# 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 -

tem List	>> Personner wo	uncation				
General Information	IRB Number:	19-2497	Study Status:	Approved	Expiration Date:	11/08/2021
2. Project Personnel	PI:	Hannah, Marcus	IRB:	Non-Biomedical		
Training and Conflict of Interact	Sponsor:	1000 Feathers			Faculty Advisor:	Matamoros, Mike
naming and connector interest	Study Title:	Wizard Tester jeffhart				
COI Disclosures / IRB Training						
Submission Routing	Reference Id:	<u>316942</u>	Submission Status:	Unsubmitted		
Submit Form	Date Submitted:	Not Submitted	Date PI Certified:	Not Certified	Date FA	Not Certified
<u>FA Certification Needed</u>					Cerunea:	
<u>PI Certification Needed</u>						
Submission Management	>> Personnel Mo	dification Submission				
View History	To Modify your P	roject Personnel, selec	t from the following opti	ons:		
View PDF						
	Co "Add Inter	nai Personnei" to add	new UNC-CH or Hospital	i investigator to your	study	
Delete Submission	Add Exte	rnal Personnel" to add	new External Site perso	onnel or Independent	Investigator to your st	udy
	🦉 "Revise Po	ersonnel" to edit an Inv	estigator currently on th	ne study (IE: role, em	ail address, phone nur	nber)
	📥 "Remove I	Personnel" to delete ar	n Investigator from the st	tudy		
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## 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:

The study "Add Internal Personnel" to add new UNC-CH or Hospital Investigator to your study

a "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.



### >> 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:
Search

# Complete the profile entry as appropriate and save.

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

.ast Name * 🔍	Cantrell
irst Name *	Celeste
Address	CB: 720 Martin Luther King Jr Blvd, Room 200A , Campı
hone *	(919) 843-5018
JNC Email * 🔞	ccantrell@unc.edu
Department Name 🔍	Office of Human Research Ethics
external Institution *	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 *         O Principal Investigator         O Co-investigator         O Study Coordinator         Image: Research Assistant         O Regulatory Associate	
O 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) O Yes  No	
Save	

# 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

a "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

<u>Remove Personnel</u>

### >> 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 Pe	ersonnel			
>> Curren	t Project Personnel			
🐉 Clie	ck the "Revise" linl	k below to edit the cho	sen Investigator currently on the study.	
Liaison	Full Name	Role	Department	2
Univers	ity of North Carolina	a at Chapel Hill (UNC-CH	1)	
	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	<u>Revise</u>
	Hollowell, Kelley	Study Coordinator	Office of Research Information Systems	Revise
	Lovick, Derrick	Research Assistant	Office of Research Information Systems	<u>Revise</u>

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 * 🔍	Matamoros
First Name *	Mike
Address	CB: 9999
Phone *	(919) 966-3113
UNC Email * 🔞	matamoro@email.unc.edu
Department Name 🔍	Office of Human Research Ethics
External Institution *	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.

University of North Carolina at Chapel Hill (UNC-CH)

S	o	e	*

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

If other, please

describe

Save

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)

$\bigcirc$	Yes	$\bigcirc$	No	

Cancel

\delta Add In	ternal Personnel	Add External Personnel	Revise Personnel	Remove Personnel
Assig	ERT: STUDY MODIFICATION	REQUIRED	t personnel or revising project personnel wi	ithin External Institutions will
> Modifie	d Project Personnel	Juouon war are rersonner		
mounto				
Action	Full Name	Role	Department	
University	of North Carolina at Chapel	Hill (UNC-CH)		
Being Being	Revised Hartman, Jeff Revised Hannah, Marcus	Principal Investigator Co-investigator	Office of Research Information System Office of Research Information System	s <u>View</u> <u>Undo</u> s <u>View</u> <u>Undo</u>
> Current	t Project Personnel			
Liaison	Full Name	Role	Department	
University	of North Carolina at Chanel	Hill/UNC-CH)		
oniversity	Hannah Marcue	Principal Investigator	Office of Research Information	Sustama
-	Hartman, Marcus	Co investigator	Office of Research Information	Svetame
-	Hollowell, Kelley	Study Coordinator	Office of Research Information	Systems
		and a contained		

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.

### **IRBIS** Personnel Modification Application

# 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. <u>Click here to jump to Full Study Modification.</u>



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



- 🖧 "Add External Personnel" to add new External Site personnel or Independent Investigator to your study
- ${\mathscr S}$  "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.



### >> Modified Project Personnel

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

						Remove F	Personnel				
					3	>> Current	Project Personnel				
						🚑 Clie	k "Remove" belov	w to delete the chosen	Investigator from the study.		
						Liaison	Full Name	Role	Department	&	
						Univers	ity of North Carolina	a at Chapel Hill (UNC-C	H)		
							Hannah, Marcus Matamoros, Mike	Principal Investigator Faculty Advisor	Office of Research Information Systems Office of Human Research Ethics	Remove	
						*	Hartman, Jeff	Co-investigator	Office of Research Information Systems	Remove	
пушс	iex.cii	iii:evei	it=nome.personner	พบนการสามากการสามาระ	enu-510559#:		Slatteny John	Co-investigator	Office of Research Information Systems	Remove	
٢	Kronc	os Workt	orce 🔇 IRB	risdev.research.unc.edu	says	D 10	. 1&1 E-Mail und On	Study Coordinator Research Assistant	Office of Research Information Systems Office of Research Information Systems	Remove Remove	
el M	Rei	movel	Personnel	o you want to remove Lovici	k, Derrick from your Project	Personner:	×				
ourl	>> (	Curren	t Project Perso		ОК	Cancel					
l Inte I Ext		🖧 Cli	ck "Remove" bel	ow to delete the chosen	n Investigator from the s	study.					
ise I	L	iaison	Full Name	Role	Department		2	Click of	n 'Remove' and confi	rm.	
re de	ι	Jnivers	ity of North Caroli	na at Chapel Hill (UNC-C	CH)						
iere			Hannah, Marcus Matamoros, Mike	Principal Investigator Faculty Advisor	Office of Research Info Office of Human Resea	ormation System arch Ethics	ns <u>Remove</u>				
emai		*	Hartman, Jeff	Co-investigator	Office of Research Info	ormation System	ms <u>Remove</u>				
Pro			Slattery, John	Co-investigator Study Coordinator	Office of Research Info	ormation System	ns <u>Remove</u>				
			Lovick, Derrick	Research Assistant	Office of Research Info	ormation System	ns <u>Remove</u>				
of No											
Revis											
Adde											

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 External Personnel	Revise Personnel	Remove I	Personnel
Modified Project F	Personnel				
Action	Full Name	Role	Department		
Jniversity of North C	arolina at Chapel Hil	II (UNC-CH)			
🐉 Being Revised	Matamoros, Mike	Faculty Advisor	Office of Human Research Ethics	<u>View</u>	<u>Undo</u>
👵 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	<u>Undo</u>
🖧 Being Removed	Lovick, Derrick	Research Assistant	Office of Research Information Systems	View	<u>Undo</u>
Current Project Pe	ersonnel	Pele	Decement		
• Current Project Pe iaison Full Nam	ersonnel	Role	Department		
Current Project Pe iaison Full Nam Jniversity of North Ca	ersonnel 1e arolina at Chapel Hil	Role II (UNC-CH)	Department		
Current Project Pe iaison Full Nam Jniversity of North Ca Hannah Matamo	ersonnel ne arolina at Chapel Hil I, Marcus oros, Mike	Role II (UNC-CH) Principal Investigator Faculty Advisor	Department Office of Research Information S Office of Human Research Ethics	ystems S	
Current Project Pe iaison Full Nam Jniversity of North Ca Hannah Matamo Hartmar	ersonnel ne arolina at Chapel Hil ı, Marcus oros, Mike n, Jeff	Role II (UNC-CH) Principal Investigator Faculty Advisor Co-investigator	Department Office of Research Information S Office of Human Research Ethics Office of Research Information S	ystems 5 ystems	
Current Project Periliaison Full Nam Jniversity of North Ca Hannah Matamo that Matamo Slattery,	ersonnel arolina at Chapel Hil ı, Marcus oros, Mike n, Jeff ı, John	Role II (UNC-CH) Principal Investigator Faculty Advisor Co-investigator Co-investigator	Department Office of Research Information S Office of Human Research Ethics Office of Research Information S Office of Research Information S	ystems s ystems ystems	
Current Project Period Liaison Full Nam Jniversity of North Ca Hannah Matamo Slattery, Hollowe	ersonnel arolina at Chapel Hil I, Marcus oros, Mike n, Jeff , John II, Kelley	Role I (UNC-CH) Principal Investigator Faculty Advisor Co-investigator Co-investigator Study Coordinator	Department Office of Research Information S Office of Human Research Ethics Office of Research Information S Office of Research Information S Office of Research Information S	ystems s ystems ystems ystems	

### Adding external personnel:

>> Personnel Modification Submission

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

The study "Add Internal Personnel" to add new UNC-CH or Hospital Investigator to your study

a "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 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.

emove I	Personnel			
Curren	t Project Personnel			
🖧 Clie	ck "Remove" belo	w to delete the choser	Investigator from the study.	
Liaison	Full Name	Role	Department	&
Univers	ity of North Carolina	a at Chapel Hill (UNC-Cl	H)	
	Hannah, Marcus	Principal Investigator	Office of Research Information Systems	Remove
	Llortmon loff	Co_investigator	Office of Research Information Systems	Remove
*	Hartman, Jen	00-investigator		

### **External Institutions**



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

>> Modified	Project I	Personnel						
External In	stitution	IS						
Action		Full Name	Ro	le	Department			
Duke Unive	ersity							
🙈 Being F	Removed	Williamson, Zion	E	<del>xternal Site Pl</del>	Basketball Ops	View	<u>Undo</u>	
>> Current F	Project P	ersonnel						
Liaison	Full Nan	ne	Role		Department			
University o	f North C	arolina at Chapel H	lill (UNC-CH)					
	Hannal	n, Marcus	Principal Inve	estigator	Office of Research Info	rmation Systems		
*	Hartma	ın, Jeff	Co-investigat	tor	Office of Research Info	rmation Systems		
	Hollowe	ell, Kelley	Study Coord	inator	Office of Research Info	rmation Systems		
External Ins	stitution	s						
Liaison	F	ull Name		Role		Department		
Duke Unive	rsity							
*	٧	Villiamson, Zion		External Site	e Pl	Basketball Ops		

### External personnel can be revised:

evise Pe	ersonnel			
Curren	t Project Personnel			
🔊 Clie	ck the "Revise" lin	k below to edit the cho	sen Investigator currently on the study.	
Liaison	Full Name	Role	Department	
Lidison	T un runne		n n	<i></i>
Univers	ity of North Carolina	n at Chapel Hill (UNC-CH	1)	
Univers	ity of North Carolina Hannah, Marcus	Principal Investigator	Office of Research Information Systems	Revise
Univers	ity of North Carolina Hannah, Marcus Hartman, Jeff	Principal Investigator Co-investigator	Office of Research Information Systems Office of Research Information Systems	Revise Revise

### **External Institutions**



# Revision is reflected in the summary.

>> Modified	d Projec	t Personnel								
External Ir	nstitutio	ons								
Action		Full Name		Role		Department				
Duke Univ	ersity									
🐉 Being	Revised	Williamson, Zion	Г	External S	Site PI	Basketball Ops		<u>View</u>	<u>Undo</u>	
>> Current	Project	Personnel								
Liaison	Full N	ame	Role		De	partment				
University	of North	Carolina at Chapel	Hill (UNC-CH	H)						
	Hann	ah, Marcus	Principal Investigator		Of	Office of Research Information Systems				
*	Hartn	nan, Jeff	Co-investigator		Of	Office of Research Information Systems				
	Hollo	well, Kelley	Study Coo	ordinator	Of	ffice of Research Info	rmation S	Systems		
External In	nstitutio	ons								
Liaison		Full Name		Ro	le		Departm	nent		
Duke Unive	ersity									
*	•	Williamson, Zion		E	ternal Site PI		Basket	ball 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
<u>316943</u>	n/a	Personnel Modification	Being Routed	n/a	n/a	n/a
<u>316873</u>	4/5/2021	Initial	Approved	n/a	4/5/2021	
Showing 1 to 2 of 2 e	ntries					
All Submissions for	IRB Number 20-1871			S	earch:	
Reference ID 💠	Date Routing Complete 💠	Submission Type 💠	Submission Status 💠	Full Board Agenda 💠	Action Date 💠	Letters
<u>316686</u>	4/1/2021	Personnel Modification	Submitted To IRB	n/a	n/a	
<u>297065</u>	6/18/2020	Initial	Exempted	n/a	2/3/2021	
All Submissions for	r IRB Number 20-1845			S	earch:	
Reference ID 💠	Date Routing Complete	Submission Type 🔷 🗘	Submission Status 💠	Full Board Agenda 💠	Action Date 💠	Letters
<u>316260</u>	11/5/2020	Personnel Modification	Acknowledged	n/a	11/5/2020	
<u>316258</u>	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.



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 Pl and/or if you want to add external personnel.

Submit a Modification Submit a Renew Submit a Renew	val	bmit a Closure
	Create a Modification	
Use the choices below to begin the process of c	reating your Modification.	
Study Only Modification	Personnel Only Modification	Full Study Modification
Modify the Study Only	Modify the Project Personnel Only	Modify Personnel and Study
Choose	Choose	Choose
Use this option t	o 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	The Application can be submitted at this time by clicking the yellow submit button located on the bottom left of
Post Approval Submissions	>> Modification Information Reference ID: 316944
Modification Information     Continuing with Modifications     General Information	To modify an approved study, edit the individual answers that make up the application. The questions belo cannot be processed until the actual changes have been made throughout the application.
Part A. Questions Common to All Studies	1. Provide a prier non-tecninical summary of any changes you will be making to the study (i.e., study application, pro and should contain the defails that you and/or your sponsor find relevant (e.g., master protocol/amendment versio IRB FOR CLARITY OR LENGTH. *
O Part B. Direct Interaction	B / U ===   x <sub>2</sub> x <sup>2</sup> ]
Part C. Existing Data, Records, Specimens	I am adding a questionnaire. I am adding NC State University as an additional external site
Part D. The Consent Process	
Ø Data Security Requirements	
Ocnsent Forms	body p  Tips and Techniques on using the HTML Editor
O Attachments	<ol> <li>Is this study in Data Analysis only (i.e. enrollment, intervention and follow-up are complete)? *</li> </ol>
O Approving Depts	<ul> <li>○ Yes ● No</li> <li>Total number of subjects enrolled to date: ★</li> </ul>
Cover Memo	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.

>> Personn	nel Modification Submis	ssion					
To Modify y	your Project Personnel	select from the fo	llowing options:				
💩 "Ado 💩 "Ado ኞ "Rev 🖧 "Rer	d Internal Personnel" to d External Personnel" to vise Personnel" to edit move Personnel" to de	o add new UNC-CH to add new Externa an Investigator cu lete an Investigato	l or Hospital Investiga al Site personnel or In rrently on the study (I r from the study	ntor to your study dependent investigator to your study IE: role, email address, phone number			
nce you a ubmitted t	are done, click "Submit to the IRB for review.	Form" to submit y	our Personnel Modifie	cations to Routing. Once the Principal	nvestigator and Faculty Ad	visor (where applicable) certify	y the Personnel Modifica
Add Inte	ternal Personnel		S Add External Perso	onnel 🔊 Revis	e Personnel	Remove Per	rsonnel
			7				
Modified	d Project Personnel						
At this time	ie, no investigators are b	eing added, revised	, or removed to/from the	e Project Personnel.			
At this time	e, no investigators are b Project Personnel	eing added, revised	, or removed to/from the	e Project Personnel.			
At this time > Current I Liaison	e, no Investigators are b Project Personnel Last Name	eing added, revised	or removed to/from the Department Nan	e Project Personnel.		Role	
At this time Current I Liaison University	e, no Investigators are b Project Personnel Last Name v of North Carolina at C	First Name	or removed to/from the Department Nan	e Project Personnel. ne		Role	
At this time > Current I Liaison University	ie, no investigators are b Project Personnel Last Name r of North Carolina at C Hannah	First Name hapel Hill (UNC-C Marcus	or removed to/from the Department Nan H) Office of Rese	e Project Personnel. ne earch Information Systems		Role Principal Investigator	view
At this time > Current I Liaison University	Project Personnel Last Name of North Carolina at C Hannah Hartman	First Name hapel Hill (UNC-C Marcus Jeff	or removed to/from the Department Nan H) Office of Rese Office of Rese	e Project Personnel.		Role Principal Investigator Co-investigator	view view
At this time > Current I Liaison University	e, no investigators are b Project Personnel Last Name of North Carolina at C Hannah Hartman Hollowell	First Name First Name hapel Hill (UNC-C Marcus Jeff Kelley	or removed to/from the Department Nan H) Office of Rese Office of Rese	e Project Personnel.		Role Principal Investigator Co-investigator Study Coordinator	view view view
At this time > Current I Liaison University External In	Project Personnel Last Name of North Carolina at C Hannah Hartman Hollowell stitutions	First Name hapel Hill (UNC-C Marcus Jeff Kelley	or removed tolfrom the Department Nan H) Office of Rese Office of Rese	e Project Personnel.		Role Principal Investigator Co-investigator Study Coordinator	view view view
At this time > Current I Liaison University xternal In Liaison	Project Personnel Last Name of North Carolina at C Hannah Hartman Hollowell astitutions Last Name	First Name hapel Hill (UNC-C Marcus Jeff Kelley	or removed tolfrom the Department Nan H) Office of Rese Office of Rese First Name	e Project Personnel. ne earch Information Systems earch Information Systems arch Information Systems arch Information Systems	Role	Role Principal Investigator Co-investigator Study Coordinator	view view view
At this time Current I Liaison University External In Liaison Duke Unive	Project Personnel Last Name of North Carolina at C Hannah Hartman Hollowell tstitutions Last Name versity	First Name First Name hapel Hill (UNC-C Marcus Jeff Kelley	Department Nam Department Nam H) Office of Rese Office of Rese Office of Rese First Name	e Project Personnel. ne earch Information Systems earch Information Systems arch Information Systems Department Name	Role	Role Principal Investigator Co-investigator Study Coordinator	<u>view</u> view 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 (f

#### Add External Personnel

Last Name 🗙	Krzyzewski
First Name \star	Mike
Address	
Phone *	919-444-7777
Email 🗙	mike@dukebball.edu
Department Name	Basketball Ops
External Institution \star 🔍	Duke University
	Click here to make this an Independent Investigator. (more information)
Role *	
O Co-investigator	
<ul> <li>Study Coordinator</li> </ul>	
Research Assistant	
O Regulatory Associate	
O External Site PI	
O Other	
If other, please describe	
Should this person be incl roles for Independent Inve O Yes O No	uded on IRB correspondence? (PI, Faculty Advisor, Co-Investigators, External Site PI roles and all stigators will always receive)
Save Cancel	

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.

Auu External Personn	
Last Name \star	Keats
First Name \star	Kevin
Address	
Phone 🗙	919-333-2222
Email 🗙	kkeats@ncsubball.edu
Department Name	Basketball Admin
External Institution <b>*</b> 🔍	North Carolina State University (NCSU)
Role *         O Co-investigator         O Study Coordinator         O Research Assistant         O Regulatory Associate         ● External Site PI         O Other	
If other, please describe Should this person be inc roles for Independent Inve Yes O No Save Cancel	luded on IRB correspondence? (PI, Faculty Advisor, Co-Investigators, External Site PI roles and all estigators will always receive)

### **External Personnel**

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

	>> Modified Project Personnel							
	External Instituti	ons						
	Action	Full Name	Role	Department				
	Duke University							
_	📇 Being Added	Krzyzewski, Mike	Research Assistant	Basketball Ops	View	<u>Undo</u>		
1	North Carolina S	tate University (NCSU)						
	📇 Being Added	Keats, Kevin	External Site PI	Basketball Admin	View	<u>Undo</u>		

Liaison	Last Name	First Name	Department Name		Role	
University of	of North Carolina at C	hapel Hill (UNC-Cl	H)			
	Hannah	Marcus	Office of Research I	nformation Systems	Principal Investigator	<u>view</u>
*	Hartman	Hartman Jeff		nformation Systems	Co-investigator	view
	Hollowell	Kelley	Office of Research I	nformation Systems	Study Coordinator	view
External Ins	stitutions					
Liaison	Last Name		First Name	Department Name	Role	
Duke Unive	ersity					

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				
<u>316193</u>	12/3/2020	3 Modification	Submitted To IRB	n/a	n/a					
<u>316194</u>	12/3/2020	Rersonnel Modification	Submitted To IRB	n/a	n/a					
<u>295907</u>	6/15/2020	Modification	Approved	n/a	6/15/2020					
<u>278586</u>	3/24/2020	Initial	Approved	n/a	6/15/2020					

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 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.

# **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.

### SLUUY TILLE, WIZARD RESIDE JOINTAL Item List click on section name to expand Renewal Action Requested Reference ID: 316947 Post Approval Submissions Renewal Action Requested ALERT: Modifications proposed as part of this renewal must be accomplished by editing the individual answer Progress Report application. Continuing with Renewals 1. Renewal action requested by Principal Investigator (choose only one): \* General Information Study has always involved only analysis of data or specimens; there has never been any direct interaction or contact A) Continue study as approved. 2. Project Personnel Study involves (or involved) direct interaction/intervention/contact with subjects: B) Continue study as approved, including enrollment of new subjects. Attachments 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 research-related intervention and the related intervention and the related intervention and the related intervention and the re records or registry (as described in the approved protocol). In person contacts may include visits being conducted as Approving Depts 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 🕝 Cover Memo

I will be making changes to the project personnel. Choose

Item List click on section name to expand

### >> Continuing with Renewals Reference ID: 328005

- A Post Approval Submissions
- Renewal Action Requested
- Progress Report
- <u>Continuing with Renewals</u>
- General Information
- Consent Forms
- Attachments
- Approving Depts
- 🕑 Cover Memo



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.

Item List click on section name to expand

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

#### 🕑 Cover Memo

>> Renewal Action Requested Reference ID: 316948

#### ALERT: Modifications proposed as part of this renews application.

1. Renewal action requested by Principal Investigator (cho

### Study has always involved only analysis of data or s

A) Continue study as approved.
 Study involves (or involved) direct interaction/intervel
 B) Continue study as approved, including enrollr
 C) Enrollment of new subjects closed; research D) Enrollment of new subjects closed; subjects h records or registry (as described in the approved proceded)

E) All research-related interaction/intervention ar 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
- A Renewal Action Requested
- Progress Report
- A 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
- Oata Security Requirements
- Attachments
- Approving Depts
- Cover Memo
  - Home Application Status Proceed to Submit

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

sponsor find relevant (e.g., master protocol/amendment version number and date). Typical summaries are 50

Please provide the description below: \*

>> Continuing with Renewals Reference ID: 316948

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B	ι U	abe	X2	X <sup>2</sup>	)= I	- 14	· 特許	=	=	3	=								
Tips	s and	<u>Techni</u>	ques o	on usir	<u>ig the</u>	HTML	Editor											9	
. Is th	nis stu	dy in [	Data Ar	nalysis	s only	(i.e. en	rolime	nt, inte	erven	tion :	and	ollow	-up a	re co	mple	te)?	*		
) Yes	nis stu s i	idy in [ No iber of	)ata Ar subjec	nalysis ots act	s only tively p	(i.e. en particip	rollme ating (	nt, inte i.e., To	erven Ital n	tion a	and er of	ollow	-up a cts ir	re co ivolv	ed in	the i	*	entic	nal
) Yes	nis stu s	No No	Data Ar	nalysis ots act	s only	(i.e. en Darticip	rollme	nt, inte i.e., To	erven otal no	tion : umbe	and er of	ollow	-up a cts ir	re co ivolv	ed in	the i	* intervi	entio	nal
. Is th ) Yes . Tota . ter '0 . Hav is ma	nis stu s al num l'): * re the r ay inclu s	No No Iber of risks a Ide nev	Subjects subjects s desc	nalysis ots act ribed i not pre	in A.6.	(i.e. en particip , conse y listed,	rollme eating ( ent form chang	nt, inte i.e., To m, or a es in fr	erven tal no ny ot	tion : umbe ther s	and er of study f kno	subje docu wn ris	-up a cts ir imen ks, or	re co ivolv t cha	ed in nged	the i	* interv	entio / liste	inal ed ris
. Is th ) Yes o. Tota ter '0 . Hav is ma ) Yes	nis stu s () al num l'): * re the i ay inclu s () you ha	No No nber of risks a noe nev No ave pla	Data Ar subject s desc v risks i	nalysis ots act ribed i not pre	s only tively p in A.6. eviously sent s	(i.e. en particip , conse y listed, ubjects	rollme eating ( ent forr chang	nt, inte i.e., To n, or a es in fr	erven otal no ny ot eque	tion : umbe ther s ncy o	and er of study dific	ollow subje docu wn ris	-up a cts ir imen ks, or	t cha	ed in nged	the i	* interv	entio y liste	onal i
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. Is th ) Ye: . Tota . Tota	nis stu s al num P): * e the n ay inclu s you ha s ais mo	No No nber of risks a risks a	Data Ar subject s desc v risks i ns to r	ribed i not pre- re-con	s only tively p in A.6. eviously sent s	(i.e. en particip , conse y listed, ubjects	ent for chang	ei (	ent, inte (i.e., To m, or a ges in fr result o	ent, interven (i.e., Total m m, or any ot ges in frequen result of this	(i.e., Total number (i.e., Total number m, or any other s ges in frequency o result of this mo	ent, intervention and f (i.e., Total number of 	ent, intervention and follow (i.e., Total number of subje m, or any other study docu ges in frequency of known ris result of this modification?	ent, intervention and follow-up a (i.e., Total number of subjects in m, or any other study documen ges in frequency of known risks, or result of this modification? *	ent, intervention and follow-up are co (i.e., Total number of subjects involv m, or any other study document cha ges in frequency of known risks, or rem result of this modification? *	ent, intervention and follow-up are comple (i.e., Total number of subjects involved in m, or any other study document changed ges in frequency of known risks, or removal of result of this modification? * is to New Safety Information? *	ent, intervention and follow-up are complete)? (i.e., Total number of subjects involved in the i m, or any other study document changed? ges in frequency of known risks, or removal of pre result of this modification? * is to New Safety Information? *	ent, intervention and follow-up are complete)? * (i.e., Total number of subjects involved in the intervention of the study document changed? ges in frequency of known risks, or removal of previously result of this modification? * e to New Safety Information? *	ent, intervention and follow-up are complete)? * (i.e., Total number of subjects involved in the interventio

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 fo	r IRB Number 18-3410			Se	earch:	
Reference ID 💠	Date Routing Complete 💠	Submission Type 🛛 💠	Submission Status 💠	Full Board Agenda 💠	Action Date 💠	Letters
<u>316455</u>	12/15/2020	Renewal (w/ Modification)	Approved	n/a	12/21/2020	
<u>316456</u>	12/15/2020	Rersonnel Modification	Acknowledged	n/a	12/21/2020	
<u>297194</u>	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

