IRBIS changes, effective 6:00 PM, September 10, 2019

IRBIS 5.11.04 Update:

Summary of Changes

• IRB Initial Submission Types
• IRB Board Restructuring
• Additional Updates:
  ○ Current Study Personnel Quick Link View
  ○ Question 5.1 Updates
  ○ NHSR Department Approval Requirement Removal
  ○ Submit Button and RAMSeS Import Visual Timer Change
  ○ Ability to Delete NSI Attachments During Response to Stipulations
  ○ sIRB Approved Documents Display Update

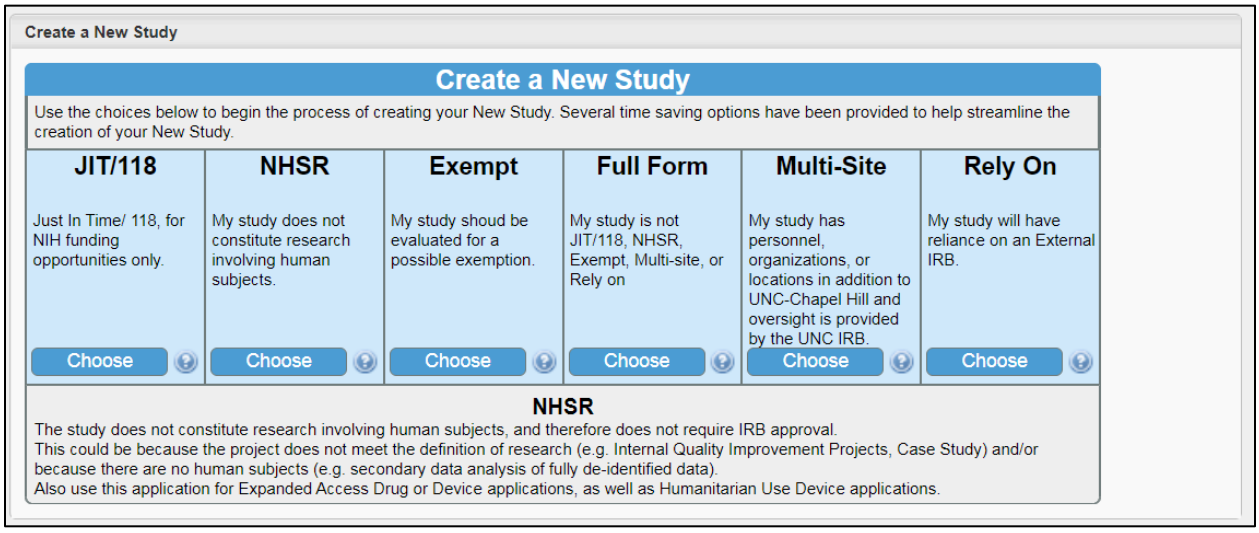
IRBIS Update Q&A Session with OHRE

A call-in Q&A update has been scheduled for September 25 @ 3 PM. Please join us to discuss this update and provide feedback about these changes and other future recommendations.
Special Guest for this call: Jon Gellert, WIRB-Copernicus Group

Zoom Meeting Details:
https://unc.zoom.us/j/387692833
Dial-in: 1-929-436-2866
Meeting ID: 387 692 833

IRB Initial Submission Types

Beginning on September 11, 2019, when creating a new initial submission, you will now be presented with several time saving options:



118/JIT: Just In Time/ 118, for NIH funding opportunities only.

The JIT/118 review is specific to NIH funding opportunities and is used when an investigator is notified that an application is likely to be funded, and is to be followed with a full review submission at a later date.

NHSR: My study does not constitute research involving human subjects.

The study does not constitute research involving human subjects, and therefore does not require IRB approval.

This could be because the project does not meet the definition of research (e.g. Internal Quality Improvement Projects, Case Study) and/or because there are no human subjects (e.g. secondary data analysis of fully de-identified data).

Also use this application for Expanded Access Drug or Device applications, as well as Humanitarian Use Device applications.

Exempt: My study should be evaluated for a possible exemption.

Some research involving human subjects may be eligible for an exemption which would result in fewer application and review requirements. This would not apply in a study that involves drugs or devices, or involves greater than minimal risk.

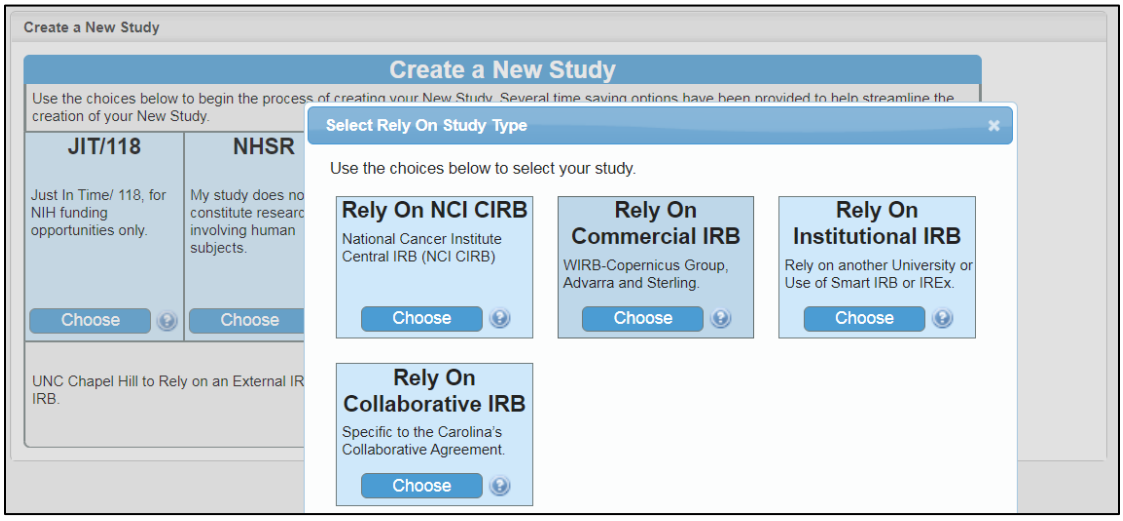
Full Form: My study is not JIT/118, NHSR, Exempt, Multi-site, or Rely On

Multi-Site: My study has personnel, organizations, or locations in addition to UNC-Chapel Hill and oversight is provided by the UNC IRB.

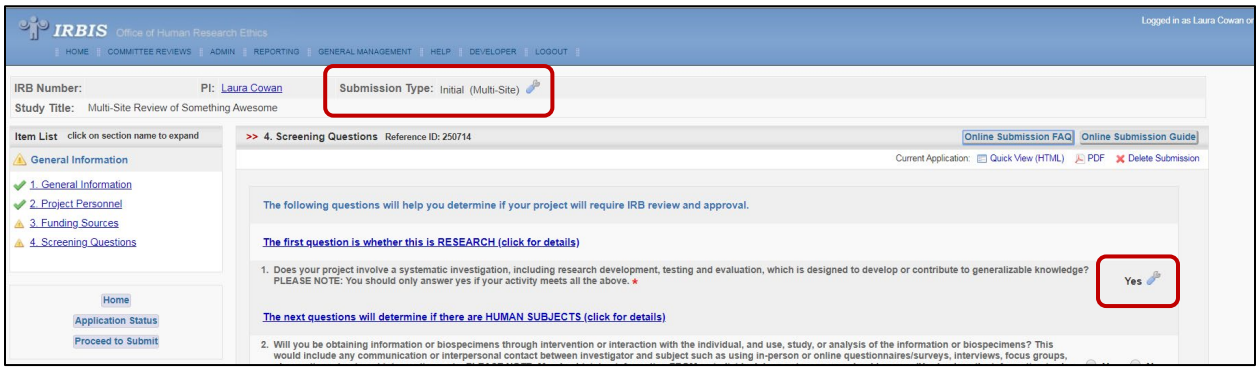
This option is needed when UNC is providing oversite for external groups, organizations or individuals via a reliance agreement. There may be research that is 'multisite' that does not require single IRB review. This includes executing reliance agreements. Other sites / personnel to rely on the UNC Chapel Hill IRB.

Rely-On: My study will have reliance on an External IRB.

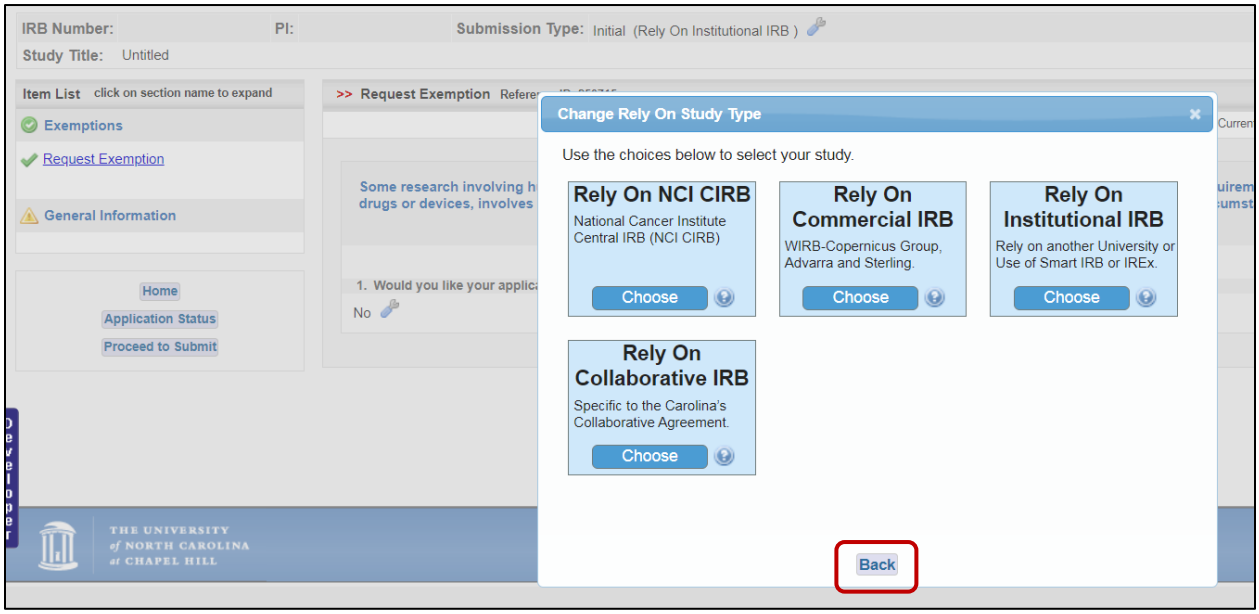
- Rely-On NCI CIRB: National Cancer Institute Central IRB (NCI CIRB).
- Rely-On Commercial IRB: WIRB-Copernicus Group, Advarra and Sterling.
- Rely-On Institutional IRB: Rely on another University or Use of Smart IRB or IREx.
- Rely-On Collaborative IRB: Specific to the Carolina's Collaborative Agreement.



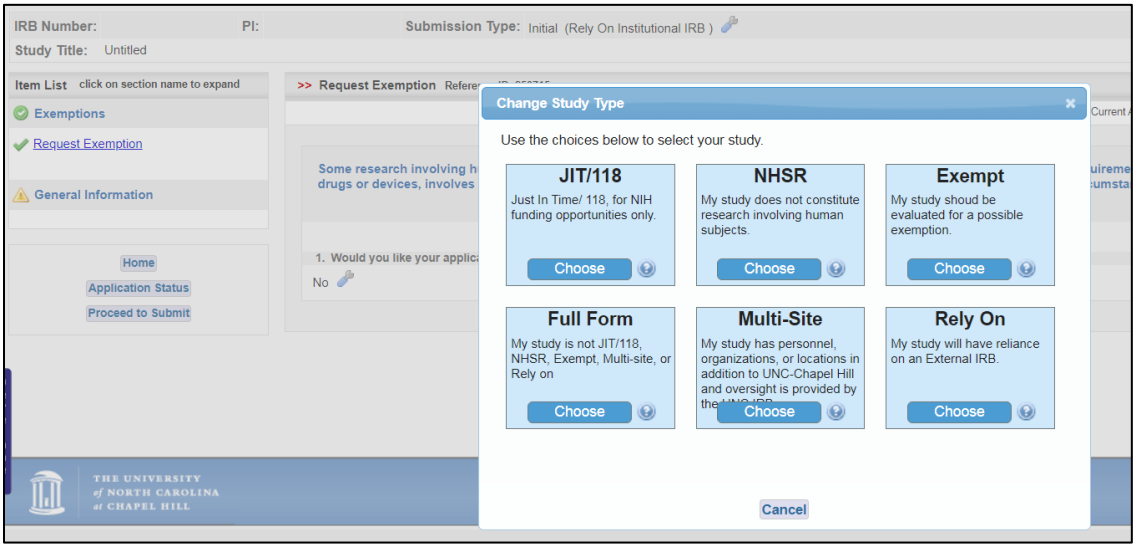
Similarly to the Renewal Submission Wizard, which was launched on July 16, 2019, if you begin with one submission type and determine you need to switch to a different initial submission type, you should select the wrench icon. This is available at the top of the screen, or on selected pre-filled questions.



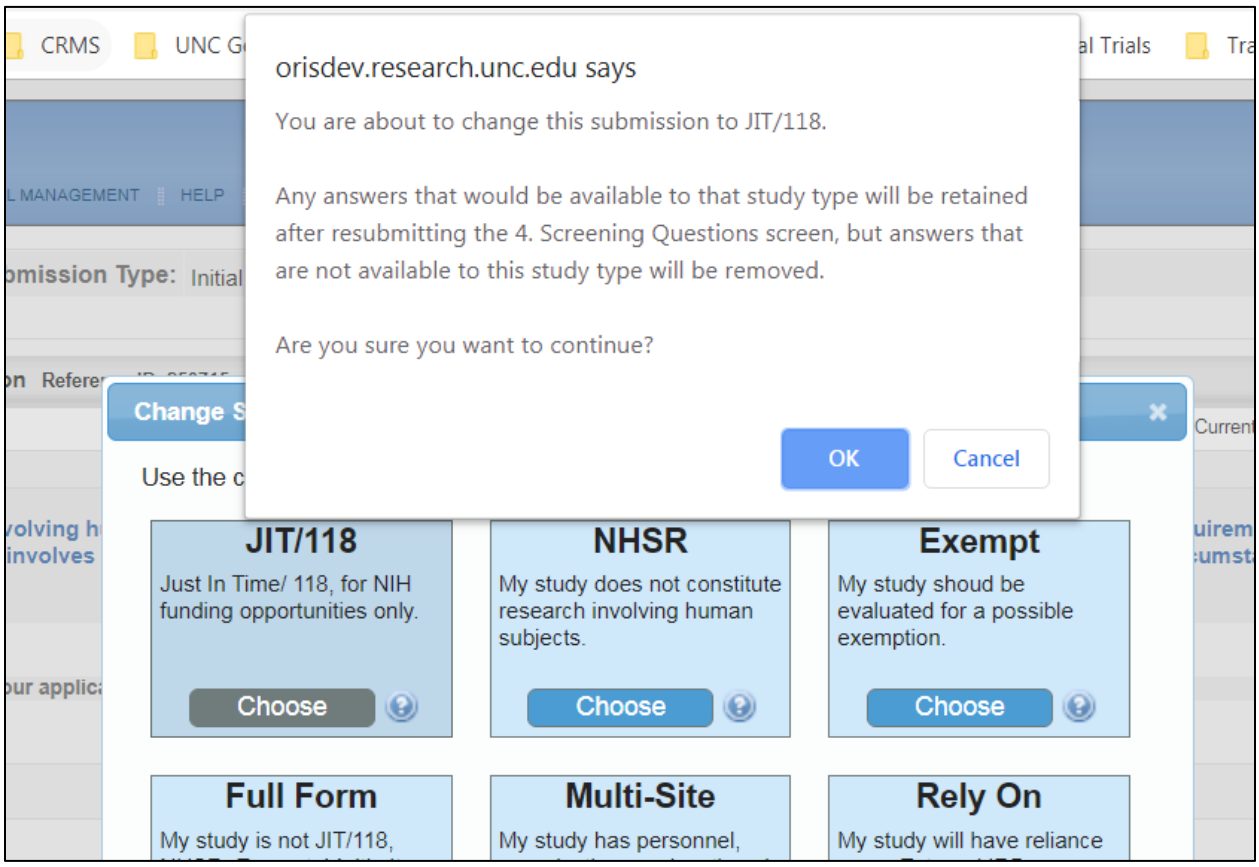
When switching from one Rely-On submission type to another, you will also have the option to switch to a different Rely-On submission, or a different type of submission all together:



If you determine that your study is not a Rely On application, you should click the **Back** button, highlighted in the above image to choose from the other application types:



If you change from one initial submission type to another, IRBIS will display a confirmation pop-up and notify you of any data that may be lost during the transition. The reason for this is that some questions are specific to certain application types, and when you convert from one to another, data that is no longer applicable to your new application type will not be retained.



IRB Board Restructuring

Per the announcement from the OHRE Director, the UNC Chapel Hill IRB's are being restructured.

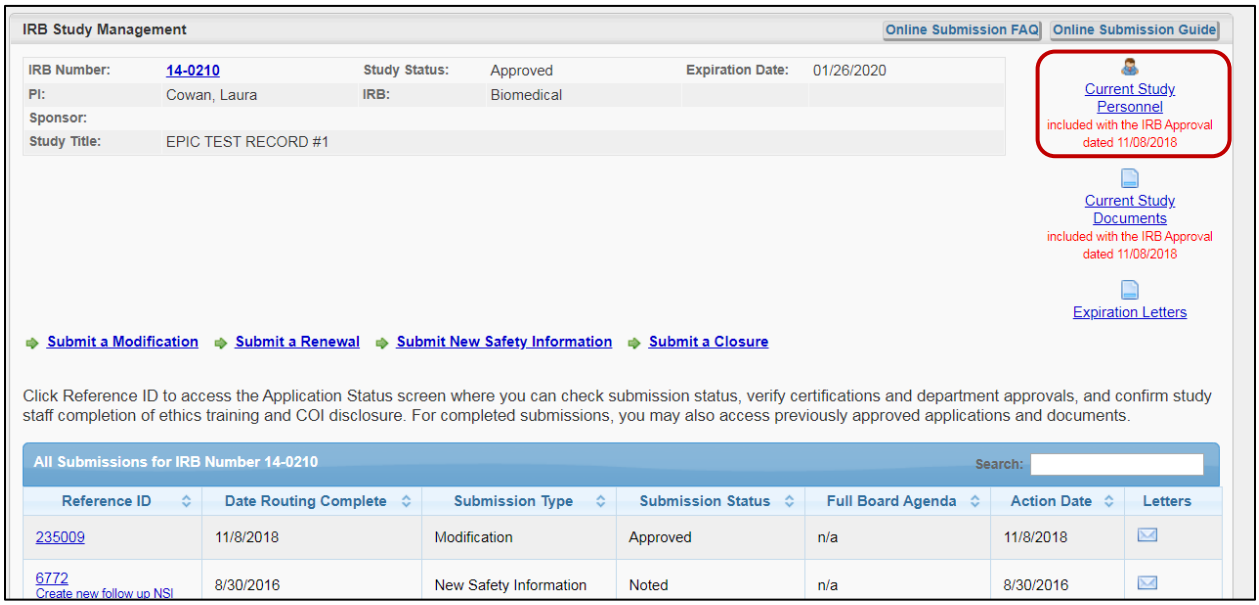
Previous Board Name	Revised Board Name
Biomedical Committee A	Board A
Biomedical Committee B	Board B
Biomedical Committee C	Board C
Biomedical Committee D	Board D
Non-Biomedical Committee E	Board E
IRB Safety Committee	Board F

As a result, the data displayed in IRBIS and in your IRBIS related letters and notifications have been changed.

Additional Updates:

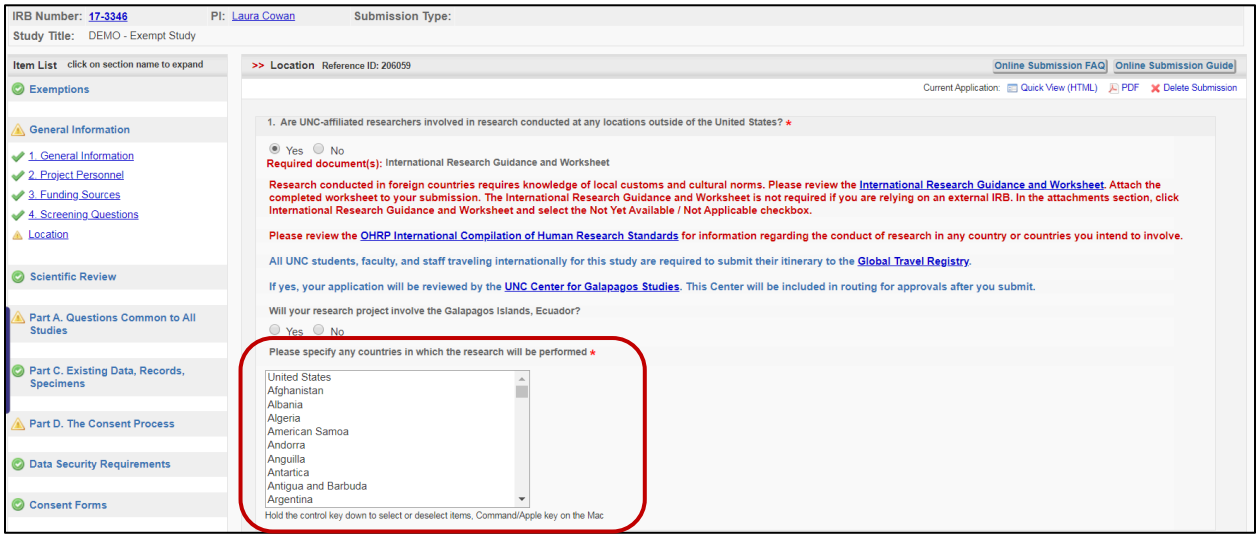
Current Study Personnel Quick Link View

On the IRB Study Management Screen, a link which displays the current, approved Study Personnel from the most recently approved IRB submission has been added:



Question 5.1 Updates

IRBIS Question, “Are UNC-affiliated researchers involved in research conducted at any locations outside of the United States?” has been revised to include a drop-down list in which you are required to select any countries in which the research will be performed:



To select multiple countries, you should hold the control key down to select or deselect items, Command/Apple key on the Mac.

Please note that for Rely-On Commercial IRB Submission types, this question will appear in General Information > Location rather than 5.1.

NHSR Department Approval Requirement Removal

The Department Routing/Certification for all NHSR requests has been waived. Previously this was waived for a subset of NHSR requests. Rather than certify during routing, Department Approvers will be notified via email at the time the NHSR determination is made.

Submit Button and RAMSeS Import Visual Timer Change

Various buttons within IRBIS have been redesigned to better inform you if the action you requested is taking place / loading and to prevent double clicking.

Ability to Delete NSI Attachments During Response to Stipulations

Researchers now have the ability to Delete, when appropriate to do so, documents uploaded as attachments to NSI Reports during the response to stipulation process.

sIRB Approved Documents Display Update

External site consent forms and attachments are now blocked from being displayed under the approved documents list unless the site has been activated.