External Research Personnel and Institutions

IRBIS has been updated to better classify research personnel external to UNC. This will impact a number of different scenarios. Examples include:

- studies where external staff are assisting with UNC research (reliance agreements)
- staff that were previously active at UNC, but have since moved to another institution and are still participating in the research in some capacity – either with their new institution or as an Independent Investigator

(i)	If your IRB applications include only research personnel from UNC Chapel Hill or UNC
U	Network and Affiliates, no change will be needed.

UNC and its Affiliates are listed at the first table, followed by a second table noting External Institutions. Example:

Last Name	First Name	Department Name	Role			
University of North Ca	rolina at Chapel Hill (UN	C-CH)				
Cowan	Laura	Office of Human Research Ethics	Principal Investigator	<u>edit</u>	remove	
Maye	Luke	Athletics Basketball Office	Co-investigator	<u>edit</u>	<u>remove</u>	
High Point Regional						
Williams	Alicia	UNC Hospitals - HighPoint	Research Assistant	<u>edit</u>	remove	
Clark	Anita	UNC Hospitals - HighPoint	Research Assistant	<u>edit</u>	<u>remove</u>	
External Institutions						
Last Name	First Name	Department Name	Role			
Davidson College						
Curry	Steph		External Site PI	<u>edit</u>	remove	
Curry	Seth		Research Assistant	edit	<u>remove</u>	
Duke University						
К	Coach	Basketball Ops	External Site PI	<u>edit</u>	remove	
Laettner	Christian		Co-investigator	<u>edit</u>	<u>remove</u>	
North Carolina State U	Iniversity (NCSU)					
Whittenburg	Dereck		External Site PI	<u>edit</u>	remove	
Tucker	PJ		Regulatory Associate	<u>edit</u>	<u>remove</u>	
Smith	Dennis		Regulatory Associate	<u>edit</u>	remove	
Wake Forest Universit	y					
Paul	Christopher		External Site PI	<u>edit</u>	<u>remove</u>	
Duncan	Timothy	Basketball Operations	Study Coordinator	<u>edit</u>	remove	
Independent Investigat	tors					
James	Lebron		Research Assistant	<u>edit</u>	remove	
Thomspon	Klay		Regulatory Associate	<u>edit</u>	remove	

Initial Applications - link research personnel to institution (UNC + External + Independent)

When completing an IRB initial application, each person listed on your IRB application is required to be linked to an institution or identified as an <u>Independent Investigator</u>.

From the General Information section > 2. Project Personnel page, click O <u>Click here to add personnel</u>

Next, click A next to the Last Name field. This will open the Personnel Search window. If the person you are adding to your project is associated with UNC or their affiliates, you must locate them using this search. They will automatically be associated with the UNC entity they are assigned to. If the person you are adding is not actively affiliated with UNC, click <u>NON UNC-CH Personnel</u> at the bottom of the screen. In this External Personnel Listing form, please enter the required information. In the External Institution field, click to search for the appropriate institution for the external personnel. Please use the search to select the appropriate external institution from the list.

Adding additional staff – quick list of relevant institutions

Once you have added a research team member from an external institution, the list of institutions will pre-populate at the top of the search screen to save you from searching again.



Adding new institutions – with caution

In the event you are unable to find the appropriate external institutions on the list, there is an option to click <u>External Institution Not Listed</u> at the bottom of the screen. Please use caution when exercising this option as it is subject to additional review.



Adding Independent Investigators – not affiliated with an institution

In the event that a research team member is participating in the research study in an unaffiliated capacity (not affiliated with an External Institution), you can check the box, Click here to make this an <u>Independent Investigator</u>. This will populate the External Institution to be displayed as 'Independent Investigators'.

Personnel Listing (fill out	the form below)
Last Name *	
First Name	
Address	
Phone *	
Email *	
Department Name	
External Institution * 🔍	
	Click here to make this an Independent Investigator.
ATTENTION: The depa for approval. If the dep	rtment named above for the PI or Faculty Advisor will receive this submission partment above DOES NOT represent the primary academic (faculty and

These researchers are grouped at the bottom of the External Institutions table:

External Institutions					
Last Name	First Name	Department Name	Role		
Davidson College					
Curry	Steph		External Site PI	<u>edit</u>	remove
Curry	Seth		Research Assistant	<u>edit</u>	remove
Duke University					
К	Coach	Basketball Ops	External Site PI	<u>edit</u>	remove
Laettner	Christian		Co-investigator	<u>edit</u>	remove
North Carolina State University	sity (NCSU)				
Whittenburg	Dereck		External Site PI	edit	remove
Tucker	PJ		Regulatory Associate	<u>edit</u>	remove
Smith	Dennis		Regulatory Associate	<u>edit</u>	remove
Wake Forest University					
Paul	Christopher		External Site PI	<u>edit</u>	remove
Duncan	Timothy	Basketball Operations	Study Coordinator	edit	remove
Independent Investigators					
James	Lebron		Research Assistant	edit	remove
Thomspon	Klay		Regulatory Associate	<u>edit</u>	remove

Post-Approval Submissions – link existing unaffiliated personnel to institution (UNC + External + Independent)

For existing IRB applications, IRB applications are required to link all unaffiliated personnel in order to submit a post-approval submission for review. All personnel required to be categorized are listed under Undefined External Institution(s):

Camarena	Paul	Medicine-Infectious Diseases	ledicine-Infectious Diseases Other			<u>remove</u>
Roos	Alexandra	Medicine-Infectious Diseases	istant	edit	remove	
Houghton	Odette	Ophthalmology - Carolina Crossing	Other		<u>edit</u>	remove
External Institut	ions					
Last Name	First Name	Department Name	Role			
Undefined Extern	al Institution(s)					
Hatcher	Jeffrey		Co-investigator	<u>edit</u>	remo	ve
Van Dam	Cornelius		Co-investigator	<u>edit</u>	remo	ve
Epperson	Kim		Study Coordinator	edit	remo	ve
Comer	Robert		Co-investigator	edit	remo	ve

In order to proceed with your submission, you will need to click edit for each, click External Institution * or assign them to be an Independent Investigator.

Once you save the affiliation, they will be moved to the appropriate external institutional grouping, and that external institution will appear on the pre-populated quick list to save you the effort of searching again if additional researchers on the list are associated with that same external institution.

External Institutions						
Last Name	First Name	Department Name	Role			
Undefined External Institution(s)						
Van Dam	Cornelius		Co-investigator	edit	<u>remove</u>	
Epperson	Kim		Study Coordinator	<u>edit</u>	remove	
Comer	Robert		Co-investigator	edit	<u>remove</u>	
Cone Health System						
Hatcher	Jeffrey		Co-investigator	<u>edit</u>	<u>remove</u>	

If you encounter a situation where a researcher is listed under the Undefined External Institutions grouping, but they have an active UNC affiliation, they have been added previously without using the UNC Personnel Search lookup directory.



In order to fix this, these personnel should be removed from the IRB application and added back on using the UNC Personnel Search lookup directory. If assistance is needed, please contact IRBIS@unc.edu.

New Research Personnel Role: External Site PI

In order to better categorize research personnel at External Institutions, a new role of External Site PI is now available.

Role *
O Co-investigator
Faculty Advisor
Project Manager or Study Coordinator
Research Assistant
Regulatory Associate
C External Site PI
Other (Read Only Access)
If other, please describe

One External Site PI is able to be assigned for each External Institution participating in the research study.

External Institutions					
Last Name	First Name	Department Name	Role		
Davidson College					
Curry	Steph		External Site PI	edit	remove
Curry	Seth		Research Assistant	edit	<u>remove</u>
Duke University					
К	Coach	Basketball Ops	External Site PI	edit	remove
Laettner	Christian		Co-investigator	<u>edit</u>	remove
North Carolina State Unive	ersity (NCSU)				
Whittenburg	Dereck		External Site PI	edit	remove
Tucker	PJ		Regulatory Associate	edit	remove
Smith	Dennis		Regulatory Associate	<u>edit</u>	remove
Wake Forest University					
Paul	Christopher		External Site PI	edit	remove
Duncan	Timothy	Basketball Operations	Study Coordinator	edit	remove
Independent Investigators					
James	Lebron		Research Assistant	edit	remove
Thomspon	Klay		Regulatory Associate	<u>edit</u>	remove

Updated view for training and institutions

In addition to the changes to the Project Personnel section, the Personnel tab on the Application status screen has also been updated to better reflect the reorganized personnel list:

Full Name	Role	Deptartment Name	IRB Training	COI WebID	COI Number	Initial COI Disclcosure	Potential Conflict	COI Review Process	COI Review Resu
University of	North Carolina at C	hapel Hill (UNC-CH)							
uke Maye	Co-investigator	Athletics Basketball Office	×	196761	17-08512	×		Unsubmitted	
aura Cowan	Principal Investigator	Office of Human Research Ethics	×	196760	17-08511	×		Unsubmitted	
High Point Re	egional UNC Health	Care							
licia Williams	Research Assistant	UNC Hospitals - HighPoint	×			Responsibility of affiliate site (ch	neck Attachments for a cu	rrent COI Validation Form)	
nita Clark	Research Assistant	UNC Hospitals - HighPoint	×			Responsibility of affiliate site (ch	neck Attachments for a cu	rrent COI Validation Form)	
External Institu	tions								
Davidson Co	llege	1							
teph Curry	External Site PI		×	196764	17-08515	×		Unsubmitted	
eth Curry	Research Assistant		×		n/a	n/a	n/a		n/a
Duke Univers	sity								
hristian Laettner	Co-investigator		×	196766	17-08517	×		Unsubmitted	
oach K	External Site PI	Basketball Ops	×	196763	17-08514	×		Unsubmitted	
North Carolin	a State University (NCSU)							
ereck Whittenburg	External Site PI		×	196765	17-08516	×		Unsubmitted	
J Tucker	Regulatory Associate		×		n/a	n/a	n/a		n/a
ennis Smith	Regulatory Associate		×		n/a	n/a	n/a		n/a
Wake Forest	University								
hristopher Paul	External Site PI		×	196762	17-08513	×		Unsubmitted	
mothy Duncan	Study Coordinator	Basketball Operations	×	196767	17-08518	×		Unsubmitted	
Independent	Investigators								
lay Thomspon	Regulatory Associate		×		n/a	n/a	n/a		n/a
-	D. I.A. St. J.		¥		pla	- 1-	- 1-		a la

Updated IRB Correspondence and COI Requirements

IRB Correspondence is required to be sent to the following roles:

- PI, Faculty Advisor and Co-Investigators, External Site PI, and all <u>Independent Investigators</u>. The messages will be delivered regardless of the answer in the yes/no question below.
- All other research personnel can select whether or not IRB correspondence is needed at the bottom of the edit pop-up for each research team member.

Should this person be included on IRB correspondence? (PI, Faculty Advisor and Co-Investigators will always
receive)
🔍 Yes 🔍 No

These changes will allow us to make additional refinements to the IRBIS system as we move forward.

(i)	If yo
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you have any questions or concerns. Please contact IRBIS@unc.edu