

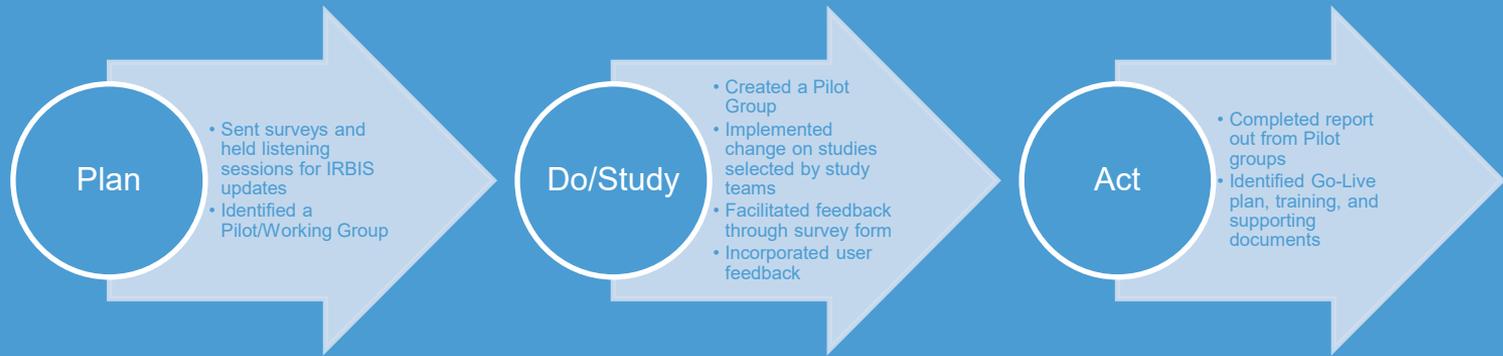
New IRBIS Personnel Modification Application

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)

➔ [Submit a Modification](#) ➔ [Submit a Renewal](#) ➔ [Submit New Safety Information](#) ➔ [Submit a Closure](#)

Create a Modification

Use the choices below to begin the process of creating your Modification.

Study Only Modification Modify the Study Only Choose ⓘ	Personnel Only Modification Modify the Project Personnel Only Choose ⓘ	Full Study Modification Modify Personnel and Study Choose ⓘ
---	---	--

Use this option to modify the personnel only. If modifying the PI or external, use Full Study Modification.

Let's draft a personnel only modification:

➔ [Submit a Modification](#) ➔ [Submit a Renewal](#) ➔ [Submit New Safety Information](#) ➔ [Submit a Closure](#)

Create a Modification

Use the choices below to begin the process of creating your Modification.

Study Only Modification Modify the Study Only Choose ⓘ	Personnel Only Modification Modify the Project Personnel Only Choose ⓘ	Full Study Modification Modify Personnel and Study Choose ⓘ
---	---	--

Use this option to modify the personnel only. If modifying the PI or external, use Full Study 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

Item List

General Information

- [2_Project Personnel](#)

Training and Conflict of Interest

- [COI Disclosures / IRB Training](#)

Submission Routing

- [Submit Form](#)
- [FA Certification Needed](#)
- [PI Certification Needed](#)

Submission Management

- [View History](#)
- [View PDF](#)
- [Delete Submission](#)

IRB
University of North Carolina - Chapel Hill
720 Martin Luther King, Jr. Blvd.
Bldg. 385, 2nd Floor
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113

>> Personnel Modification

IRB Number:	19-2497	Study Status:	Approved	Expiration Date:	11/08/2021
PI:	Hannah_Marcus	IRB:	Non-Biomedical	Faculty Advisor:	Matamoros_Mike
Sponsor:	1000 Feathers				
Study Title:	Wizard Tester jeffhart				

Reference Id:	316942	Submission Status:	Unsubmitted		
Date Submitted:	Not Submitted	Date PI Certified:	Not Certified	Date FA Certified:	Not Certified

>> 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.

>> 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
	Matamoros, Mike	Faculty Advisor	Office of Human Research Ethics
★	Hartman, Jeff	Co-investigator	Office of Research Information Systems
	Slattery, John	Co-investigator	Office of Research Information Systems
	Hollowell, Kelley	Study Coordinator	Office of Research Information Systems
	Lovick, Derrick	Research Assistant	Office of Research Information Systems

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.

>> Personnel Modification Submission

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

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-  "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.

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

Add Internal Personnel ✕

Personnel Search
Enter the last name of the person you are looking for:

PID: 

First Name:

Last Name:

Complete the profile entry as appropriate and save.

Add Cantrell, Celeste D for IRB Number 19-2497 - Reference Id 316939

Last Name *	<input type="text" value="Cantrell"/>
First Name *	<input type="text" value="Celeste"/>
Address	<input type="text" value="CB: 720 Martin Luther King Jr Blvd, Room 200A, Campu"/>
Phone *	<input type="text" value="(919) 843-5018"/>
UNC Email *	<input type="text" value="ccantrell@unc.edu"/>
Department Name *	<input type="text" value="Office of Human Research Ethics"/>
External Institution *	<input type="text" value="University of North Carolina at Chapel Hill (UNC-CH)"/>

ATTENTION: The department named above for the PI or Faculty Advisor will receive this submission for approval. If the department above DOES NOT represent the primary academic (faculty and students) or administrative (staff) department of the individual named, choose the correct department. Students should not list their employing department (e.g., Work Study) unless that department is directly supervising this research.

Role *

- Principal Investigator
- Co-investigator
- Study Coordinator
- Research Assistant
- Regulatory Associate
- Other

If other, please describe

Should this person be included on IRB correspondence? (PI, Faculty Advisor, Co-Investigators, External Site PI roles and all roles for Independent Investigators will always receive)

Yes No

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

>> 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.

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

Revise Personnel

>> Current Project Personnel

 Click the "Revise" link below to edit the chosen Investigator currently on the study.

Liaison	Full Name	Role	Department	
University of North Carolina at Chapel Hill (UNC-CH)				
	Hannah, Marcus	Principal Investigator	Office of Research Information Systems	Revise
	Matamoros, Mike	Faculty Advisor	Office of Human Research Ethics	Revise
	Hartman, Jeff	Co-investigator	Office of Research Information Systems	Revise
	Slattery, John	Co-investigator	Office of Research Information Systems	Revise
	Hollowell, Kelley	Study Coordinator	Office of Research Information Systems	Revise
	Lovick, Derrick	Research Assistant	Office of Research Information Systems	Revise

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

Revise Matamoros, Mike for IRB Number 19-2497

Last Name *

First Name *

Address

Phone *

UNC Email *

Department Name

External Institution *

ATTENTION: The department named above for the PI or Faculty Advisor will receive this submission for approval. If the department above DOES NOT represent the primary academic (faculty and students) or administrative (staff) department of the individual named, choose the correct department. Students should not list their employing department (e.g., Work Study) unless that department is directly supervising this research.

Role *

Principal Investigator

Co-investigator

Faculty Advisor

Study Coordinator

Research Assistant

Regulatory Associate

Other

If other, please describe

Should this person be included on IRB correspondence? (PI, Faculty Advisor, Co-Investigators, External Site PI roles and all roles for Independent Investigators will always receive)

Yes No

[Add Internal Personnel](#)
[Add External Personnel](#)
[Revise Personnel](#)
[Remove Personnel](#)

ALERT: STUDY MODIFICATION REQUIRED

Assigning the ROLE of Principal Investigator to a new project personnel or revising project personnel within External Institutions will require modifying the Study in conjunction with the Personnel Modification form.

>> Modified Project Personnel

Action	Full Name	Role	Department		
University of North Carolina at Chapel Hill (UNC-CH)					
Being Revised	Hartman, Jeff	Principal Investigator	Office of Research Information Systems	View	Undo
Being Revised	Hannah, Marcus	Co-investigator	Office of Research Information Systems	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

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.

Submit Personnel Modification for IRB Number 21-0034

You have changes to Personnel which requires a Full Study modification.

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.

Remove Personnel

>> Current Project Personnel

 Click "Remove" below to delete the chosen Investigator from the study.

Liaison	Full Name	Role	Department	
University of North Carolina at Chapel Hill (UNC-CH)				
	Hannah, Marcus	Principal Investigator	Office of Research Information Systems	Remove
	Matamoros, Mike	Faculty Advisor	Office of Human Research Ethics	
★	Hartman, Jeff	Co-investigator	Office of Research Information Systems	Remove
	Slattery, John	Co-investigator	Office of Research Information Systems	Remove
		Study Coordinator	Office of Research Information Systems	Remove
		Research Assistant	Office of Research Information Systems	Remove

orisdev.research.unc.edu says

Do you want to remove Lovick, Derrick from your Project Personnel?

OK

Cancel

 Click "Remove" below to delete the chosen Investigator from the study.

Liaison	Full Name	Role	Department	
University of North Carolina at Chapel Hill (UNC-CH)				
	Hannah, Marcus	Principal Investigator	Office of Research Information Systems	Remove
	Matamoros, Mike	Faculty Advisor	Office of Human Research Ethics	
★	Hartman, Jeff	Co-investigator	Office of Research Information Systems	Remove
	Slattery, John	Co-investigator	Office of Research Information Systems	Remove
	Hollowell, Kelley	Study Coordinator	Office of Research Information Systems	Remove
	Lovick, Derrick	Research Assistant	Office of Research Information Systems	Remove

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.

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

Action	Full Name	Role	Department		
University of North Carolina at Chapel Hill (UNC-CH)					
Being Revised	Matamoros, Mike	Faculty Advisor	Office of Human Research Ethics	View	Undo
Being Added	Roberts, John	Study Coordinator	Office of Human Research Ethics	View	Undo
Being Added	Cantrell, Celeste	Research Assistant	Office of Human Research Ethics	View	Undo
Being Removed	Lovick, Derrick	Research Assistant	Office of Research Information Systems	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
	Matamoros, Mike	Faculty Advisor	Office of Human Research Ethics
★	Hartman, Jeff	Co-investigator	Office of Research Information Systems
	Slattery, John	Co-investigator	Office of Research Information Systems
	Hollowell, Kelley	Study Coordinator	Office of Research Information Systems
	Lovick, Derrick	Research Assistant	Office of Research Information Systems

Adding external personnel:

>> 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.

Add External Personnel



Adding External personnel to IRB Number 19-2497 requires a Full Study Modification and the Study to be a MULTI-SITE.

You will need to delete this personnel modification and create a Full Study Modification.

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.

Remove Personnel ✕

>> Current Project Personnel

 Click "Remove" below to delete the chosen Investigator from the study.

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

External Institutions

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



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:

Revise Personnel ✕

>> Current Project Personnel

 Click the "Revise" link below to edit the chosen Investigator currently on the study.

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

External Institutions

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

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.

Item List

General Information

- [2. Project Personnel](#)

Training and Conflict of Interest

- [COI Disclosures / IRB Training](#)

Submission Routing

- ⚠ [Submit Form](#)
- ⚠ [PI Certification Needed](#)

Submission Management

- [View History](#)
- [View PDF](#)
- [Delete Submission](#)

IRB
University of North Carolina - Chapel Hill
720 Martin Luther King, Jr. Blvd.
Bldg. 385, 2nd Floor
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113

Submit Personnel Modification for IRB Number 18-3410

**Are you ready to submit this Personnel Modification?
Please review the Personnel Modification and submit below.**

The final step in this process is to have the personnel modification submission certified by the PI; the IRB will not receive this personnel modification submission until the PI has certified.

Submit to Routing

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.

[Submit a Modification](#) → [Submit a Renewal](#) → [Submit New Safety Information](#) → [Submit a Closure](#)

Create a Modification

Use the choices below to begin the process of creating your Modification.

Study Only Modification Modify the Study Only Choose 	Personnel Only Modification Modify the Project Personnel Only Choose 	Full Study Modification Modify Personnel and Study Choose 
---	---	--

Use this option to modify the Study, including but not limited to the Project 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.

Item List	click on section name to expand
✓	Post Approval Submissions
✓	Modification Information
✓	Continuing with Modifications
✓	General Information
✓	Part A. Questions Common to All Studies
✓	Part B. Direct Interaction
✓	Part C. Existing Data, Records, Specimens
✓	Part D. The Consent Process
✓	Data Security Requirements
✓	Consent Forms
✓	Attachments
✓	Approving Depts
✓	Cover Memo

The Application can be submitted at this time by clicking the yellow submit button located on the bottom left of the page.

>> **Modification Information** Reference ID: 316944

To modify an approved study, edit the individual answers that make up the application. The questions below cannot be processed until the actual changes have been made throughout the application.

1. Provide a brief non-technical summary of any changes you will be making to the study (i.e., study application, protocol, and should contain the details that you and/or your sponsor find relevant (e.g., master protocol/amendment version, IRB FOR CLARITY OR LENGTH). *

I am adding a questionnaire.
I am adding NC State University as an additional external site|

body p

[Tips and Techniques on using the HTML Editor](#)

2. Is this study in Data Analysis only (i.e. enrollment, intervention and follow-up are complete)? *

Yes No

Total number of subjects enrolled to date: *

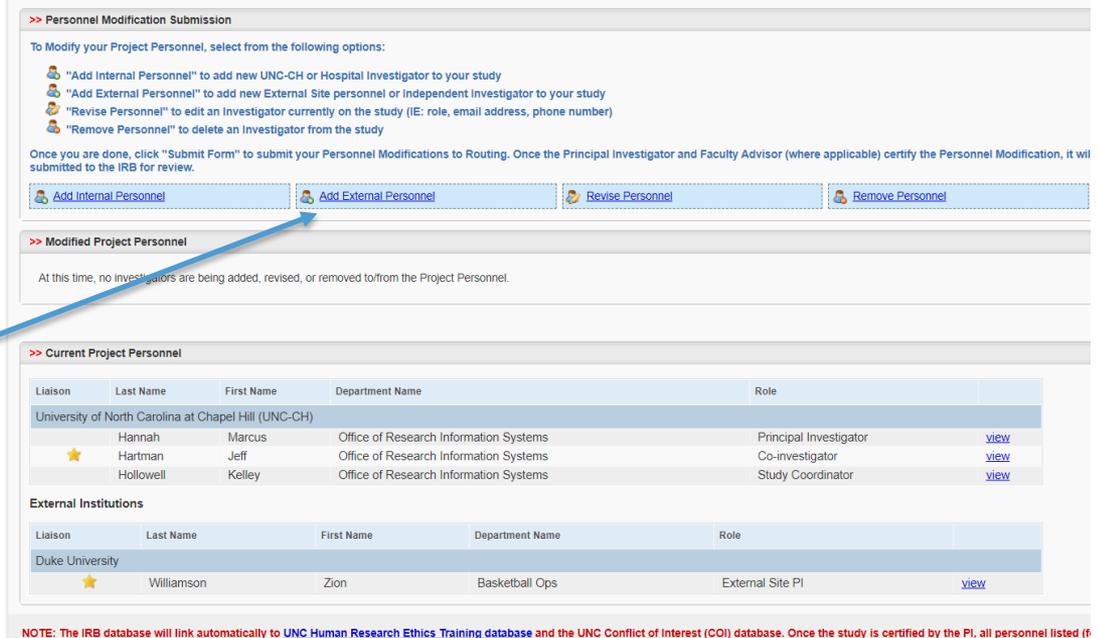
5

Is this study currently open to the enrollment of new subjects? *

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.



>> 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
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- "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.

>> 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

NOTE: The IRB database will link automatically to [UNC Human Research Ethics Training database](#) and the [UNC Conflict of Interest \(COI\) database](#). Once the study is certified by the PI, all personnel listed for the study will be automatically linked to the IRB database.

Add External Personnel ✕

Last Name *

First Name *

Address

Phone *

Email *

Department Name

External Institution * 

Click here to make this an Independent Investigator. ([more information](#))

Role *

- Co-Investigator
- Study Coordinator
- Research Assistant
- Regulatory Associate
- External Site PI
- Other

If other, please describe

Should this person be included on IRB correspondence? (PI, Faculty Advisor, Co-Investigators, External Site PI roles and all roles for Independent Investigators will always receive)

Yes No

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.

Add External Personnel

Last Name *

First Name *

Address

Phone *

Email *

Department Name

External Institution *
 Click here to make this an Independent Investigator. ([more information](#))

Role *

- Co-investigator
- Study Coordinator
- Research Assistant
- Regulatory Associate
- External Site PI
- Other

If other, please describe

Should this person be included on IRB correspondence? (PI, Faculty Advisor, Co-Investigators, External Site PI roles and all roles for Independent Investigators will always receive)
 Yes No

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: <input type="text"/>
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: 11/03/2021
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.

The screenshot displays a web interface for creating a renewal. At the top, there are four navigation links: [Submit a Modification](#), [Submit a Renewal](#), [Submit New Safety Information](#), and [Submit a Closure](#). Below these is a blue header bar with the text "Create a Renewal". Underneath the header, a message reads: "Use the choices below to begin the process of creating your Renewal." There are three main options presented in light blue boxes:

- No Changes**: "I will not be making any changes to my study." Below this is a "Choose" button with a help icon.
- Personnel Modification Only**: "I will be making changes to the project personnel." This option is highlighted with a red border. Below this is a "Choose" button with a help icon.
- Study Modification**: "I will be making changes to my study." Below this is a "Choose" button with a help icon.

A red arrow points from the "Personnel Modification Only" text in the left sidebar to the "Personnel Modification Only" option in the wizard. A yellow arrow points from the "Study Modification" text in the left sidebar to the "Study Modification" option in the 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.

Personnel Modification Only

I will be making changes to the project personnel.

Choose



Study Title: v12491 test journal

Item List click on section name to expand

- ⚠ Post Approval Submissions
- ⚠ [Renewal Action Requested](#)
- ⚠ [Progress Report](#)
- ⚠ [Continuing with Renewals](#)
- ✓ General Information
- ✓ [2. Project Personnel](#)
- ✓ Attachments
- ✓ Approving Depts
- ✓ Cover Memo

Home

>> Renewal Action Requested Reference ID: 316947

ALERT: Modifications proposed as part of this renewal must be accomplished by editing the individual answers to the application.

1. Renewal action requested by Principal Investigator (choose only one): *

Study has always involved only analysis of data or specimens; there has never been any direct interaction or contact

A) Continue study as approved.

Study involves (or involved) direct interaction/intervention/contact with subjects:

B) Continue study as approved, including enrollment of new subjects.

C) Enrollment of new subjects closed; research-related intervention/interaction with previously enrolled subjects contin

D) Enrollment of new subjects closed; subjects have completed all research-related intervention/interaction and the re records or registry (as described in the approved protocol). In person contacts may include visits being conducted as

E) All research-related interaction/intervention and long-term follow-up is now complete; renewal requested for data an *Once data analysis for this study has been completed and all data/specimens have been destroyed or stored of as de*

Item List click on section name to expand

 [Post Approval Submissions](#)

 [Renewal Action Requested](#)

 [Progress Report](#)

 [Continuing with Renewals](#)

 [General Information](#)

 [Consent Forms](#)

 [Attachments](#)

 [Approving Depts](#)

 [Cover Memo](#)

>> Continuing with Renewals Reference ID: 328005

1. Are you requesting any modifications to the study application, p

Yes 

Changes to Project Personnel only? *

Yes 

Modification Specific Questions

9a. Is this study in Data Analysis only (i.e. enrollment, intervention :

Yes No

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

Study Modification
I will be making changes to my study.

Choose 

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.

Study Name: [REDACTED]

Item List click on section name to expand

- ⚠ Post Approval Submissions
 - [Renewal Action Requested](#)
 - [Progress Report](#)
 - [Continuing with Renewals](#)
- ✔ General Information
- ✔ Part A. Questions Common to All Studies
- ✔ Part B. Direct Interaction
- ✔ Part C. Existing Data, Records, Specimens
- ✔ Part D. The Consent Process
- ✔ Data Security Requirements
- ✔ Attachments
- ✔ Approving Depts
- ✔ Cover Memo

>> Renewal Action Requested Reference ID: 316948

ALERT: Modifications proposed as part of this renewal application.

1. Renewal action requested by Principal Investigator (choose one)

Study has always involved only analysis of data or specimens

A) Continue study as approved.

Study involves (or involved) direct interaction/intervention

B) Continue study as approved, including enrollment of new subjects

C) Enrollment of new subjects closed; research-related interaction/intervention continues

D) Enrollment of new subjects closed; subjects have been followed up in the approved protocol *records or registry (as described in the approved protocol)*

E) All research-related interaction/intervention are complete *Once data analysis for this study has been complete*

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

Item List click on section name to expand

- Post Approval Submissions
 - Renewal Action Requested
 - Progress Report
 - Continuing with Renewals
- General Information
- Part A. Questions Common to All Studies
- Part B. Direct Interaction
- Part C. Existing Data, Records, Specimens
- Part D. The Consent Process
- Data Security Requirements
- Attachments
- Approving Depts
- Cover Memo

[Home](#)
[Application Status](#)
[Proceed to Submit](#)

>> Continuing with Renewals Reference ID: 316948

1. Are you requesting any modifications to the study application, project personnel, the consent documents, or any rel

Yes

Changes to Project Personnel only? *

No

Provide a brief non-technical summary of any changes you will be making to the study (i.e., **study application** sponsor find relevant (e.g., master protocol/amendment version number and date). Typical summaries are 50

Please provide the description below: *

[Tips and Techniques on using the HTML Editor](#)

Modification Specific Questions

9a. Is this study in Data Analysis only (i.e. enrollment, intervention and follow-up are complete)? *

Yes No

9b. Total number of subjects actively participating (i.e., Total number of subjects involved in the interventional part of t
 enter '0'): *

9c. Have the risks as described in A.6., consent form, or any other study document changed?
*This may include new risks not previously listed, changes in frequency of known risks, or removal of previously listed risks. **

Yes No

9d. Do you have plans to re-consent subjects as a result of this modification? *

Yes No

9e. Is this modification being submitted in response to New Safety Information? *

Yes No

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: <input type="text"/>
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!**

irbis@unc.edu



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL