

IRBIS changes, effective 5:00 PM, January 4, 2018

**IRBIS 5.09.03 Update:**

New sIRB tab for Researchers to view multisite related documents:

The screenshot shows the IRBIS application interface. On the left is a navigation menu with items like 'Scientific Review', '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', and 'Cover Memo'. At the bottom of the menu are 'Home' and 'Application Status' buttons. The main content area has a top navigation bar with tabs: 'Routing', 'Routing Comments', 'Status History', 'Submitted Documents', 'Addenda', 'Personnel', and 'sIRB'. The 'sIRB' tab is highlighted with a red box. Below the tabs is a table of external institutions and their personnel. The table has columns for 'External Institution', 'Has or will the external institution agree to rely on the UNC-Chapel Hill IRB?', 'Local Consent Forms', 'Local Context Worksheet', and 'Agreement'. A yellow triangle icon is present next to the 'External Institution' column for each institution. Below the main table is a section for 'Independent Investigators' with columns for 'Personnel', 'Role', 'Ethics', 'CV', 'MD License', 'Confirmation form', and 'Agreement'.

External Institution	Has or will the external institution agree to rely on the UNC-Chapel Hill IRB?	Local Consent Forms	Local Context Worksheet	Agreement		
Children's Hospital of Philadelphia (CHOP)	No	✗	✗	✗		
<b>Personnel</b>	<b>Role</b>	<b>Ethics</b>	<b>CV</b>	<b>MD License</b>		
Peyton Manning	Co-investigator	✗	✗	✗		
Ohio State University	Yes	📄	✗	✗		
<b>Personnel</b>	<b>Role</b>	<b>Ethics</b>	<b>CV</b>	<b>MD License</b>		
Braxton Miller	External Site PI	✗	✗	✗		
John Wayne	External Site PI	✗	✗	✗		
University of California	Yes	✗	✗	✗		
<b>Personnel</b>	<b>Role</b>	<b>Ethics</b>	<b>CV</b>	<b>MD License</b>		
Jared Goff	Study Coordinator	✗	✗	✗		
Aaron Rodgers	External Site PI	✗	✗	✗		
University of Florida	No	✗	✗	✗		
<b>Personnel</b>	<b>Role</b>	<b>Ethics</b>	<b>CV</b>	<b>MD License</b>		
Timothy Tebow	External Site PI	✗	✗	✗		
University of Mississippi	Yes	✗	✗	✗		
<b>Personnel</b>	<b>Role</b>	<b>Ethics</b>	<b>CV</b>	<b>MD License</b>		
Michael Oher	Other	✗	✗	✗		
<b>Independent Investigators</b>						
<b>Personnel</b>	<b>Role</b>	<b>Ethics</b>	<b>CV</b>	<b>MD License</b>	<b>Confirmation form</b>	<b>Agreement</b>
Steve Austin	Research Assistant	✗	✗	✗	✗	✗
Kevin Hart	Co-investigator	✗	✗	✗	✗	✗
Bon Jovi	Research Assistant	✗	✗	✗	✗	✗

By clicking on the icon, Researchers will be able to view the current approval status of the site, as well as the history if changes have been made. Please note the yellow triangle indicating that the sites have not yet been approved.

New read-only Researcher view of the Personnel tab:

The screenshot displays a web interface for managing research submissions. On the left is a navigation menu with sections like 'Exemptions', 'Scientific Review', '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', and 'Cover Memo'. At the bottom of the menu are 'Home' and 'Application Status' buttons. The main content area is titled 'Training and Conflict of Interest entered for this Submission' and contains a table with the following data:

Full Name	Role	Department Name	IRB Training	GCP	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
- University of North Carolina at Chapel Hill (UNC-CH)										
Marcus Hannah	Principal Investigator	Office of Research Information Systems	✗	✗	237840	17-49440	✗		Unsubmitted	
Kelley Hollowell	Co-investigator	Office of Research Information Systems	✗	✗	237839	17-49439	✗		Unsubmitted	
Laura Cowan	Other	Office of Human Research Ethics	✓	✓	n/a	n/a				n/a
John Slattery	Other	Office of Research Information Systems	✗	✗	n/a	n/a				n/a
John Stephenson	Other	Office of Research Information Systems	✓	✗	n/a	n/a				n/a
- UNC REX Healthcare										
Caitlin Hollowell	Co-investigator	UNC Hospitals - Rex	✗	✗	Responsibility of affiliate site (check Attachments for a current COI Validation Form)					
External Institutions										
External Institution					COI Policy			Assurance Letter	Management Plan	
- Children's Hospital of Philadelphia (CHOP)					Policy Undetermined			✗	✗	
Full Name	Role	Department Name	IRB Training	GCP	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
Peyton Manning	Co-investigator	QB	✗	✗	Policy Undetermined					
External Institution					COI Policy			Assurance Letter	Management Plan	
- Ohio State University					Policy Undetermined			✗	✗	
Full Name	Role	Department Name	IRB Training	GCP	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
Braxton Miller	External Site PI	Quarterback	✗	✗	Policy Undetermined					
John Wayne	External Site PI		✗	✗	Policy Undetermined					

This revised view includes the CITI Good Clinical Practice (GCP) status as well as the COI policy for external sites.

If Researchers manually enter an external site name (rather than using the lookup), a hard stop for the submission until the data is validated.

External Site COI Policy:

- Undetermined (default)
- TBD
- UNC Policy
- Site Policy

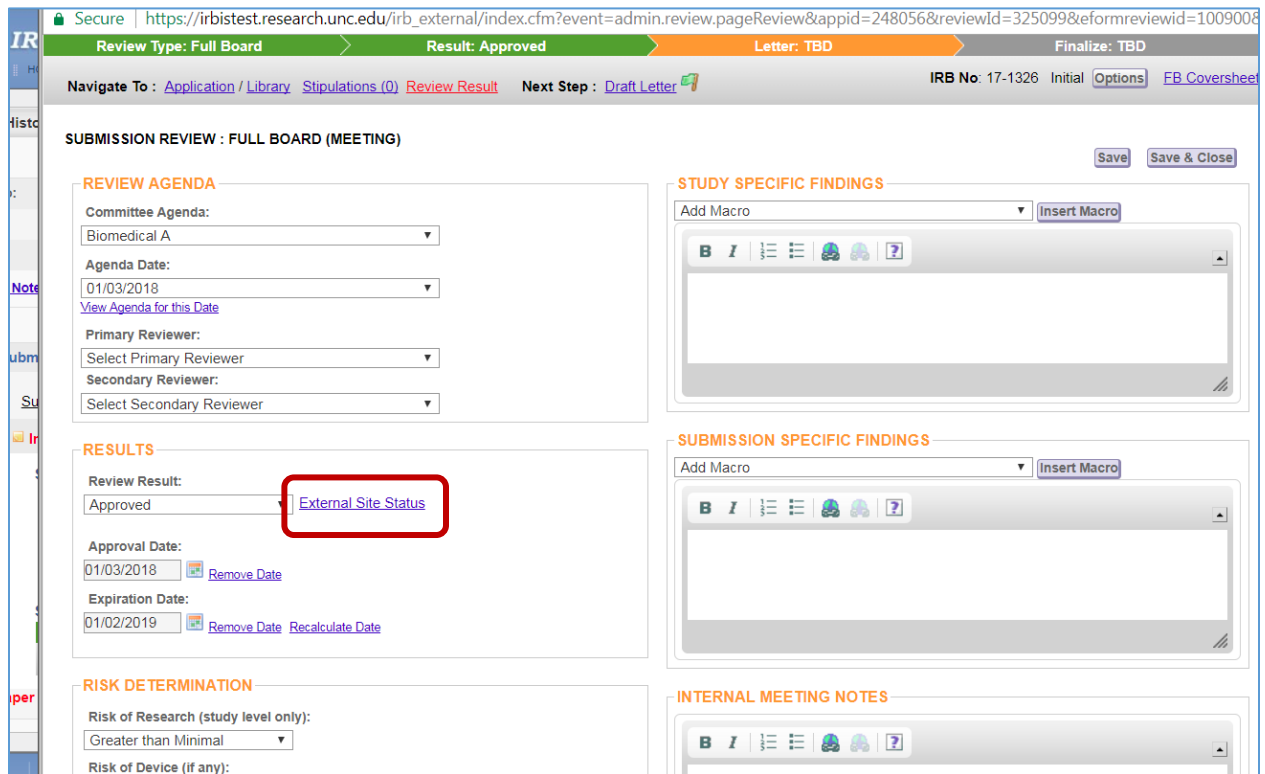
Once changed from Undetermined, it is not possible to return. The Policy must be set by someone with a new role "IRB COI Policy Manager". Until the policy is set, the submission is not able to be finalized. John Roberts will be responsible for setting this policy for the time being.

If the external site elects to use UNC's COI Policy, UNC COIs will be automatically triggered via AIR and the existing COI hardstop will be applicable.

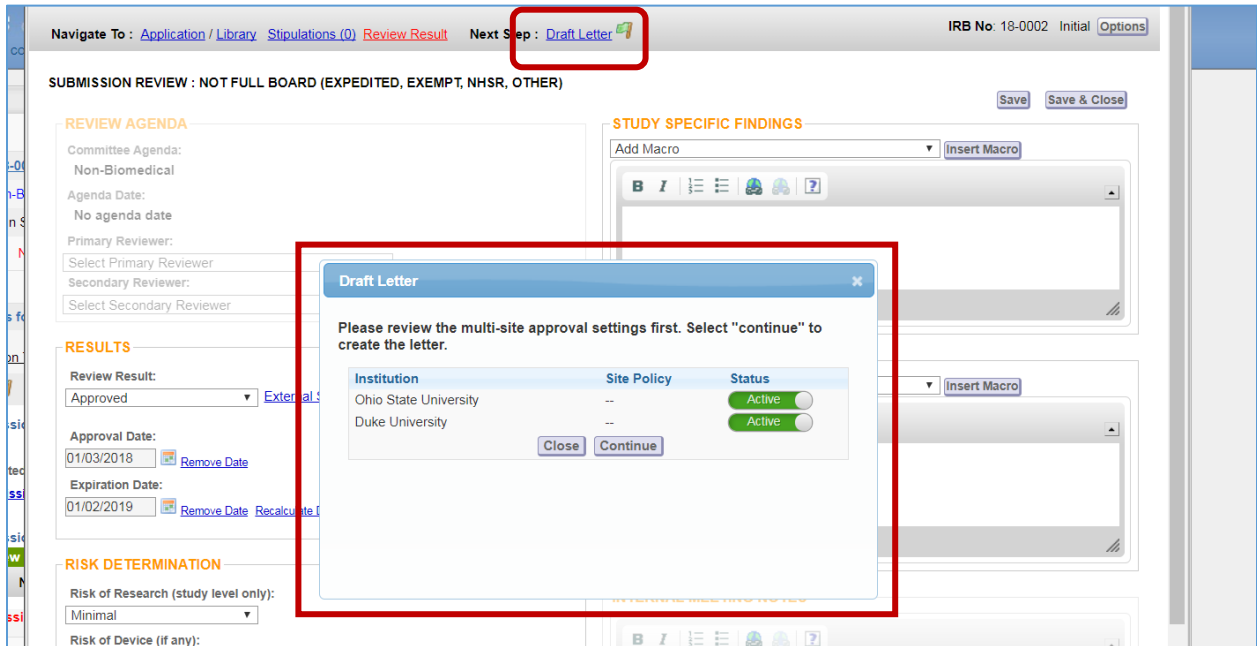
IRBIS will now auto generate COIs for all internal staff added during a modification submission (UNC, Rex, other Affiliates), per existing UNC policies.

Please note: During the transition, a COI override may be required for certain scenarios. For example: Co-Is (non faculty) who had for one reason or another missed having a COI manually triggered. Please contact [IRBIS@unc.edu](mailto:IRBIS@unc.edu) if you believe your submission is eligible for a modification related COI override. The COI office is aware that this may be the case for a temporary amount of time.

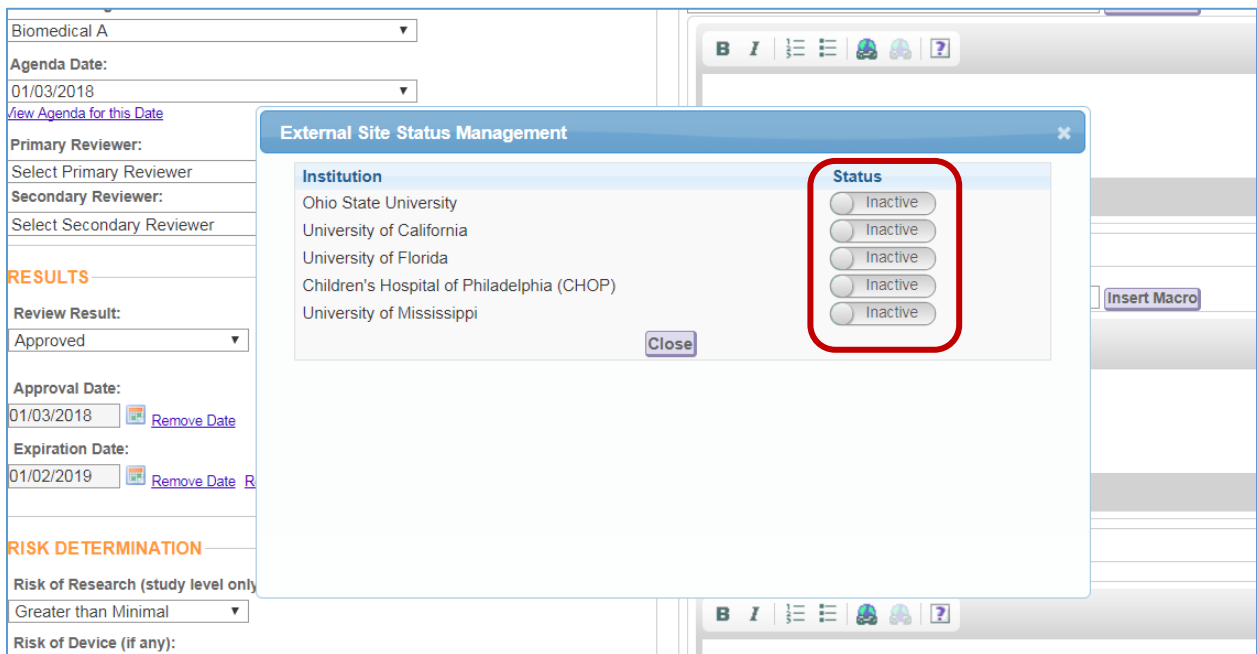
The Review Results screen has been updated so that when a submission is set to 'Approved' and External Site Status link appears:



You will be required to review and confirm this screen after entering the review results and clicking Draft Letter:



Sites will be marked as Inactive by default:



When a site is activated, you should indicate this via the toggle:

**External Site Status Management**

Institution	Status
Ohio State University	Active
University of California	Active
University of Florida	Active
Children's Hospital of Philadelphia (CHOP)	Active
University of Mississippi	Active

When active, the sites are automatically included in the approval letter template:

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.

IRB Authorization Agreements have been executed for the UNC IRB to provide IRB review and continuing oversight for human subjects research performed for this study at the organizations identified below:

- Ohio State University
- University of California
- University of Florida
- Children's Hospital of Philadelphia (CHOP)
- University of Mississippi

A participating organization not included on this list may not proceed with human subjects research for this study until the UNC IRB approval for the organization is granted. Please note that approval for additional participating organizations requires a modification to the study.

CC:  
Steve Austin  
Kevin Hart  
Kelley Hollowell, Office of Research Information Systems

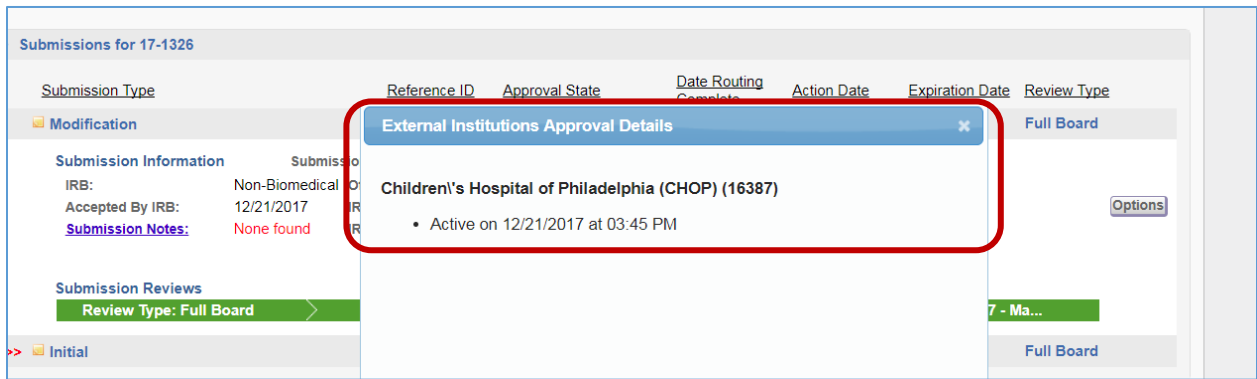
Once approved, please note the green circle icon indicating that each of these external sites have now been approved:

Notes: None found

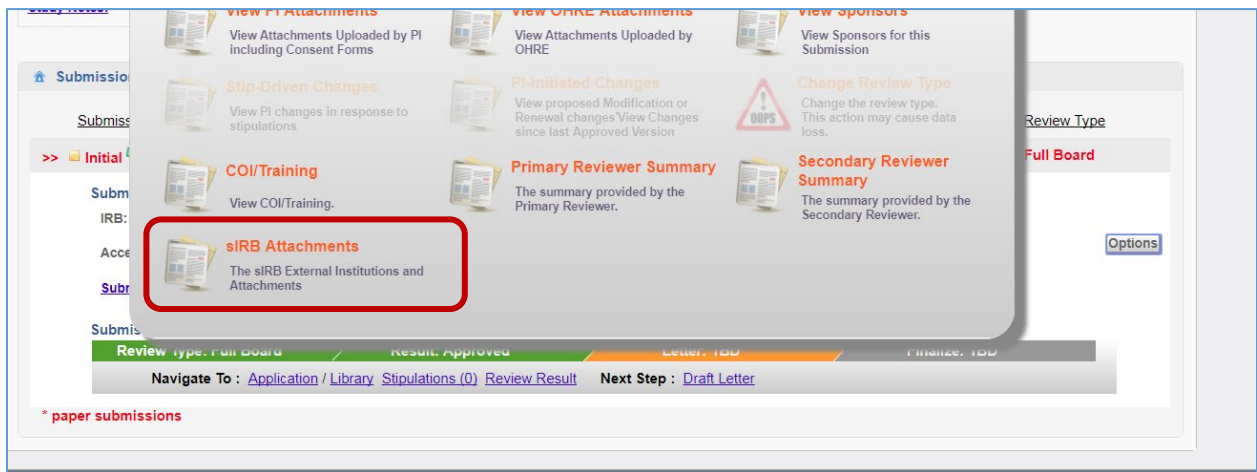
**View sIRB External Institutions and Attachments**

External Institution	Has or will the external institution agree to rely on the UNC-Chapel Hill IRB?	Local Consent Forms	Local Context Worksheet	Agreement
<input checked="" type="checkbox"/> Children's Hospital of Philadelphia (CHOP)	No	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<b>Personnel</b>	<b>Role</b>	<b>Ethics</b>	<b>CV</b>	<b>MD License</b>
Peyton Manning	Co-investigator	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> Ohio State University	Yes	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<b>Personnel</b>	<b>Role</b>	<b>Ethics</b>	<b>CV</b>	<b>MD License</b>
Braxton Miller	External Site PI	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
John Wayne	External Site PI	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

By clicking on the icon, you can see the history of that sites status:



Under the Options tab, a new sIRB Attachments tab is now available:



Here, Admin users will be able to download copies of sIRB related Attachments, regardless of submission status (e.g. if Barbara or John need to upload a revised copy of the Local Context Worksheet or Agreement). Here you will also be able to easily see the status of the external sites.

Any other changes should be done by the Researcher during a normal modification submission.

Researchers new to the application on the current submission are now flagged for special attention:

External Institution				COI Policy				Assurance Letter	Management Plan	
- University of Mississippi				Policy TBD (edit)				+	+	
Full Name	Role	Department Name	IRB Training	GCP	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
Eli Manning	External Site PI		✗	✗				Policy TBD		
Michael Oher	Other	Offensive Tackle	✗	✗				Policy TBD		