Linking OnCore Data to IRBIS

Introduction: We have recently completed Phase 1 of creating communication between OnCore and IRBIS. This exciting change also allows for UNC-IRB actions to be pushed into OnCore for *non-oncology* studies. The following instructions outline functionality currently deployed.

There are two options that users can use to link data:

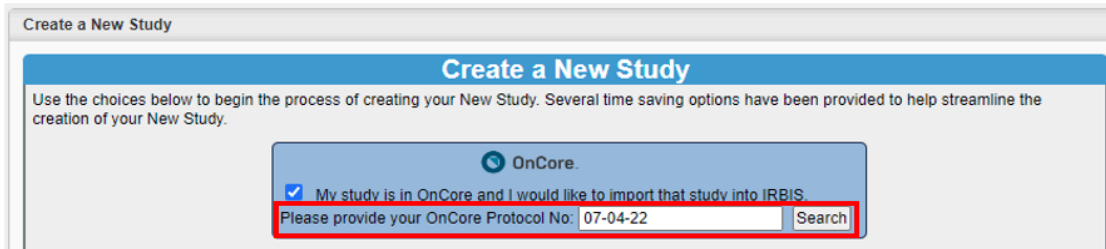| Option 1	Option 2
Import protocol information into IRBIS	Manually link data from IRBIS to OnCore via the My OnCore button in IRBIS
With this option, the title of the study, objectives, and staff list can be imported into IRBIS. This can be used for studies that have a protocol shell newly created in OnCore, and do not have a submission record recorded in IRBIS yet.	This option can be used to link studies already existing in both OnCore and IRBIS, meaning that a protocol shell exists in OnCore, and an IRBIS number has been assigned.

After either option is utilized for non-oncology studies, the completed UNC-IRB action will be pushed into in the Reviews tab of the PC Console in OnCore (see page six for further details).

Option 1: Import Protocol Information into IRBIS

1. Log in to IRBIS
2. Select the **New Study** link and check the box in the OnCore area:
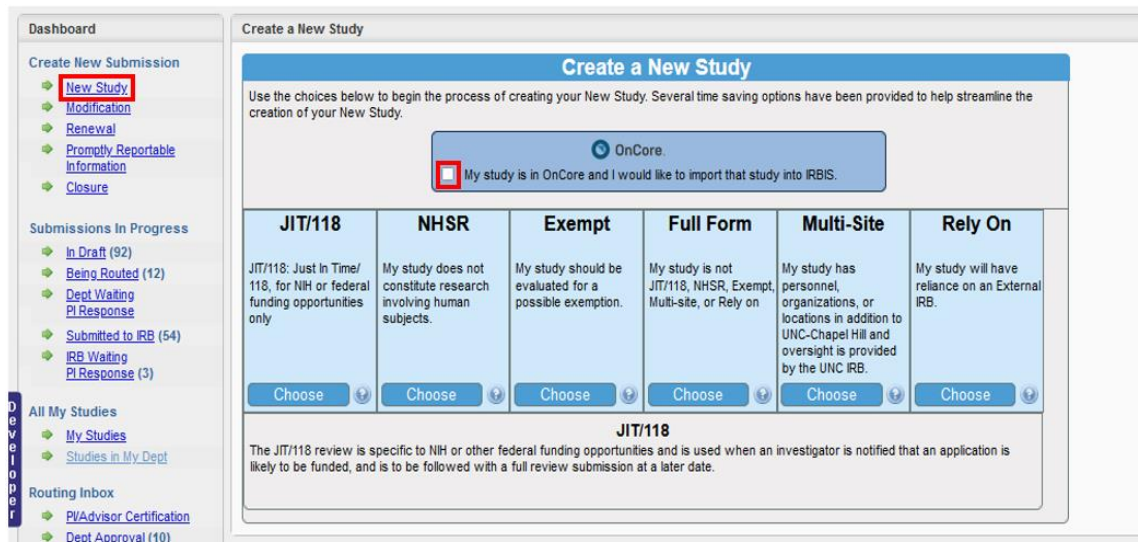
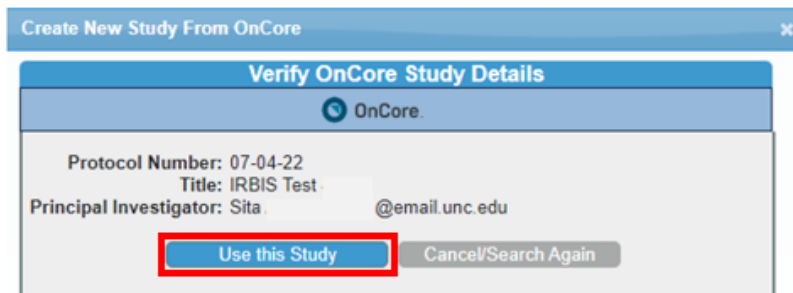3. Type the protocol number in the box that appears and select the **Search** button:

4. A pop-up window will appear with a preview of the study's protocol number, title, and name of the PI. Confirm this information is correct. Select the **Use this Study** button:
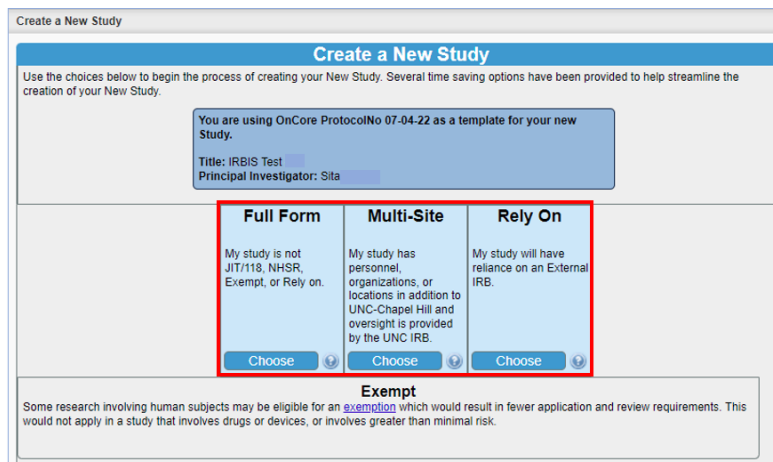

5. The next screen will feature three options. Select the **Choose** button for the appropriate option:

6. The study is created in IRBIS. The title and objectives as entered in OnCore will automatically populate in the IRBIS forms:
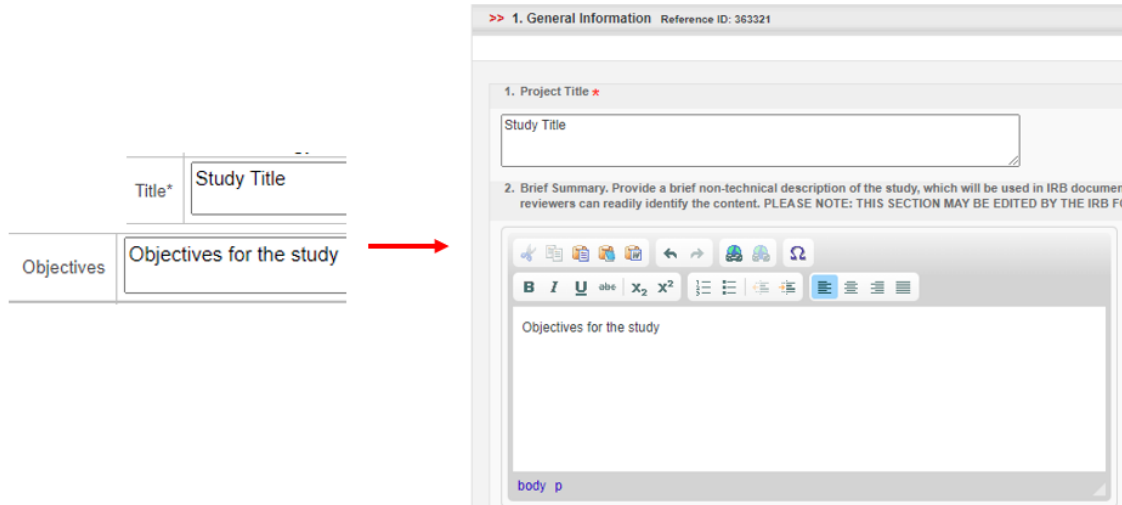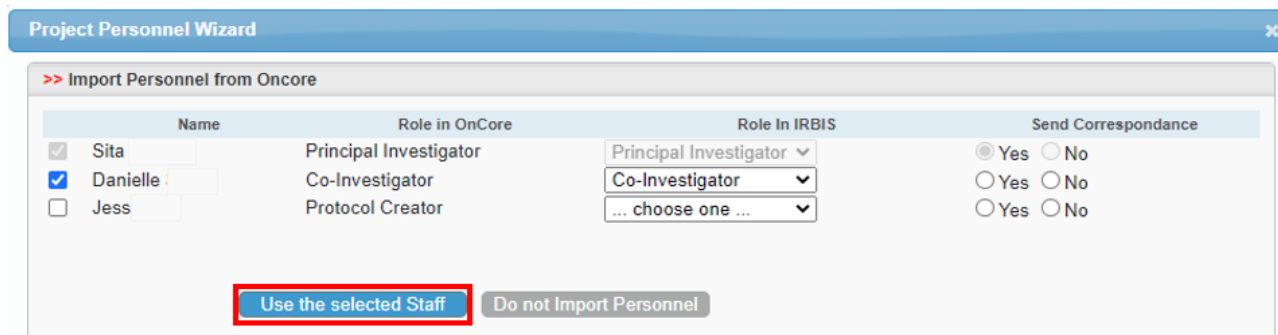

7. Select the **Save and Continue** button at the bottom of the page to advance to the Project Personnel page:

8. Upon advancing to the Project Personnel page, the Project Personnel Wizard pop-up window will appear. Select the appropriate staff members and update their roles as needed. Select the **Use the selected Staff** button when done:

9. The window will refresh and display the selected staff members and roles entered:

Liaison	Last Name	First Name	Department Name	Role		
University of North Carolina at Chapel Hill (UNC-CH)						
●		Sita	Office of Clinical Trials	Principal Investigator	edit	remove
○		Danielle	Adams School of Dentistry Pediatric Dentistry	Co-Investigator	edit	remove
○		Jess	Office of Clinical Trials	Study Coordinator	edit	remove

The imported information will be available in IRBIS. Each staff member with a checkbox checked and a valid role selected will be imported.

UNC-IRB actions will be pushed in OnCore after the review process is complete. See page 6 for more information.

Option 2: Manually link data from IRBIS to OnCore via the My OnCore button in IRBIS

1. Log in to IRBIS and select the **My Studies** link and click on the hyperlink for the appropriate study:
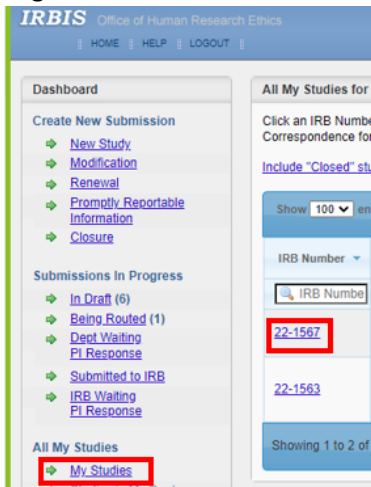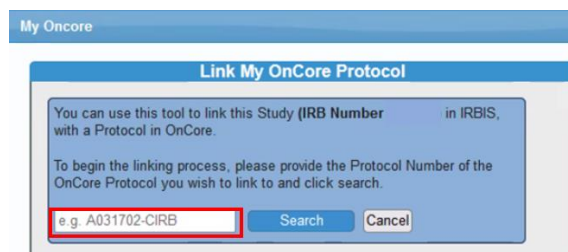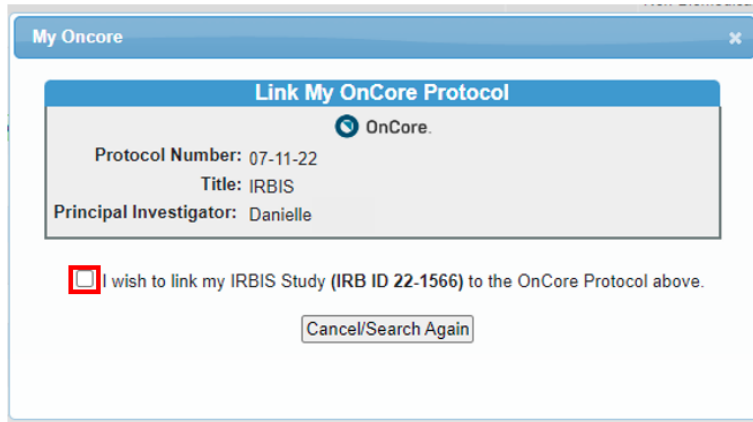

2. Select the **Reference ID** hyperlink :

3. Select the **My OnCore** button on the Application Status page:

4. Enter the protocol number in the pop-up window that appears:

5. A new pop-up window will appear. The protocol number, title, and principal investigator will be listed. Select the checkbox at the bottom of the pop-up window:

6. A new set of buttons will appear on the bottom of the pop-up window. Select the **Use this Study** button:
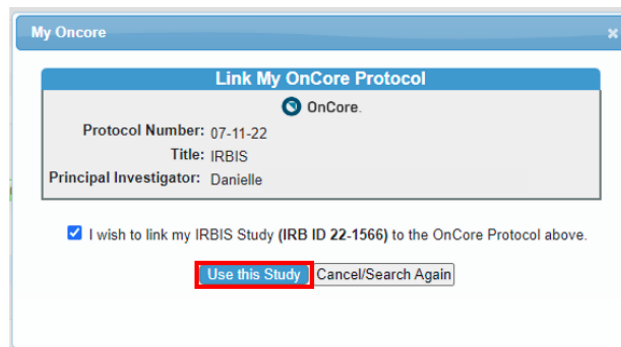
7. A warning window will appear. Click **OK** if you wish to proceed with linking the study:
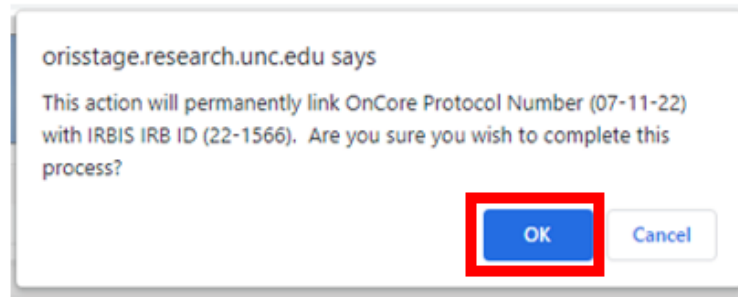
The study in IRBIS will be linked to the protocol shell in OnCore.

UNC-IRB Review Information in OnCore for Non-Oncology Studies

After a UNC-IRB action is completed by IRBIS staff, the IRB information will appear in OnCore. To view the information:

1) Navigate to **PC Console** > **Reviews** > **IRB**
2) Select the **Details** hyperlink next to the appropriate review
3) The **IRB Review Details** page will appear

RI											Add
	Review Date	Submit Date	IRB Committee	Review Reason	Review Type	Review No.	Action	Action Date	Expiration Date	Delete?	
1.	07/05/2022	07/05/2022	UNC IRB	Initial Review	Expedited	506841	Approved	07/05/2022	02/01/2025	☐	Details Edit

Example 1: Initial or Renewal/Continuing Review

Example 2: Administrative Review

For a completed Administrative Review, you will see additional text entered in the Summary field. The Expiration Date field will also be blank.

IRB Review Details

UNC-Chapel Hill									Protocol No.:06-29-22
Review Date	07/05/2022	Submit Date	07/05/2022	Committee	UNC IRB	Review Reason	Initial Review	Review Type	Expedited
Action	Approved	Action Date	07/05/2022	Expiration Date				Review No.	506841
Summary	Admin Annual Review Date: 07/04/2023								
Yes Votes		No Votes		Abstain Votes		Institution	UNC-Chapel Hill		

Details

Type	Amendment No.	Version Date	Description	Comments	Reconsent Required?
		No records found			

Reviewers

Reviewer Type	Reviewer	Attended?
	No information entered	

Communications

Communication Type	Sent To	Date	Resp. Reqd?	Responded By	Response Date	Response	Comments
			No information entered				

Global Amendments

Change Type	Amendment No.	Version Date	Change Description	Comments	Reconsent Required?
		No records found			

Close

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Note: Regardless of review type, you will still need to add related attachments, such as consent forms.