

IRBIS changes, effective 6:00 PM, July 16, 2019

IRBIS 5.11.03 Update:

Summary of Changes
<ul style="list-style-type: none">• IRB Renewal Submission Types• Renewal Conversion Wizard• Ramses Project Personnel Import Wizard

IRBIS Update Q&A Session with OHRE

A call-in Q&A update has been scheduled for July 24 @ 2 PM. Please join us to discuss this update and provide feedback about these changes and other future recommendations.

Join Zoom Meeting

<https://unc.zoom.us/j/135866140>

+1 929 436 2866 US (New York)

Meeting ID: 135 866 140



IRB Renewal Submission Types

When creating a renewal submission at the time of your annual continuing review, you will now be presented with three options:

Create a Renewal

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

<p>No Changes</p> <p>I will not be making any changes to my study.</p> <p>Choose ⓘ</p>	<p>Personnel Modification Only</p> <p>I will be making changes to the project personnel.</p> <p>Choose ⓘ</p>	<p>Study Modification</p> <p>I will be making changes to my study.</p> <p>Choose ⓘ</p>
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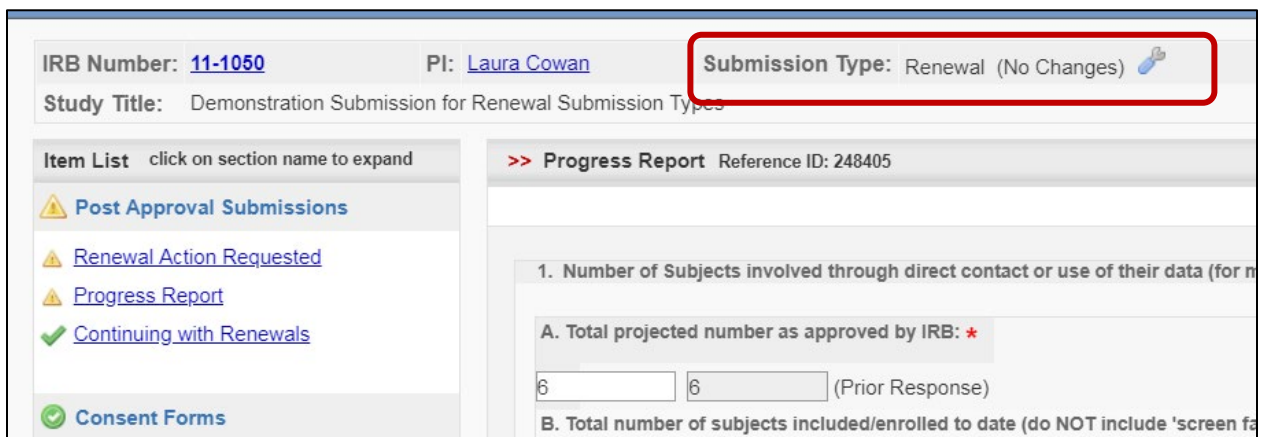
- When No Changes is selected, you have indicated that you are submitting the renewal request only, and will be presented with the Progress Report section of the application. It will not be possible to make any changes to the project personnel, study design, or any other portion of the IRB application.

For the following two renewal submission options, the renewal with modification option has been moved out of the Progress Report screen. All Modification options will now be displayed in the Continuing with Renewals section, following the Progress Report.

- When Personnel Modification Only, you will have access to the Progress Report section, Modification section, and the Project Personnel portion of the IRB application.
- If you choose Study Modification, this indicates that you will be making more substantive changes to your IRB application.

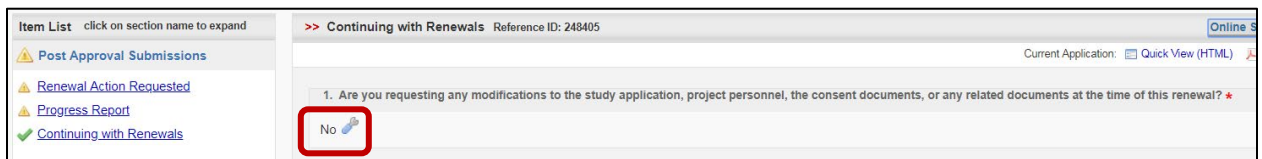
Renewal Conversion Wizard

With these new renewal submission types, we have also added a new button to convert your renewal submission from one type of request to another. If you first choose No Changes, but later determine changes are needed, simply click the wrench icon at the top of the screen:



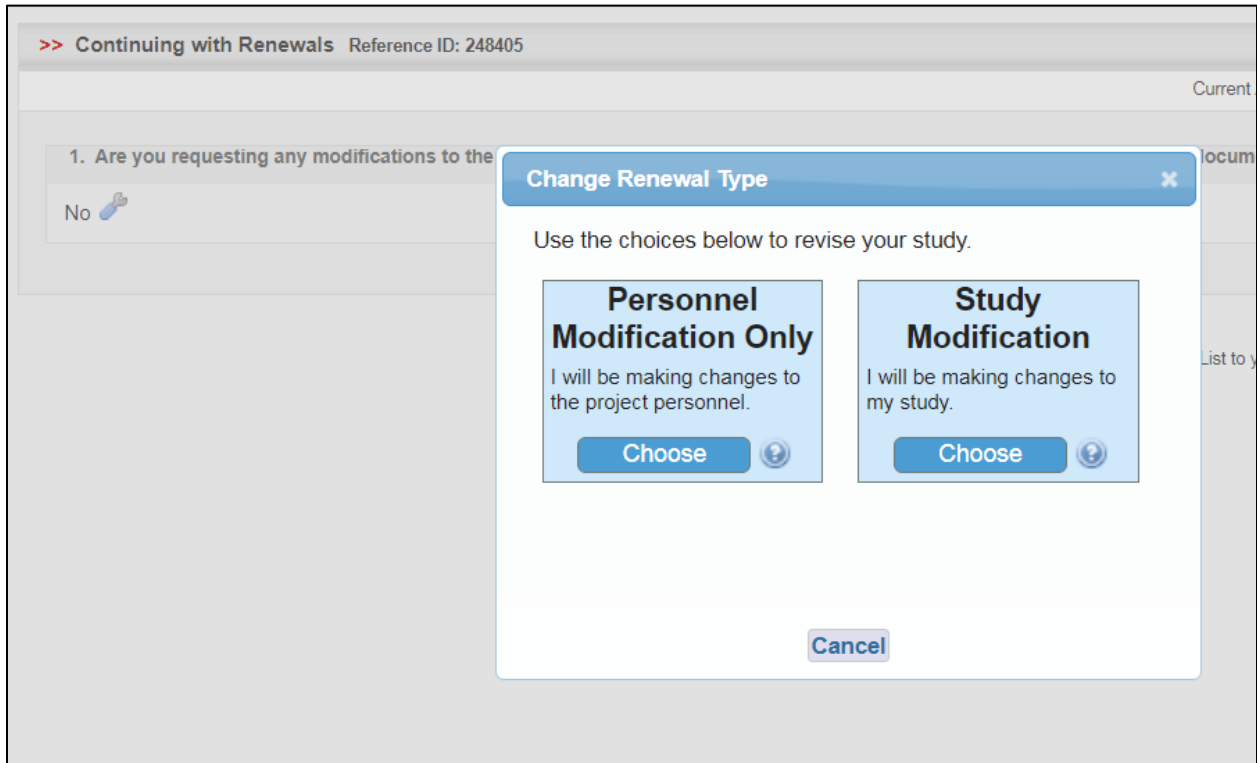
The screenshot shows the top section of the IRB application interface. At the top, it displays the IRB Number (11-1050), PI (Laura Cowan), and Submission Type (Renewal (No Changes)). A red box highlights the Submission Type dropdown menu, which includes a wrench icon for editing. Below this, there is a section for the Progress Report (Reference ID: 248405) with a table for 'Number of Subjects involved through direct contact or use of their data (for n)'. The table has two rows: 'A. Total projected number as approved by IRB: *' with input fields for '6' and '6' (Prior Response), and 'B. Total number of subjects included/enrolled to date (do NOT include 'screen fa'.

This change request can also be selected from the Continuing with Renewals screen where you would indicate what changes are needed. The No Changes Renewal comes pre-populated with the answer locked as no, but it can be changed by clicking the wrench icon:

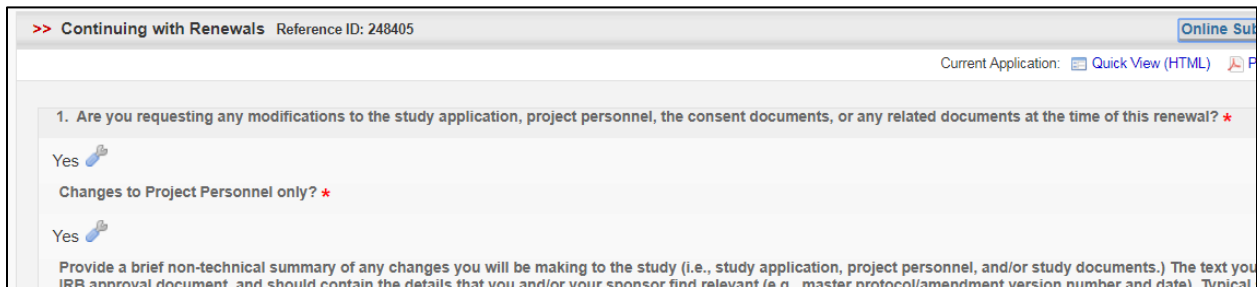


The screenshot shows the 'Continuing with Renewals' screen (Reference ID: 248405). The left sidebar shows an 'Item List' with 'Continuing with Renewals' selected. The main content area shows a question: '1. Are you requesting any modifications to the study application, project personnel, the consent documents, or any related documents at the time of this renewal? *'. The answer is 'No', which is highlighted with a red box and has a wrench icon next to it, indicating it can be edited.

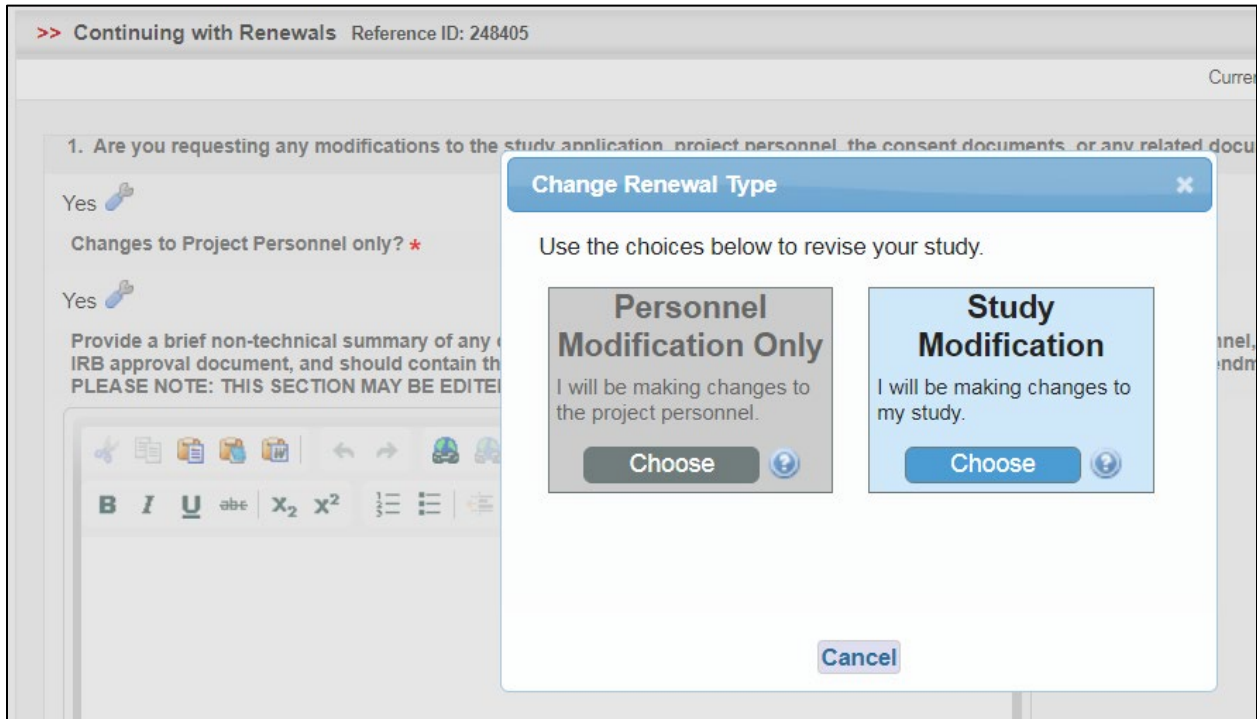
When selected, you will have the option to choose either the Renewal Type of Personnel Modification Only, or Study Modification:



If Personnel Modification Only is selected, the Continuing with renewals screen will be displayed with the appropriate pre-populated answers:



If you determine that additional changes are needed, you have the option to click the wrench icon and choose the Study Modification renewal type:



The Personnel Modification Only option will be greyed out, and there is no option to select no changes. Once a more comprehensive version of the Renewal submission is unlocked, it is not possible to move backwards. If you decide this action is needed prior to Submitting to Routing, we recommend that you click Delete Submission in the upper right-hand corner of the screen.

We hope that these options will facilitate more expeditious renewal submission application completion, OHRE reviews, and better understanding between researchers and the IRB about which types of changes they are making.

[Ramses Project Personnel Import Wizard](#)

If on an initial submission, no research project personnel have yet been added, researchers will have the option to use the Ramses look up tool to select a Ramses proposal and import the Ramses number, funding source(s) and relevant Research Project Personnel.

- List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB.
- If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not faculty or staff) list them here as project personnel; consult with your IRB.
- If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel.

The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated. **If a change to the Principal Investigator is requested during the course of the study, a [PI Change Form](#) must be submitted. ***

[Click here to add personnel](#)
[Click here to import personnel from your RAMSeS Proposal](#)

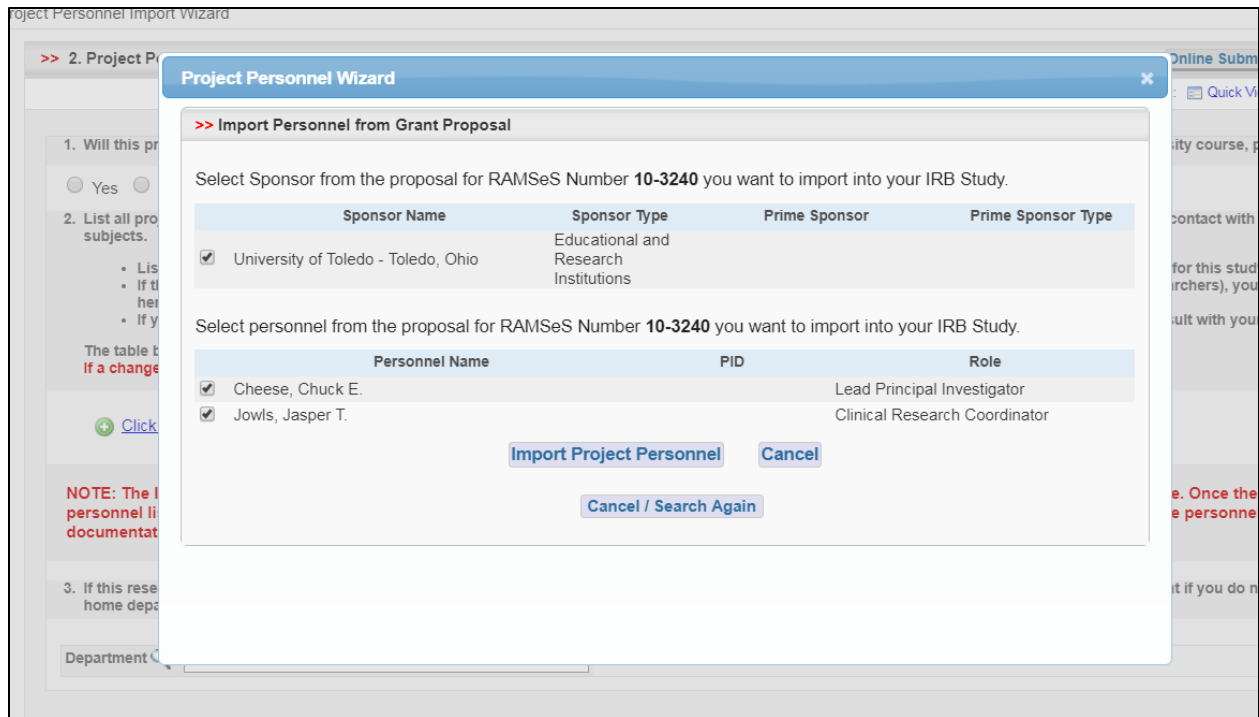
NOTE: The IRB database will link automatically to [UNC Human Research Ethics Training database](#) and the UNC Conflict of Interest personnel listed (for whom we have email addresses) will receive separate instructions about COI disclosures. The IRB will complete the necessary documentation is required.

3. If this research is based in a center, institute, or department (Administering Department) other than the one listed above for the PI, select the home department will be **AUTOMATICALLY** inserted when you save this page.

Department

This Project Personnel Wizard will be automatically displayed when you navigate to the General Information > Project Personnel section:

You have the option to search by Principal Investigator name, or the RAMSeS Number. When you select the related RAMSeS project, you will have the option to import sponsors and personnel directly into IRBIS. As the RAMSeS proposal may contain sponsors and staff not relevant to IRBIS, simply uncheck those that you do not wish to import.



As the roles in RAMSeS are slightly different than those in IRBIS, we would recommend a quick review to ensure all information is accurate.

For questions or comments, please contact IRBIS@unc.edu