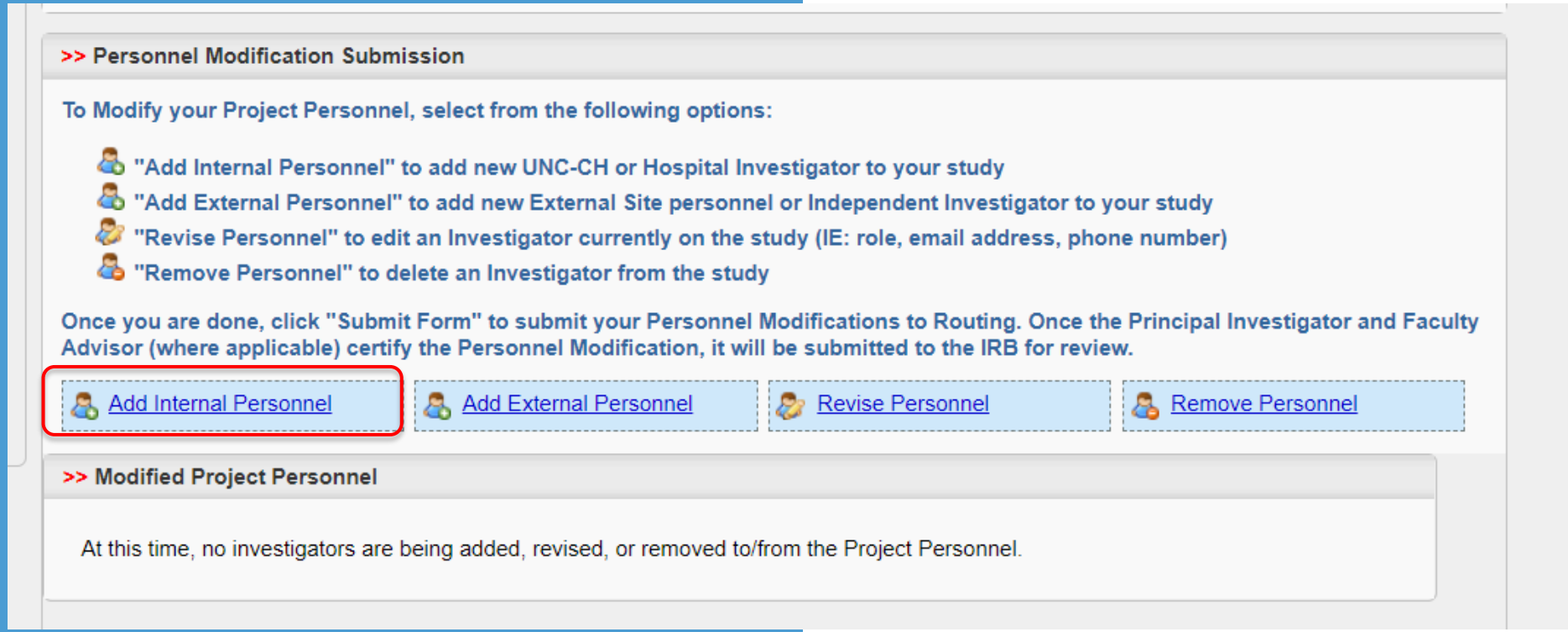
List of changes

Current personnel

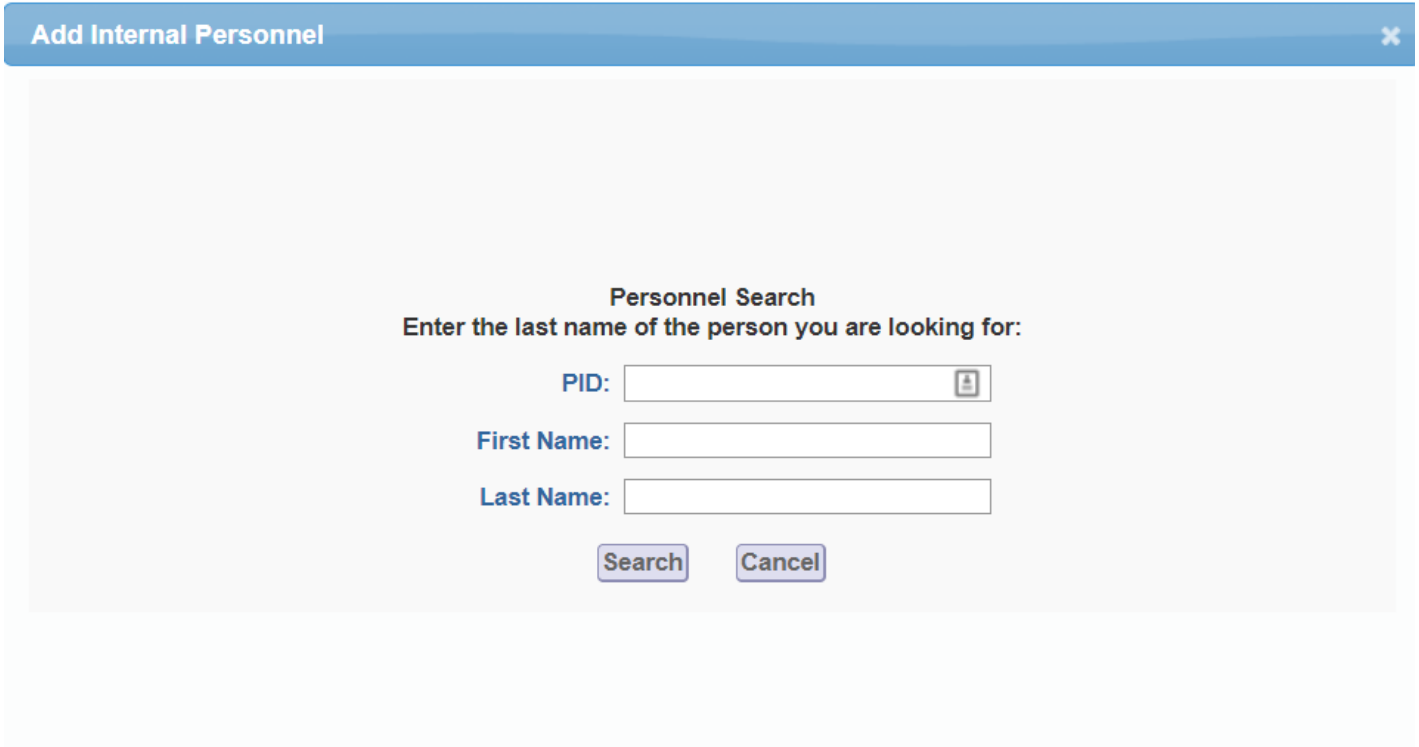


We'll add UNC-CH or UNCH personnel (including Network Entities).

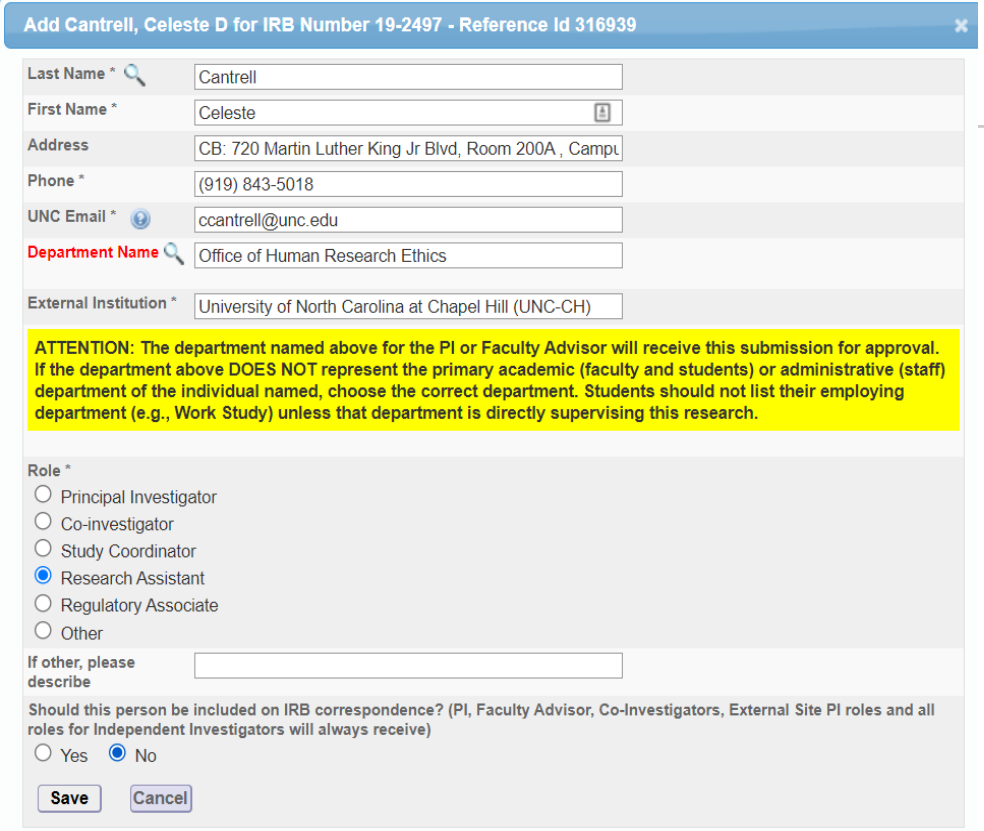
Note: if you wish to add a new PI or Faculty Advisor, you must submit a full modification.



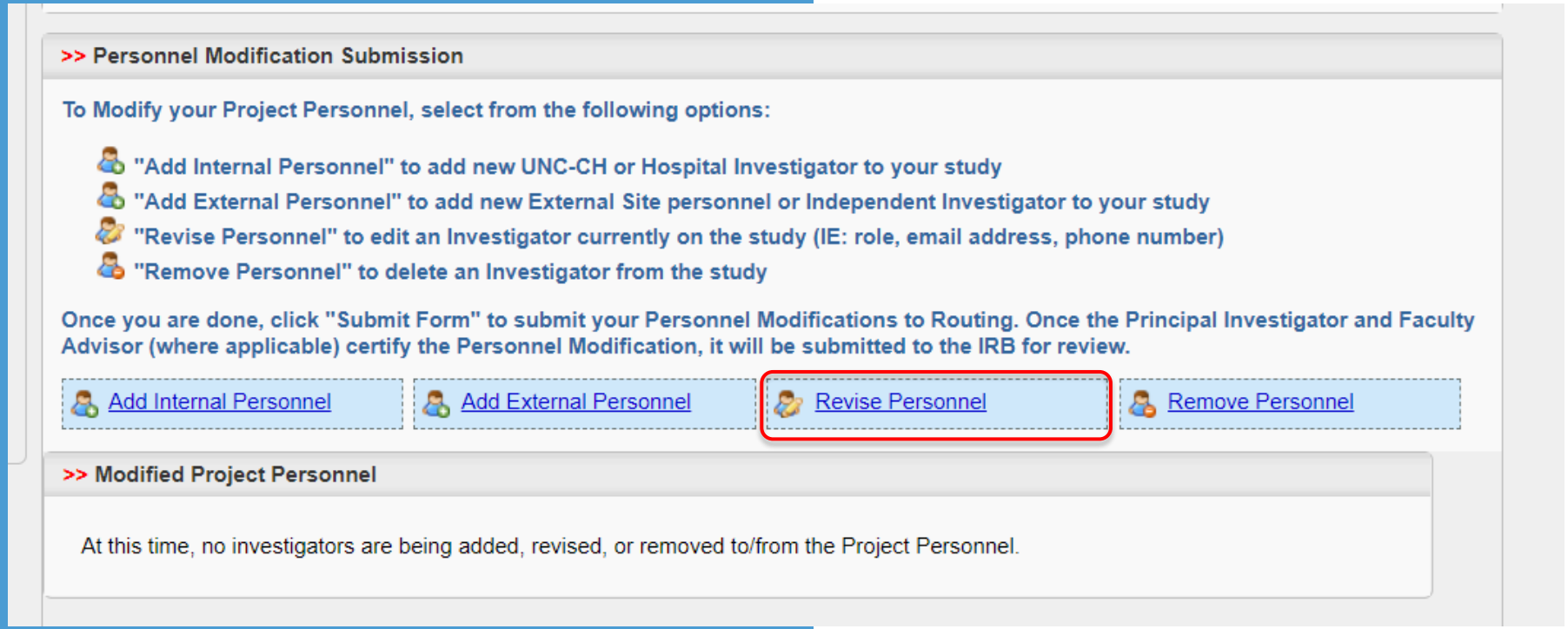
Search for the person to be added in the pop-up window.



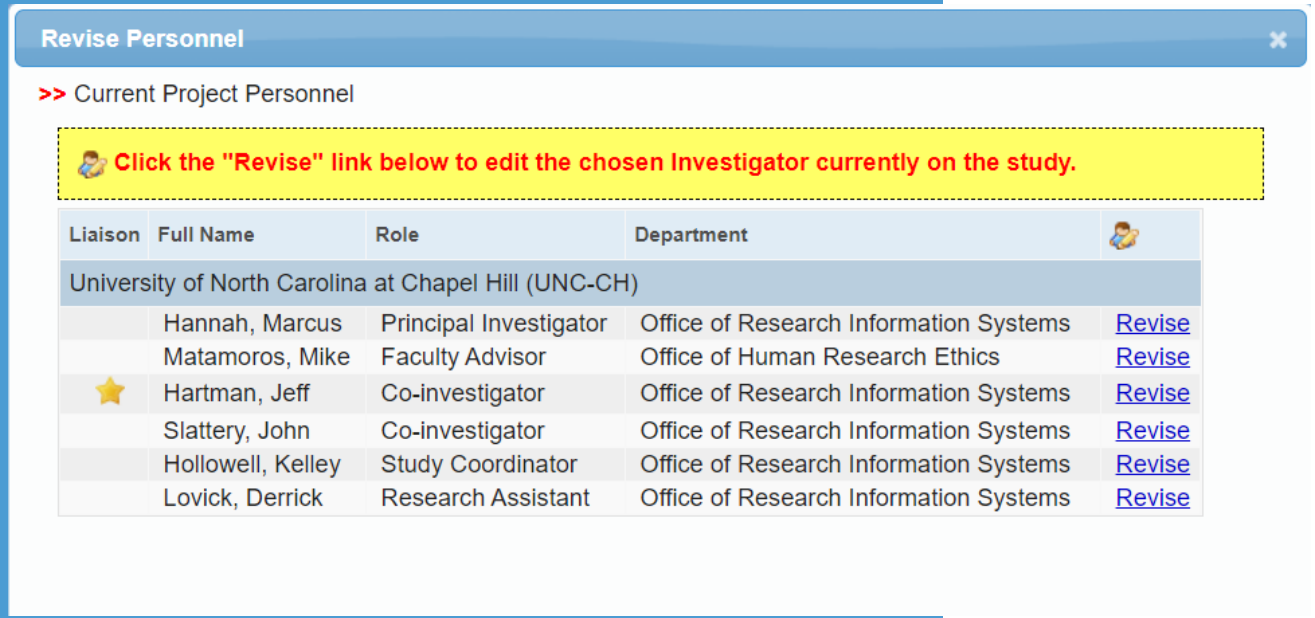
Complete the profile entry as appropriate and save.



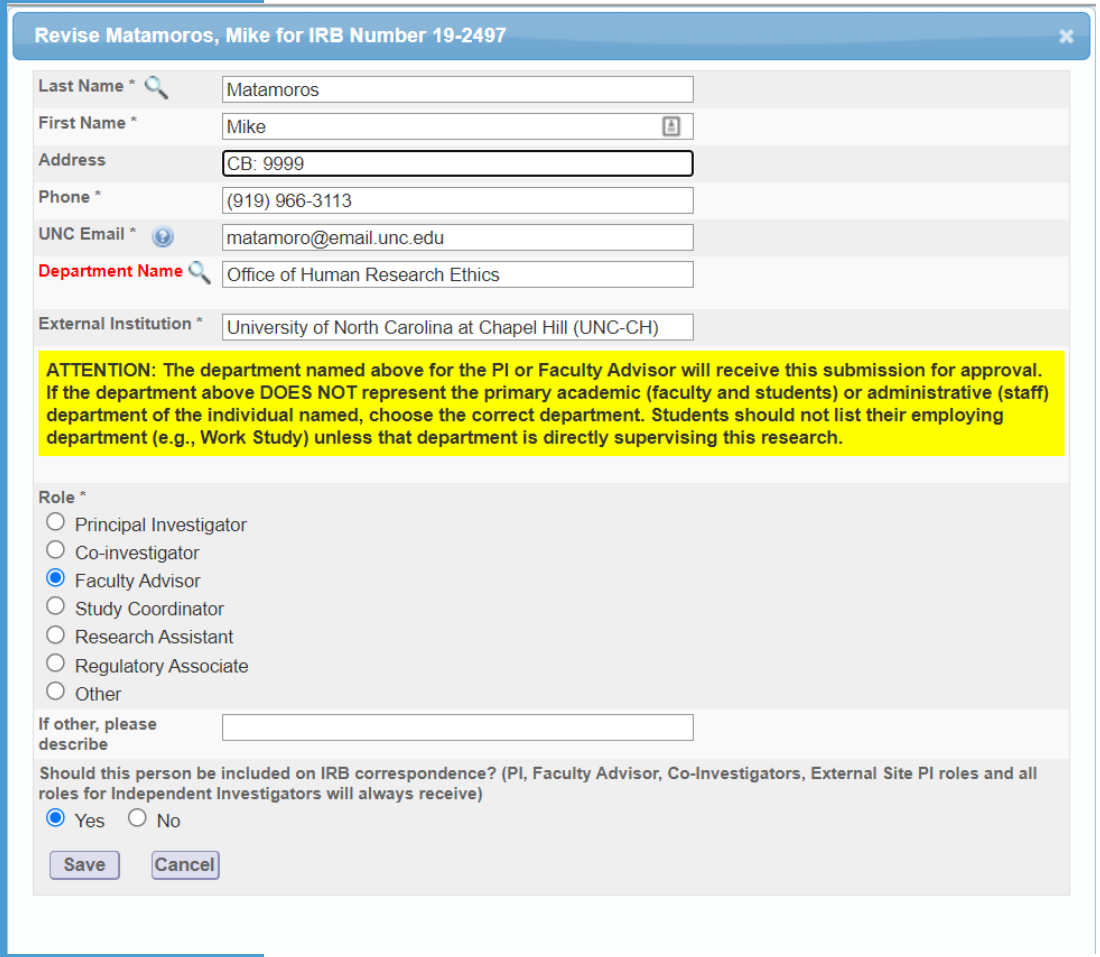
We will revise our current personnel. You can revise anyone currently on the personnel list.

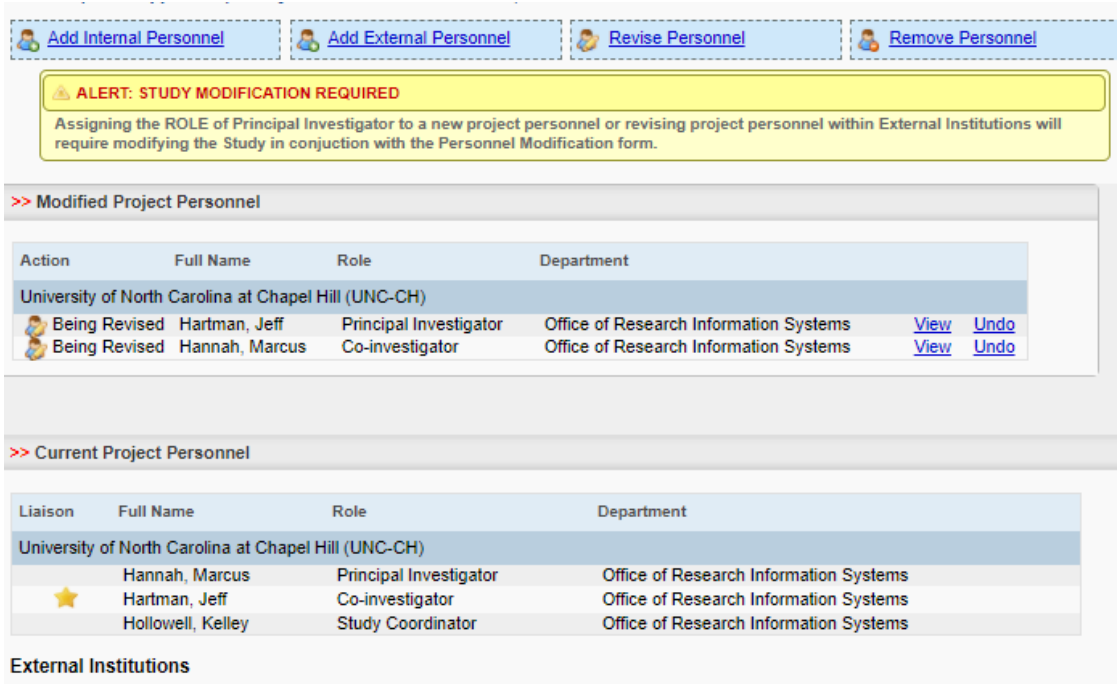


Use the ‘Revise’ option to change the profile information for a current study member.



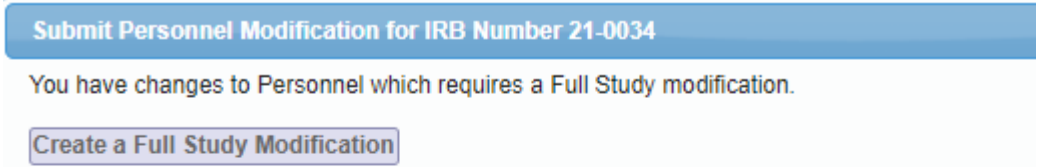
Make any necessary revisions and save. You can update the address, email address, and role.





If you make changes to the PI or Faculty Advisor's role during a Personnel Modification, IRBIS will display a reminder that this will also require a study modification.

Once you submit the form, you will be prompted to create a Full Study Modification.



We will review Full Study Modification later in the presentation.

Click here to jump to Full Study Modification.

>> Personnel Modification Submission

To Modify your Project Personnel, select from the following options:

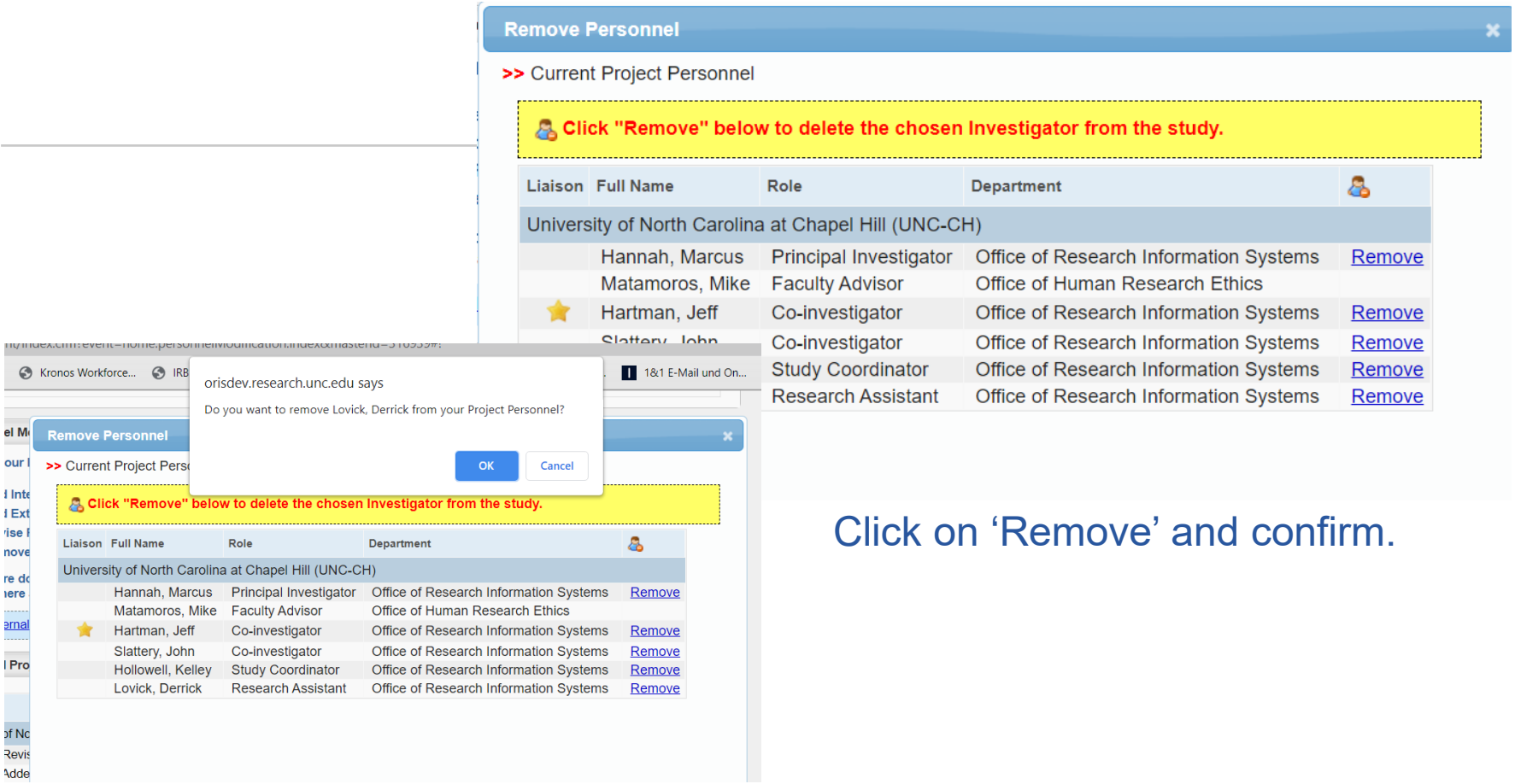
- **"Add Internal Personnel" to add new UNC-CH or Hospital Investigator to your study**
- **"Add External Personnel" to add new External Site personnel or Independent Investigator to your study**
- **"Revise Personnel" to edit an Investigator currently on the study (IE: role, email address, phone number)**
- **"Remove Personnel" to delete an Investigator from the study**

Once you are done, click "Submit Form" to submit your Personnel Modifications to Routing. Once the Principal Investigator and Faculty Advisor (where applicable) certify the Personnel Modification, it will be submitted to the IRB for review.

Add Internal Personnel | Add External Personnel | Revise Personnel | Remove Personnel

>> Modified Project Personnel

At this time, no investigators are being added, revised, or removed to/from the Project Personnel.

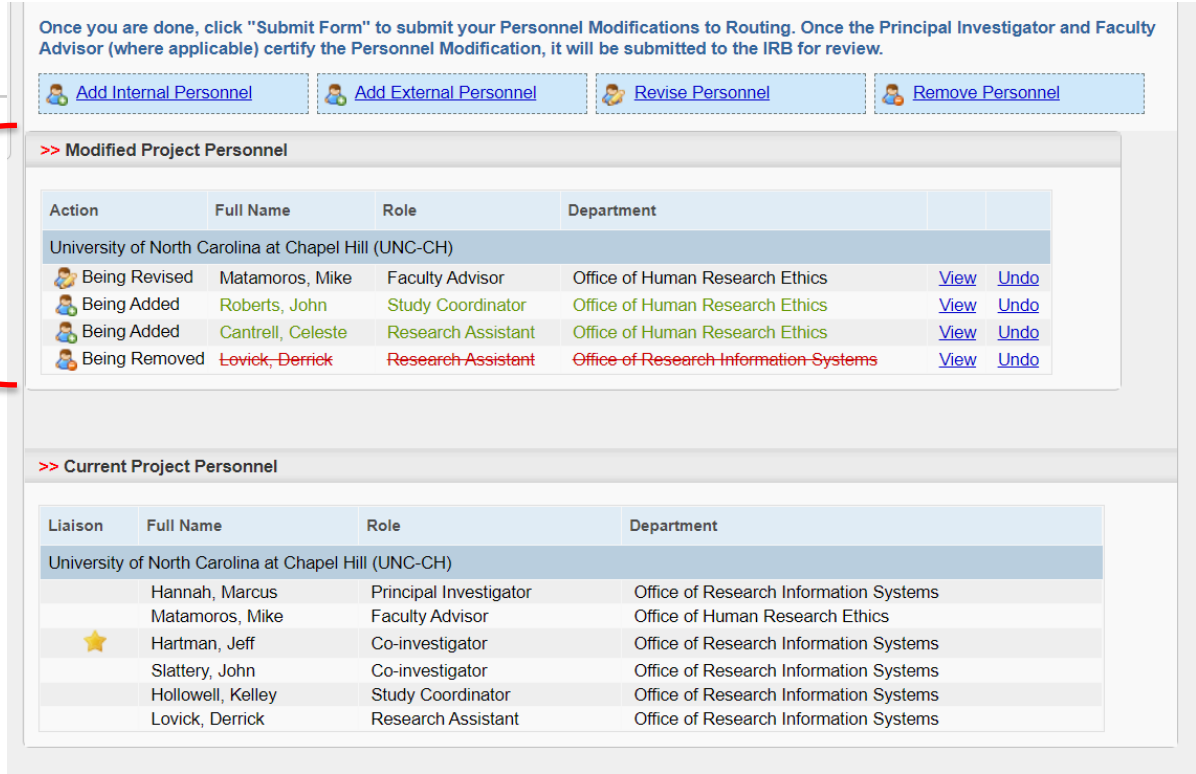


Click on ‘Remove’ and confirm.

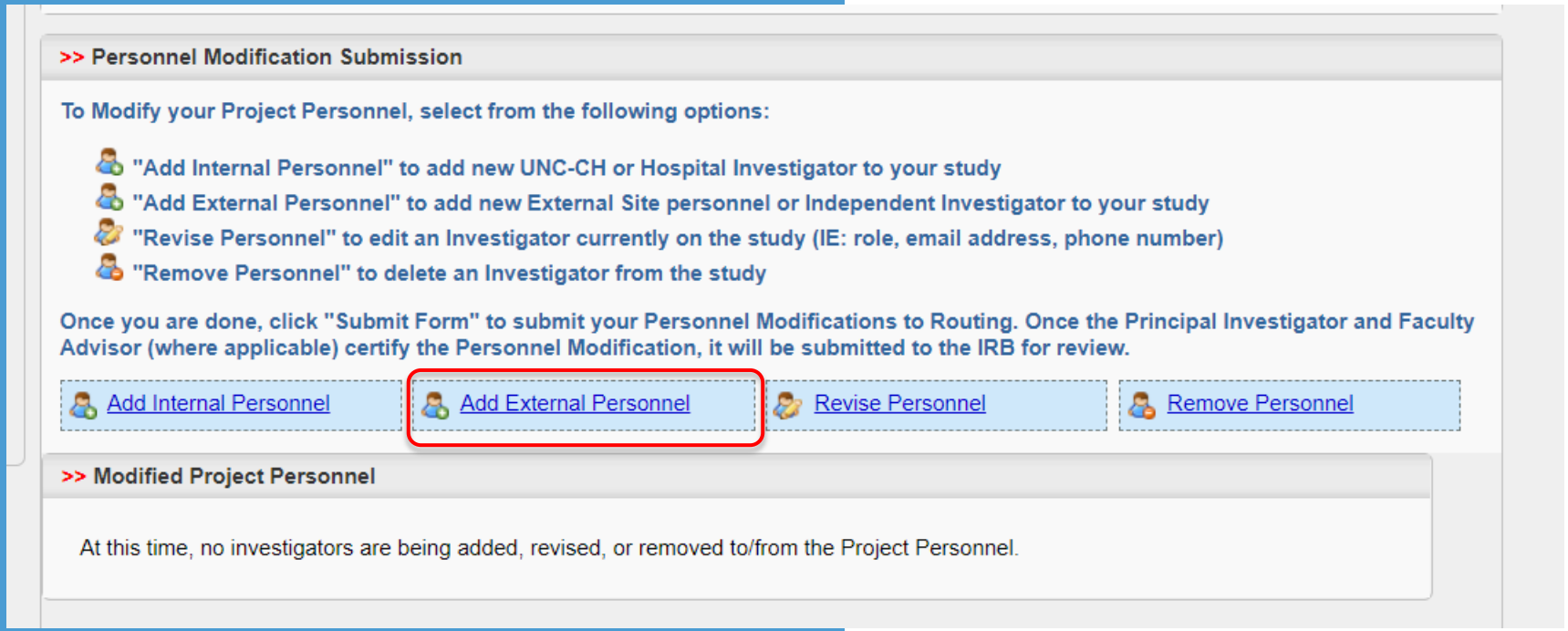
Once all changes are made, you can review what has been changed prior to submission.

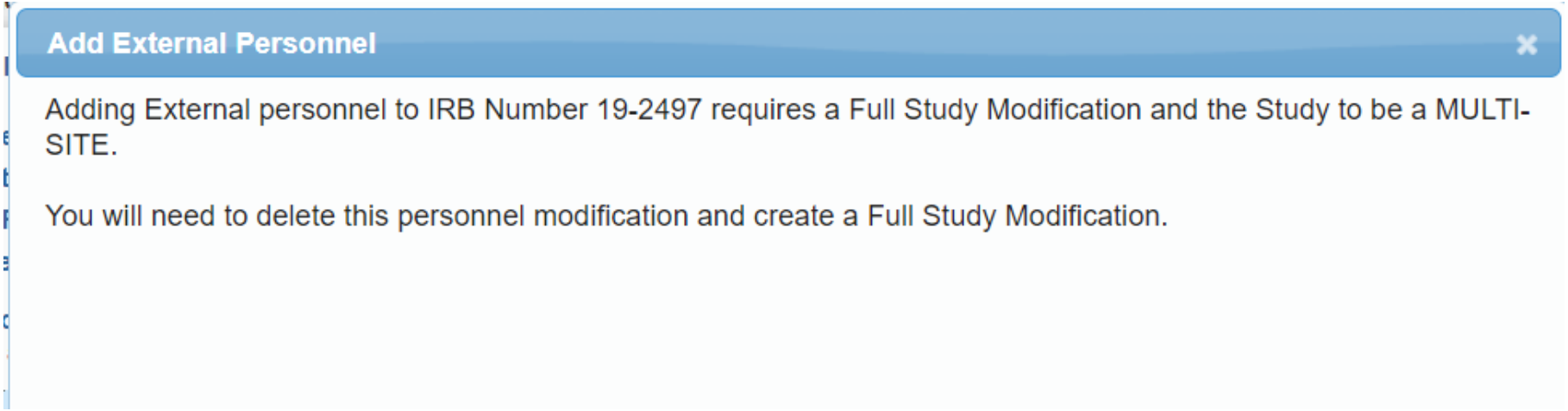
The summary of the changes will be generated by IRBIS.

At this point, you can undo the change, if needed.



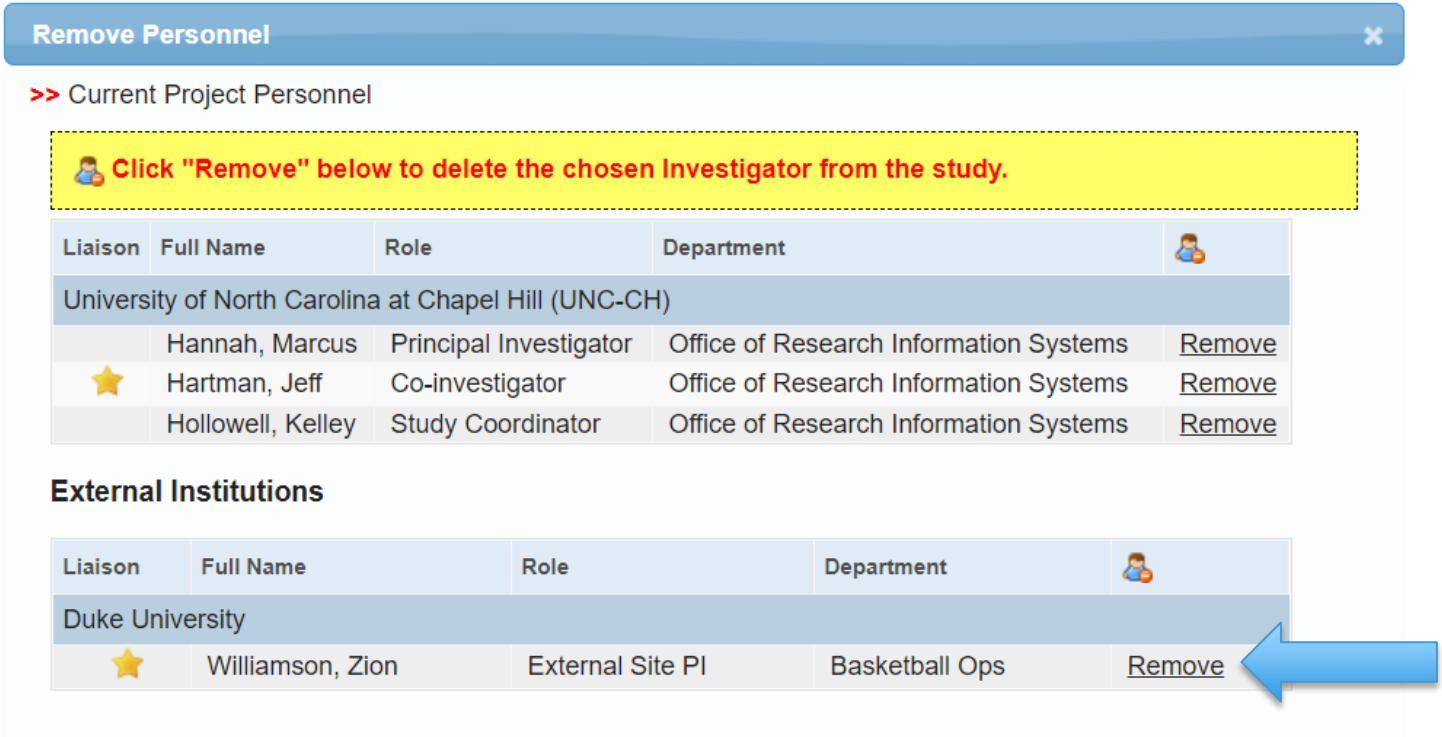
Adding external personnel:



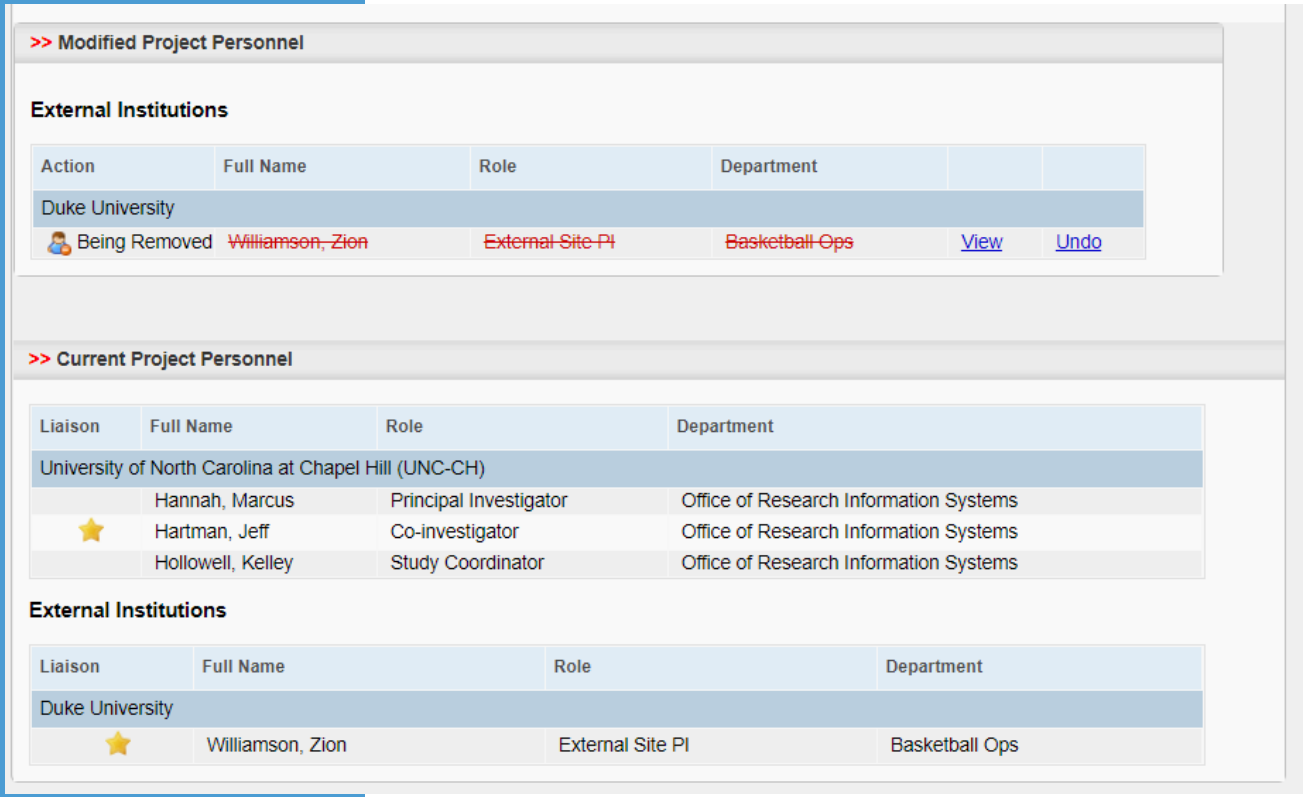


External personnel can be removed or revised, but they cannot be added during a Personnel Only modification.

Select ‘Remove’ next to your external investigator to be removed.



The changes to external personnel display similar to how internal changes were summarized.



>> Modified Project Personnel

External Institutions

Action	Full Name	Role	Department		
Duke University					
Being Removed	~~Williamson, Zion~~	~~External Site PI~~	~~Basketball Ops~~	View	Undo

>> Current Project Personnel

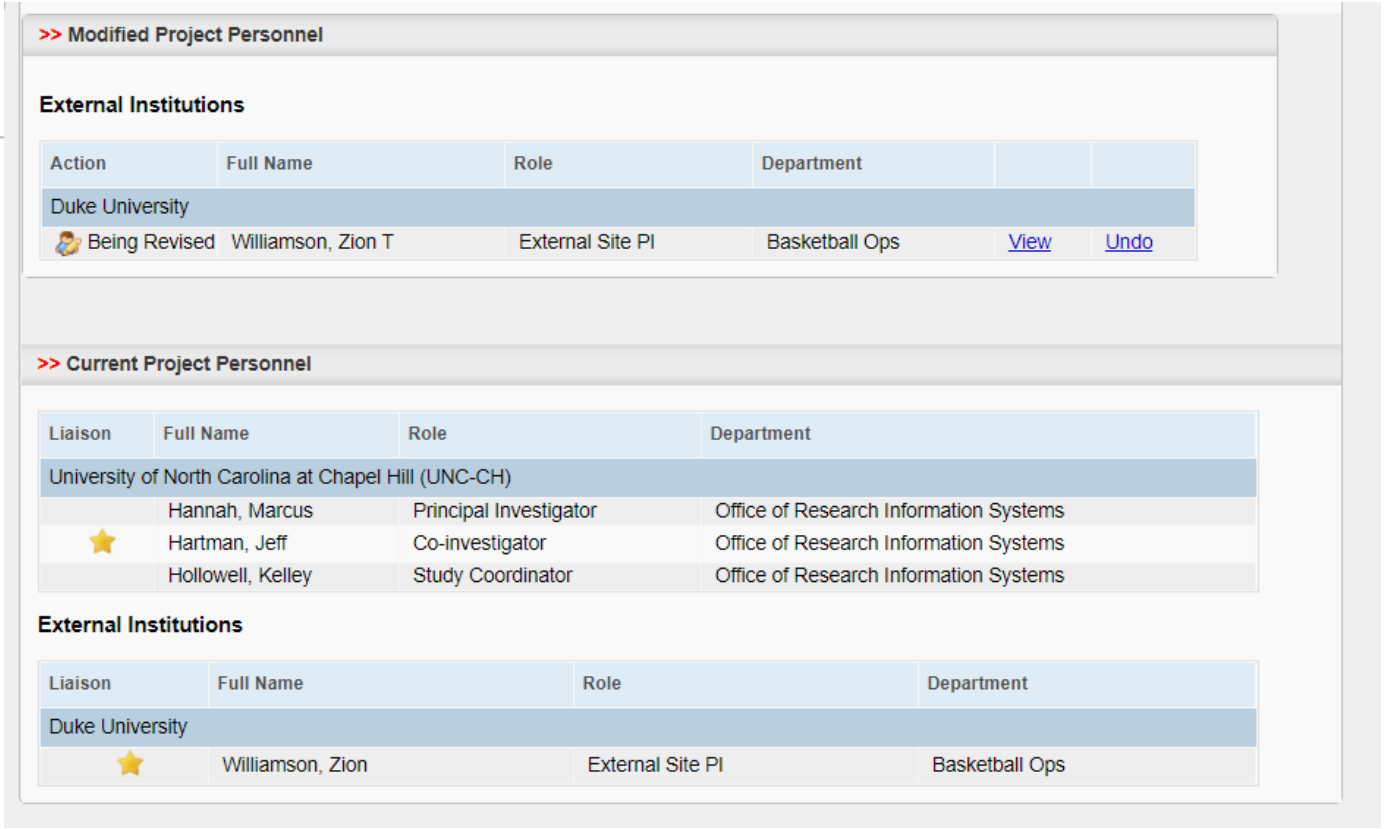
Liaison	Full Name	Role	Department
University of North Carolina at Chapel Hill (UNC-CH)			
	Hannah, Marcus	Principal Investigator	Office of Research Information Systems
★	Hartman, Jeff	Co-investigator	Office of Research Information Systems
	Hollowell, Kelley	Study Coordinator	Office of Research Information Systems

External Institutions

Liaison	Full Name	Role	Department
Duke University			
★	Williamson, Zion	External Site PI	Basketball Ops

External personnel can be revised:

Revision is reflected in the summary.



>> Modified Project Personnel

External Institutions

Action	Full Name	Role	Department		
Duke University					
Being Revised	Williamson, Zion T	External Site PI	Basketball Ops	View	Undo

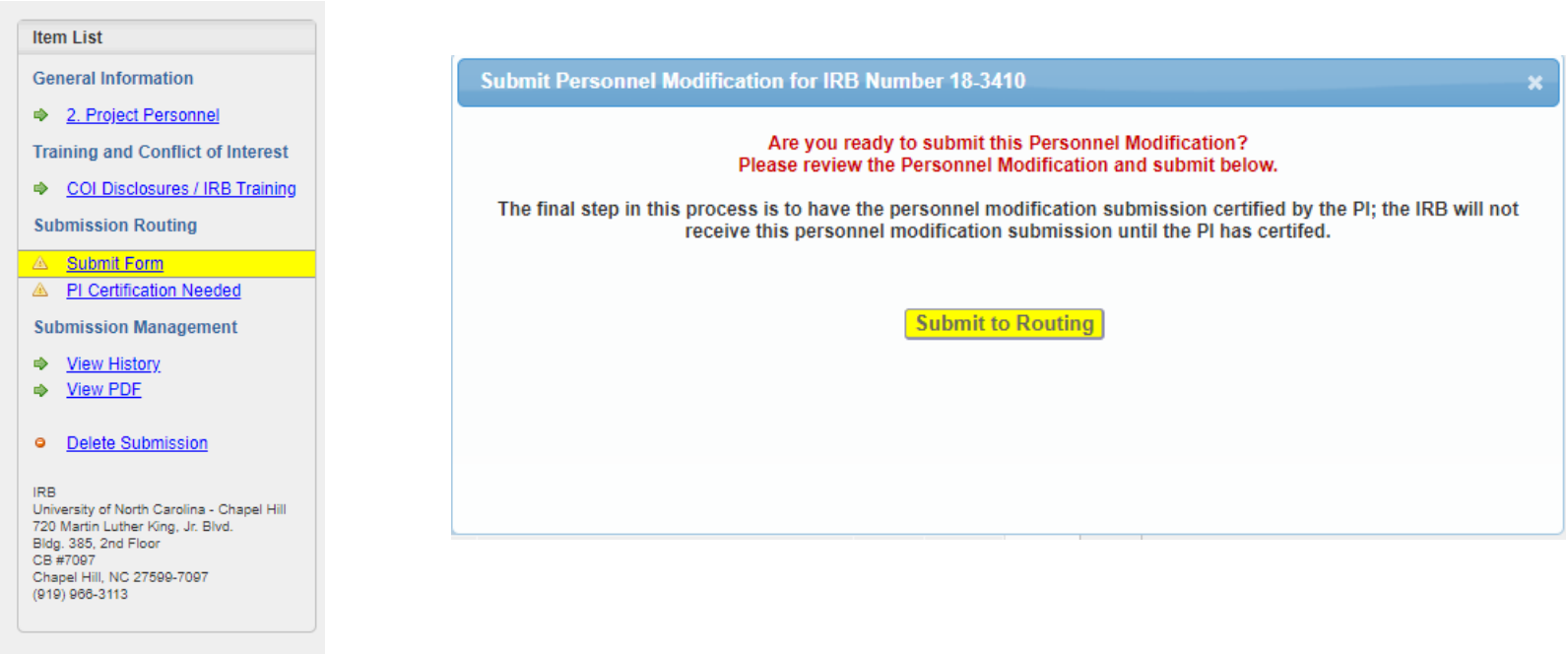
>> Current Project Personnel

Liaison	Full Name	Role	Department
University of North Carolina at Chapel Hill (UNC-CH)			
	Hannah, Marcus	Principal Investigator	Office of Research Information Systems
★	Hartman, Jeff	Co-investigator	Office of Research Information Systems
	Hollowell, Kelley	Study Coordinator	Office of Research Information Systems

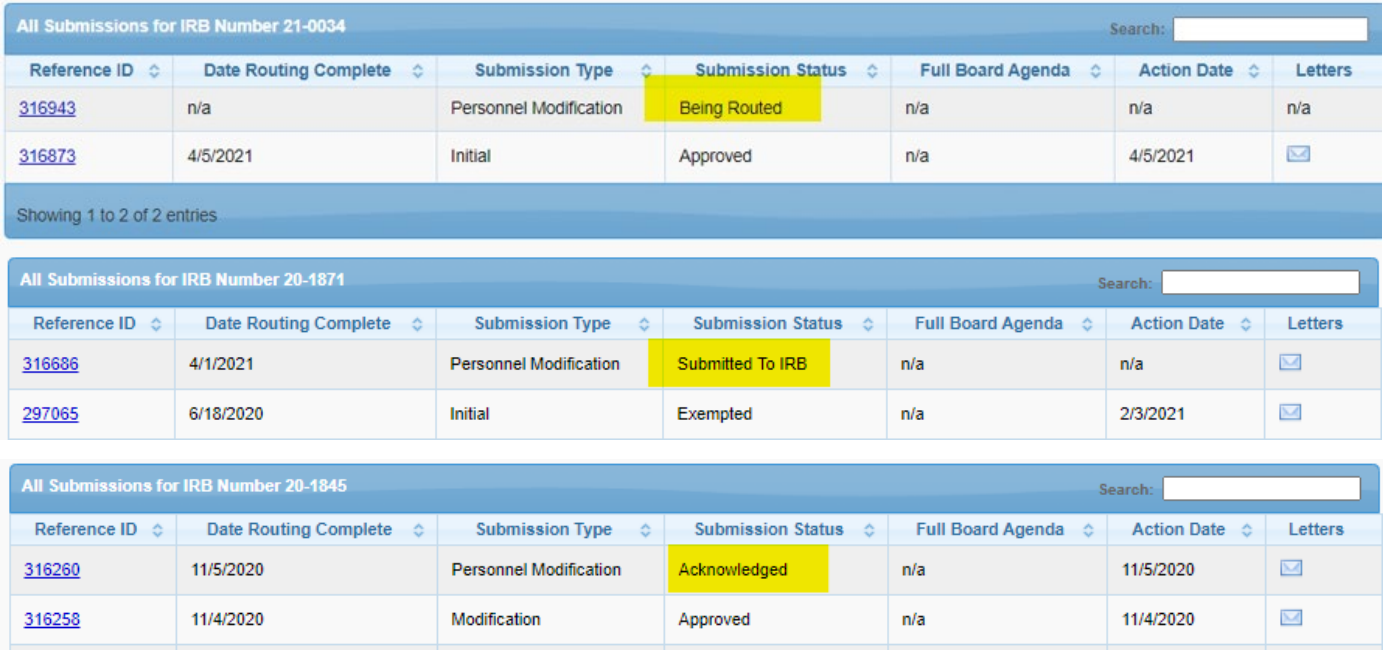
External Institutions

Liaison	Full Name	Role	Department
Duke University			
★	Williamson, Zion	External Site PI	Basketball Ops

Once you have entered all changes, submit to begin routing. There is no modification summary to complete.



Once submitted, the Personnel Modification's status can be monitored on the Study Management page.



All Submissions for IRB Number 21-0034

Search:

Reference ID	Date Routing Complete	Submission Type	Submission Status	Full Board Agenda	Action Date	Letters
316943	n/a	Personnel Modification	Being Routed	n/a	n/a	n/a
316873	4/5/2021	Initial	Approved	n/a	4/5/2021	

Showing 1 to 2 of 2 entries

All Submissions for IRB Number 20-1871

Search:

Reference ID	Date Routing Complete	Submission Type	Submission Status	Full Board Agenda	Action Date	Letters
316686	4/1/2021	Personnel Modification	Submitted To IRB	n/a	n/a	
297065	6/18/2020	Initial	Exempted	n/a	2/3/2021	

All Submissions for IRB Number 20-1845

Search:

Reference ID	Date Routing Complete	Submission Type	Submission Status	Full Board Agenda	Action Date	Letters
316260	11/5/2020	Personnel Modification	Acknowledged	n/a	11/5/2020	
316258	11/4/2020	Modification	Approved	n/a	11/4/2020	

The acknowledgement letter contains a summary of the changes that were made to personnel.

To: Kelley Hollowell
Office of Research Information Systems

From: UNC Chapel Hill Office of Human Research Ethics

Administrative Approval Date: 12/15/2020
Expiration Date of Approval: 10/28/2021
RE: Notice of IRB Administrative Approval of Personnel Changes
Submission Type: Personnel Modification

Study #: 20-3187

Study Title: Kelley's Test CR Study

This submission, Reference ID 316328, has been approved by the IRB.

The following personnel are being Added, Revised, or Removed.

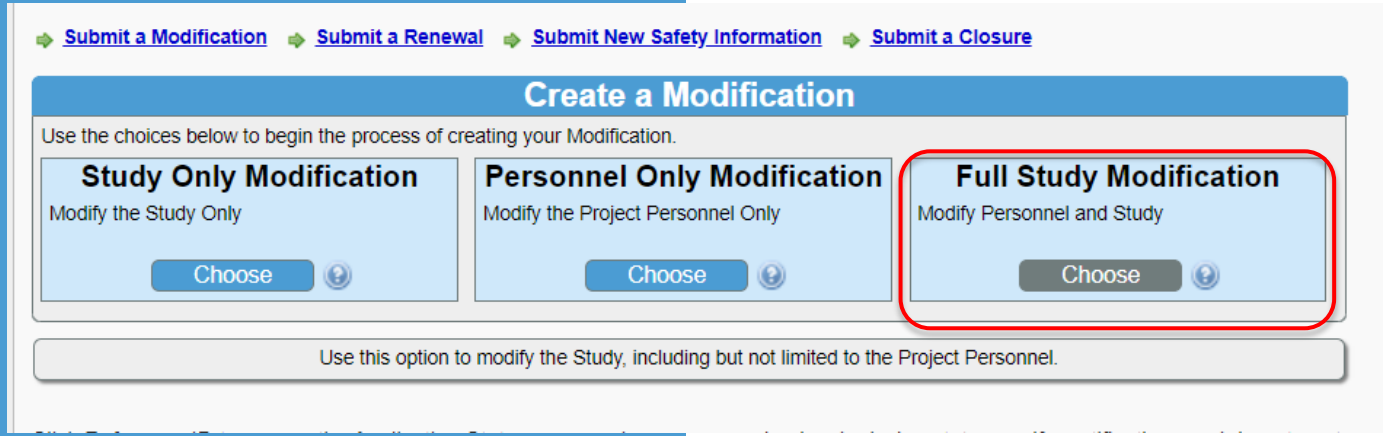
- University of North Carolina at Chapel Hill (UNC-CH)
  - **Revise:** Fennimore, Chuck (Co-investigator)
  - **Add:** Hannah, Marcus (Co-investigator)
  - **Remove:** Stephenson, John (Co-investigator)

This study was reviewed in accordance with federal regulations governing human subjects research, & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
Caitlin Hollowell, UNC Hospitals - Rex
Jeff Hartman, Office of Research Information Systems
John Slattery, Office of Research Information Systems
Jacqueline Hollowell, Lineberger Comprehensive Cancer Center
Ashley Hollowell, Sociology
Marcus Hannah, Office of Research Information Systems
Chuck Fennimore, Office of Research Information Systems

Full Study Modification

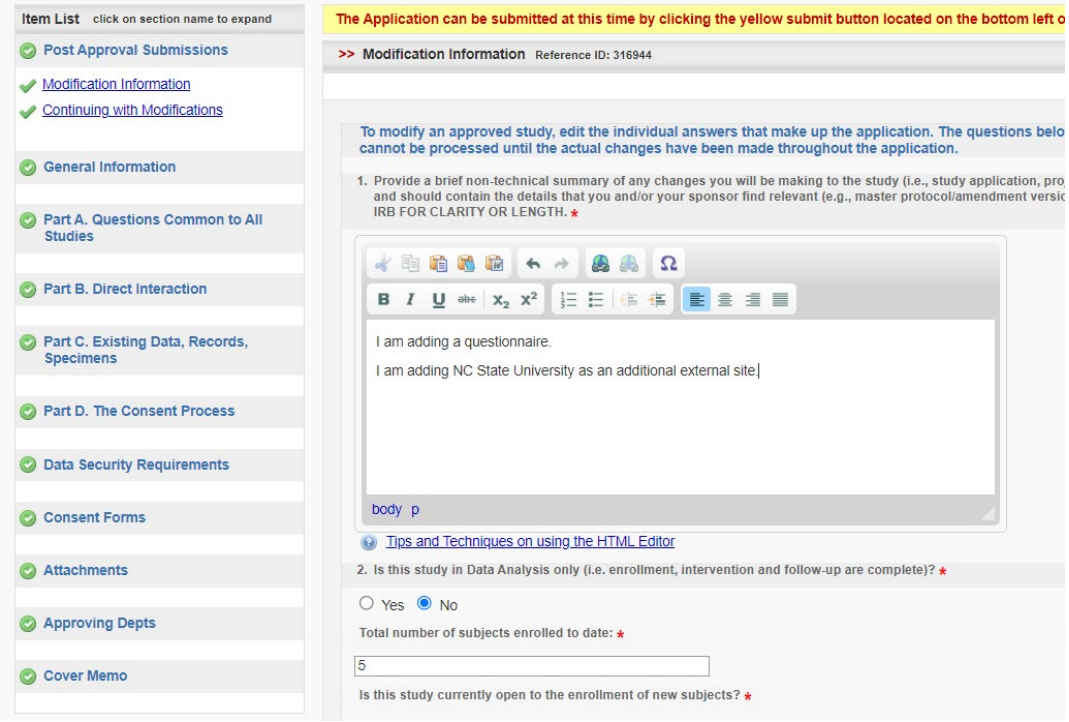
To submit changes to the study and personnel, select Full Study Modification.
You will use this option when you want to add internal personnel, including PI and/or if you want to add external personnel.



Modification Summary

While there was no need for a modification summary for a Personnel Only modification, the summary here should reflect only the changes to the study and the addition of external sites. You should not include the personnel changes in this section.

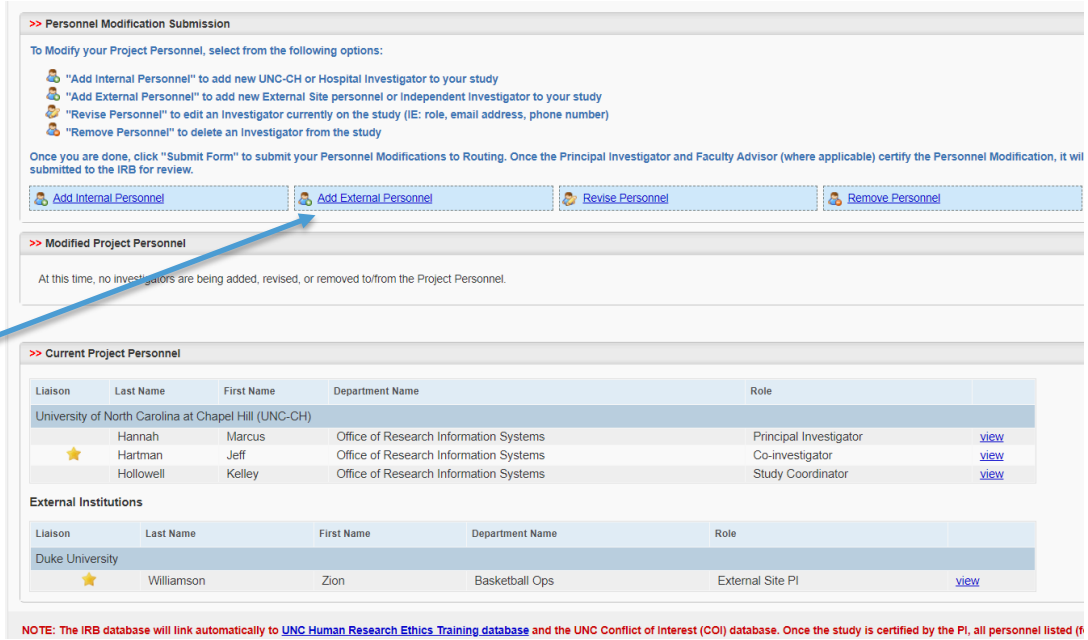
Continue to make changes as you normally would.

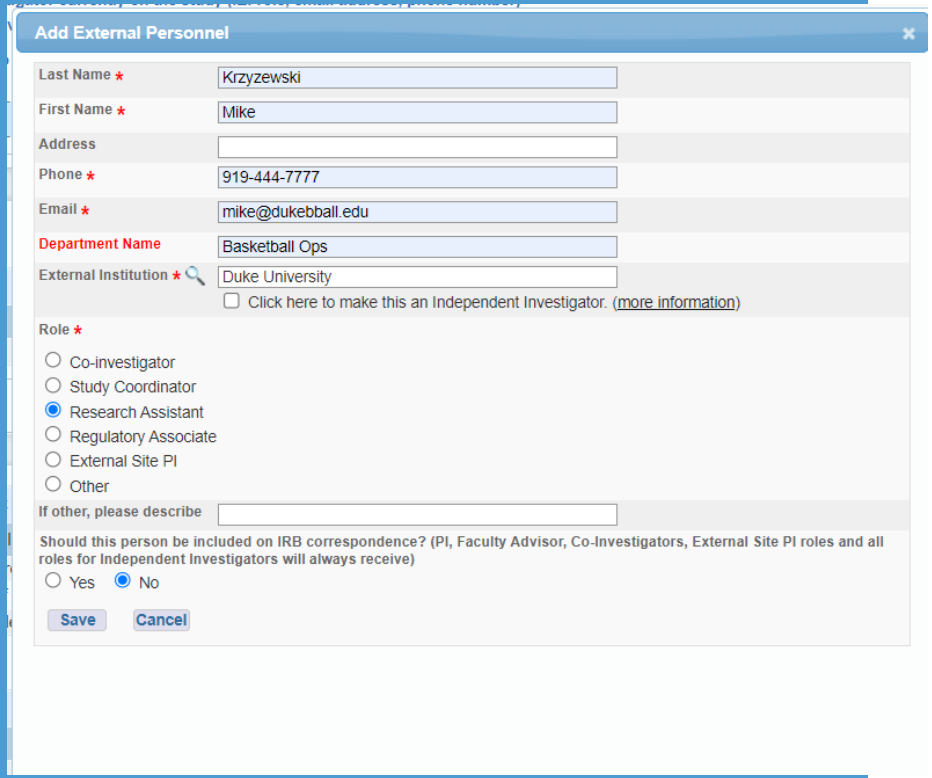


Modification Summary

The personnel changes will be done as outlined in the Personnel Only modification description.

In the Full Study modification, you can add external sites and external site personnel.

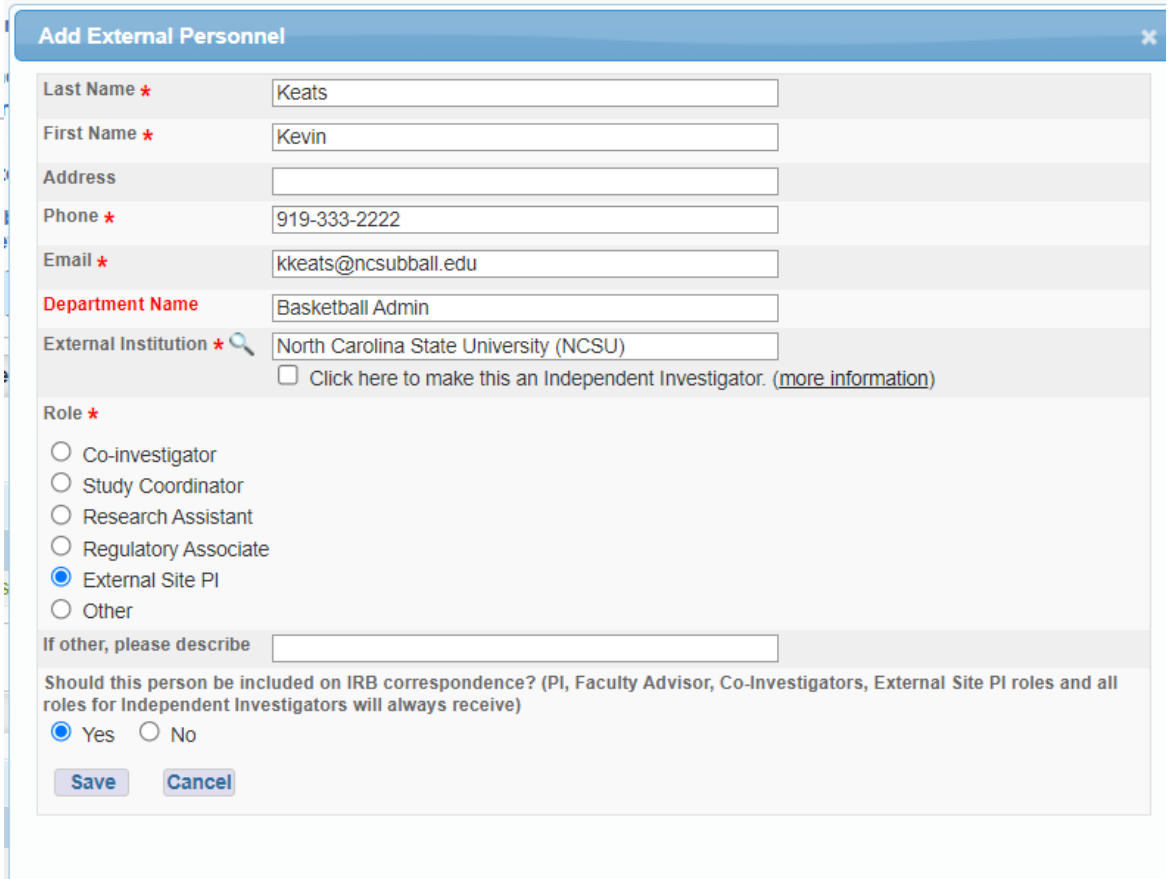




Enter personnel information as you normally would for external personnel and save.

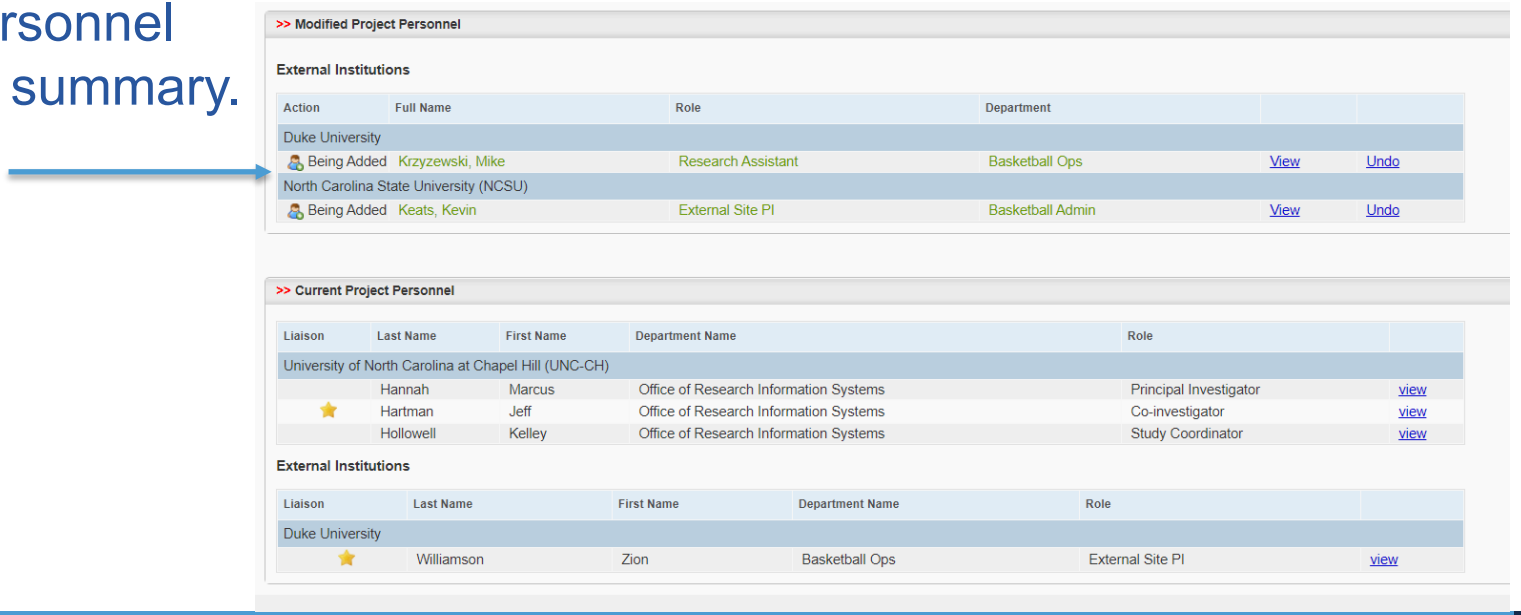
Adding an External Site

We are also adding NC State to this study. It is a new site, so the Multi-Site section will require completion as well after entering the personnel.



External Personnel

The external personnel changes are displayed in the personnel changes summary.



>> Modified Project Personnel

External Institutions

Action	Full Name	Role	Department		
Duke University					
Being Added	Krzyzewski, Mike	Research Assistant	Basketball Ops	View	Undo
North Carolina State University (NCSU)					
Being Added	Keats, Kevin	External Site PI	Basketball Admin	View	Undo

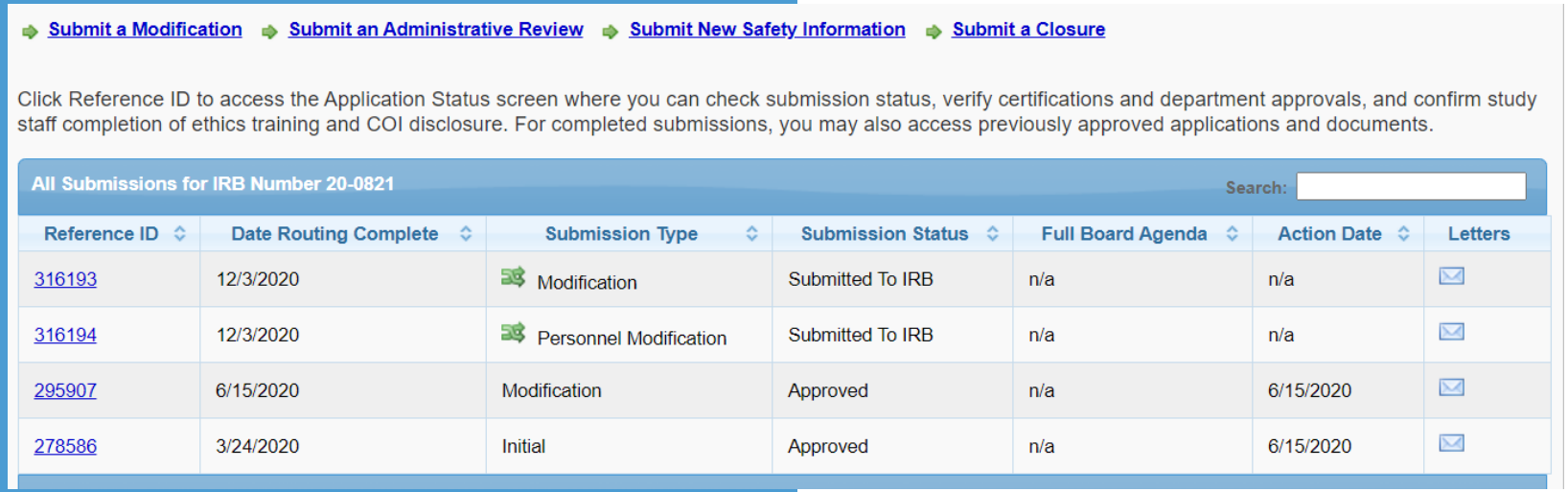
>> Current Project Personnel

Liaison	Last Name	First Name	Department Name	Role	
University of North Carolina at Chapel Hill (UNC-CH)					
	Hannah	Marcus	Office of Research Information Systems	Principal Investigator	view
★	Hartman	Jeff	Office of Research Information Systems	Co-investigator	view
	Hollowell	Kelley	Office of Research Information Systems	Study Coordinator	view

External Institutions

Liaison	Last Name	First Name	Department Name	Role	
Duke University					
★	Williamson	Zion	Basketball Ops	External Site PI	view

Once the Full Study modification is submitted, it will appear on the Study Management page as two separate submissions. This separation allows the personnel modification to be processed independent of the study modification.



Submit a Modification | Submit an Administrative Review | Submit New Safety Information | Submit a Closure

Click Reference ID to access the Application Status screen where you can check submission status, verify certifications and department approvals, and confirm study staff completion of ethics training and COI disclosure. For completed submissions, you may also access previously approved applications and documents.

All Submissions for IRB Number 20-0821 Search:

Reference ID	Date Routing Complete	Submission Type	Submission Status	Full Board Agenda	Action Date	Letters
316193	12/3/2020	Modification	Submitted To IRB	n/a	n/a	
316194	12/3/2020	Personnel Modification	Submitted To IRB	n/a	n/a	
295907	6/15/2020	Modification	Approved	n/a	6/15/2020	
278586	3/24/2020	Initial	Approved	n/a	6/15/2020	

The PM acknowledgement letter contains a summary of the changes that were made to personnel but notice that the addition of the Faculty Advisor is pending approval of the linked modification.

To: Marcus Hannah and Mike Matamoros
Office of Research Information Systems

From: UNC Chapel Hill Office of Human Research Ethics

Administrative Approval Date: 4/01/2021
Expiration Date of Approval: 11/08/2021
RE: Notice of IRB Administrative Approval of Personnel Changes
Submission Type: Personnel Modification

Study #: 19-2497

Study Title: Wizard Tester jeffhart

This submission, Reference ID 316871, has been approved by the IRB.

The following personnel are being Added, Revised, or Removed.

- **University of North Carolina at Chapel Hill (UNC-CH)**
  - **Revise:** Hollowell, Kelley (Study Coordinator)
  - **Add:** Matamoros, Mike (Faculty Advisor :: Pending Approval of Modification Reference Id 316870)

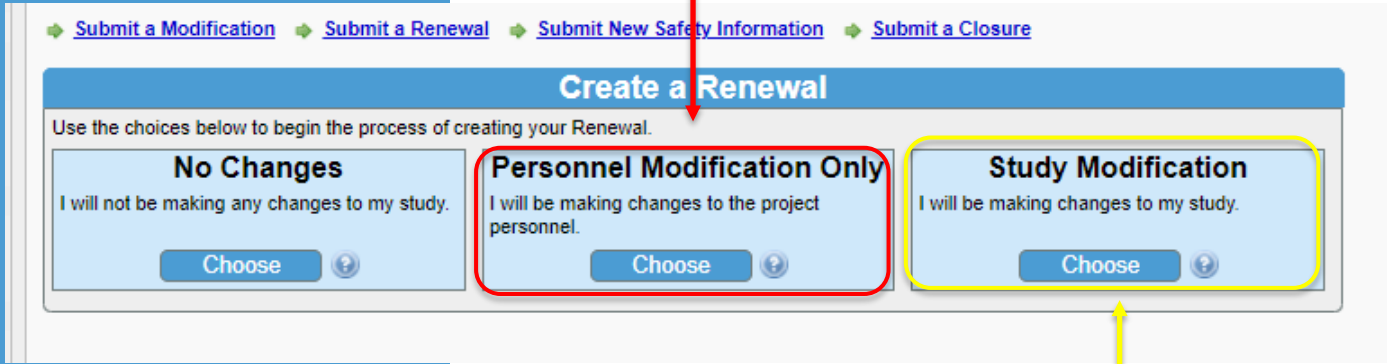
This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
Derrick Lovick, Office of Research Information Systems
Kelley Hollowell, Office of Research Information Systems
John Slattery, Office of Research Information Systems
Jeff Hartman, Office of Research Information Systems

Pairing Personnel Modification with a Renewal

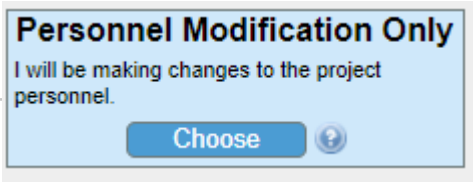
Once you begin a renewal, you will see the three submission options:

To submit a renewal with changes to personnel, select Personnel Modification Only wizard.



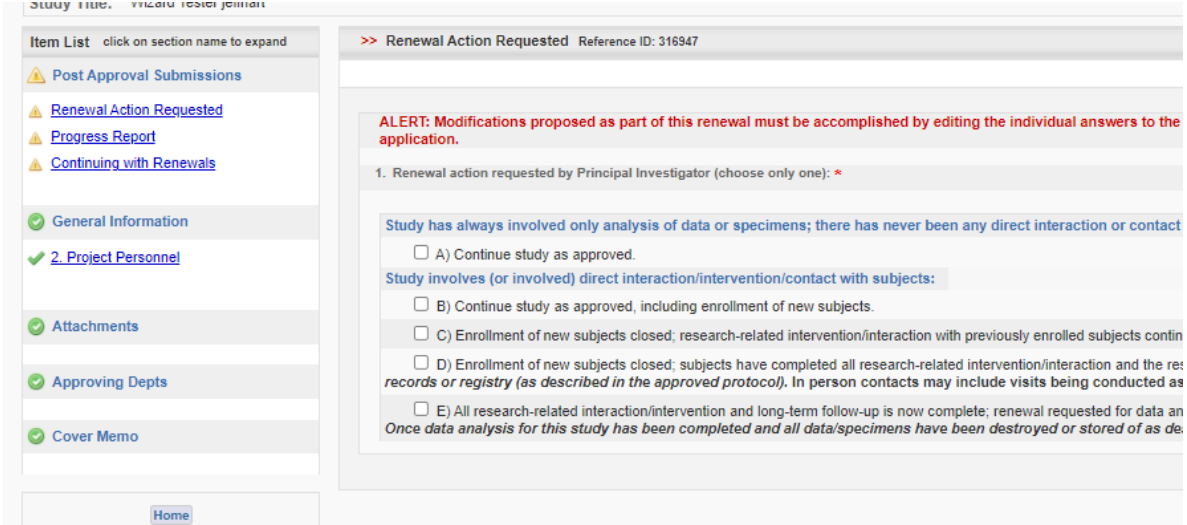
To submit a renewal with changes to the study and personnel, select Study Modification.

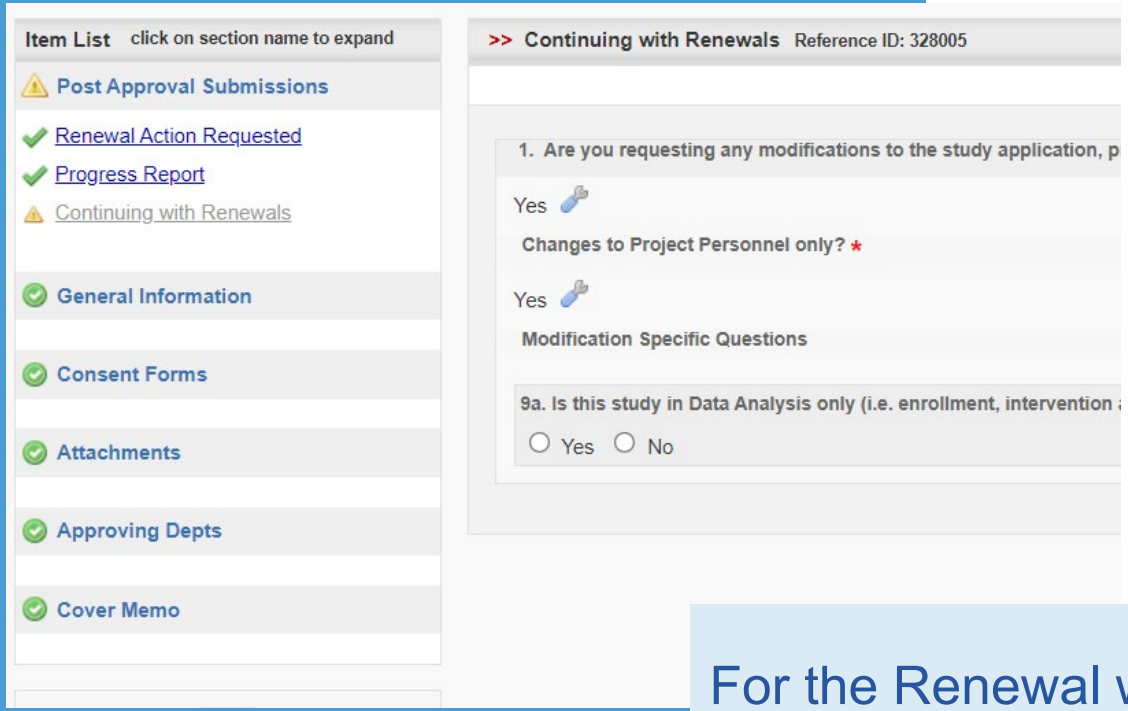
Renewal with Personnel Modification Only



The renewal application is provided along with the Project Personnel section where changes may be made.

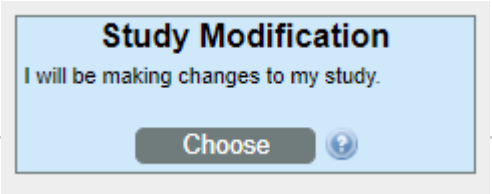
Note that there is no modification section since there is no longer any need to state the personnel changes.



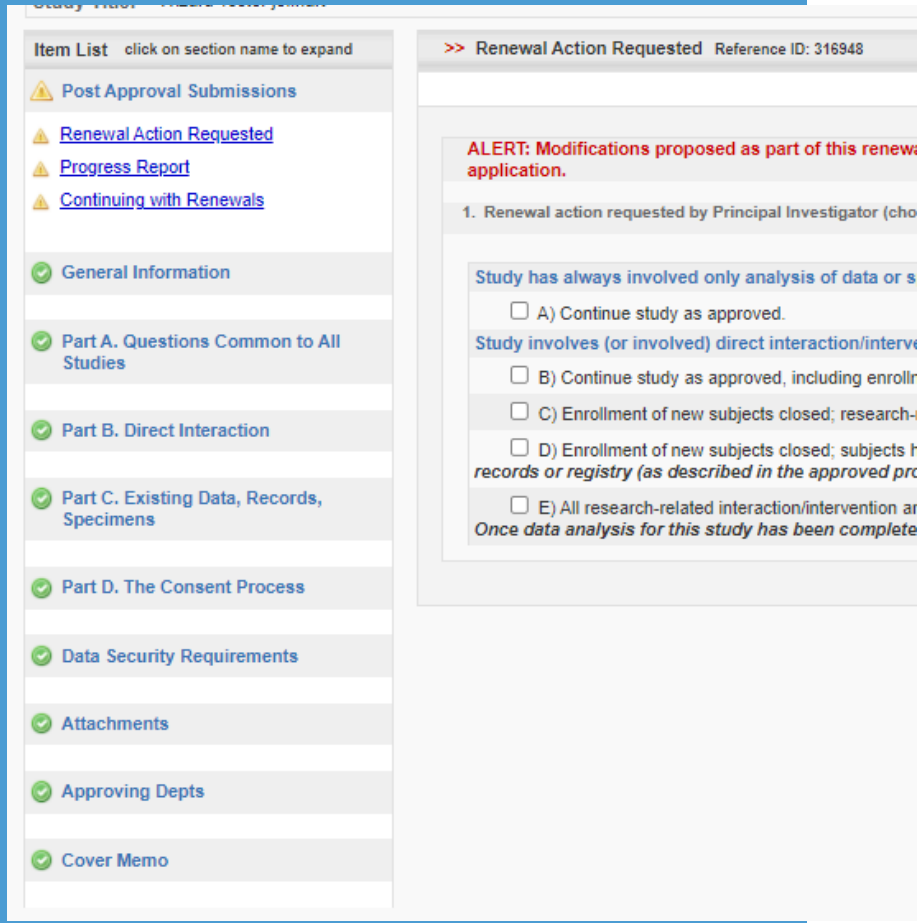


For the Renewal with personnel modification, there is no modification summary to complete. The summary of personnel changes will be generated for you.

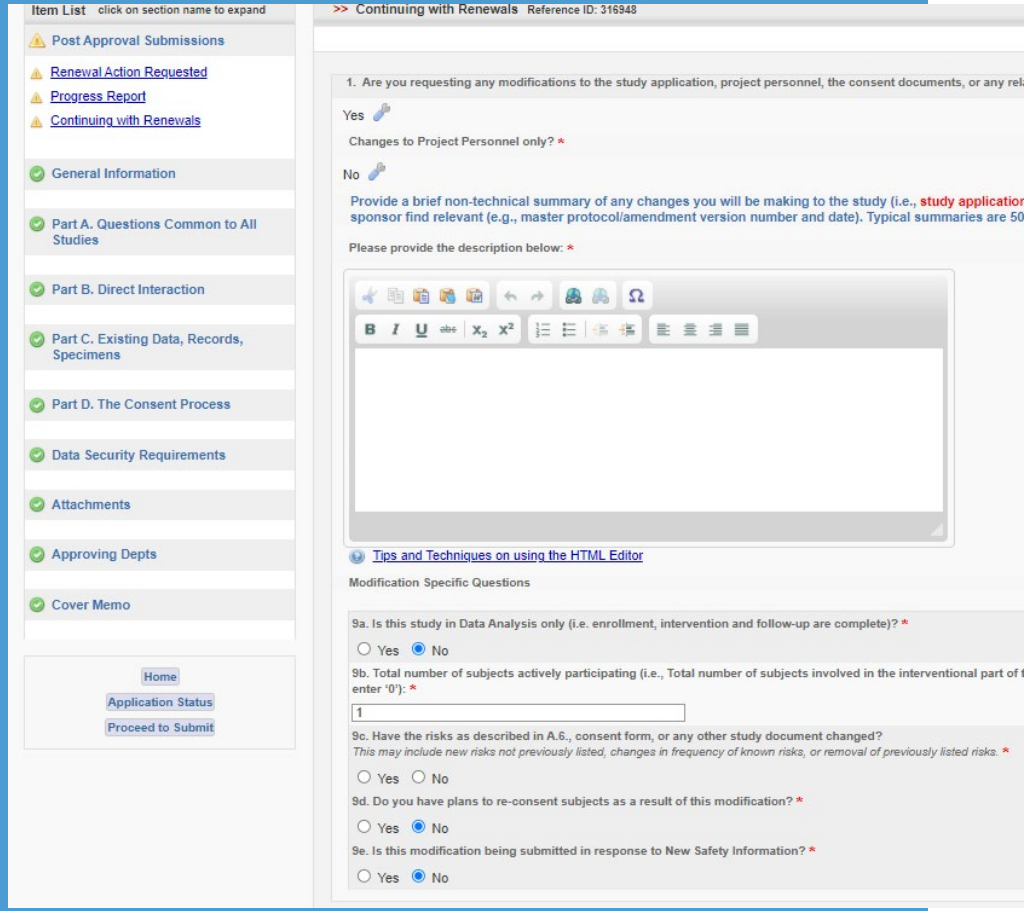
Renewal with Study Modification



Choose this option to renew your study and make any needed modifications to your study, including the Project Personnel. The OHRE does not recommend submitting requests to add additional external personnel or initiate relying/reviewing arrangements at the time of Continuing Review as this may delay renewal.

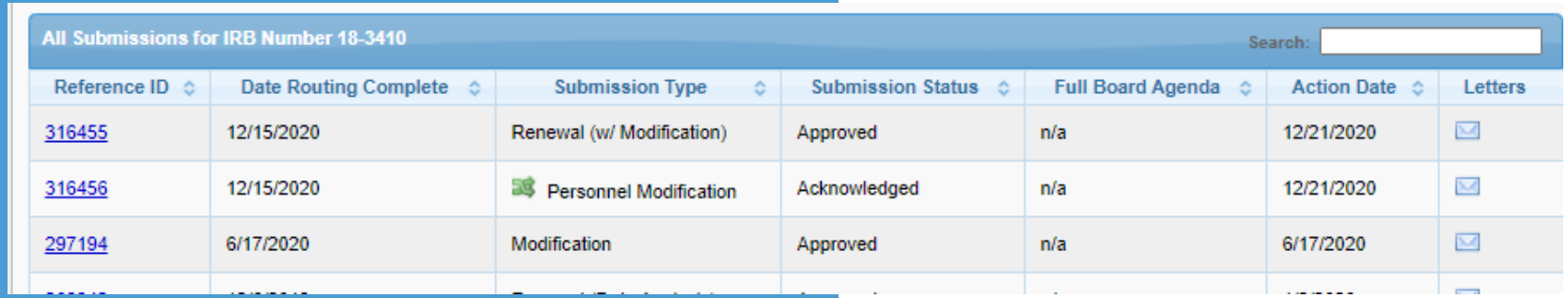


The full renewal application is provided. Any section can be updated, including the personnel section.



For the Renewal with study modification, there will be a modification summary to describe the changes to the study. There is no need to include the personnel changes.

Once the Renewal with the personnel modification is submitted, it will appear on the Study Management page as two separate submissions. This separation allows the personnel modification to be processed independent of the renewal. Note that a renewal with a study modification will be processed as a single submission.



All Submissions for IRB Number 18-3410

Search:

Reference ID	Date Routing Complete	Submission Type	Submission Status	Full Board Agenda	Action Date	Letters
316455	12/15/2020	Renewal (w/ Modification)	Approved	n/a	12/21/2020	
316456	12/15/2020	Personnel Modification	Acknowledged	n/a	12/21/2020	
297194	6/17/2020	Modification	Approved	n/a	6/17/2020	

For any questions or if you have any difficulties with IRBIS submissions, please contact us!

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