IRBIS changes, effective 6:00 PM, March 18, 2020

IRBIS System Update:

Summary of Changes

29316 – IRBIS Question A.2.2. has been updated:

PRIOR A.2.2.

Total number of subjects to be studied by the UNC-CH investigator(s) (provide exact number; if unlimited, enter 9999):

REVISED TO A.2.2

Total number of subjects to be studied by investigators being provided oversight by the UNC IRB. (provide exact number; if unlimited, enter 9999)

29578 – Administrative Review (AR) Submission reminders have been revised to temporarily remove the 60-day reminder notice. These reminders were previously automatically sent at 60 and 30 days prior your Administrative Annual Review due date.

Instead, we are adding a reminder to be sent at 44 days prior to your Administrative Annual Review due date. The Annual COIs are automatically created at 45 days, so we encourage researchers to wait until they reach the 44-day mark to submit the AR submission to potentially avoid COI complications with the timing.

We plan to reintroduce the 60 day reminder in the next update, which will provide a reminder of your current study staff and that you should submit an IRB Modification for review prior to the 45 day mark to ensure the AR process runs as smoothly as possible.

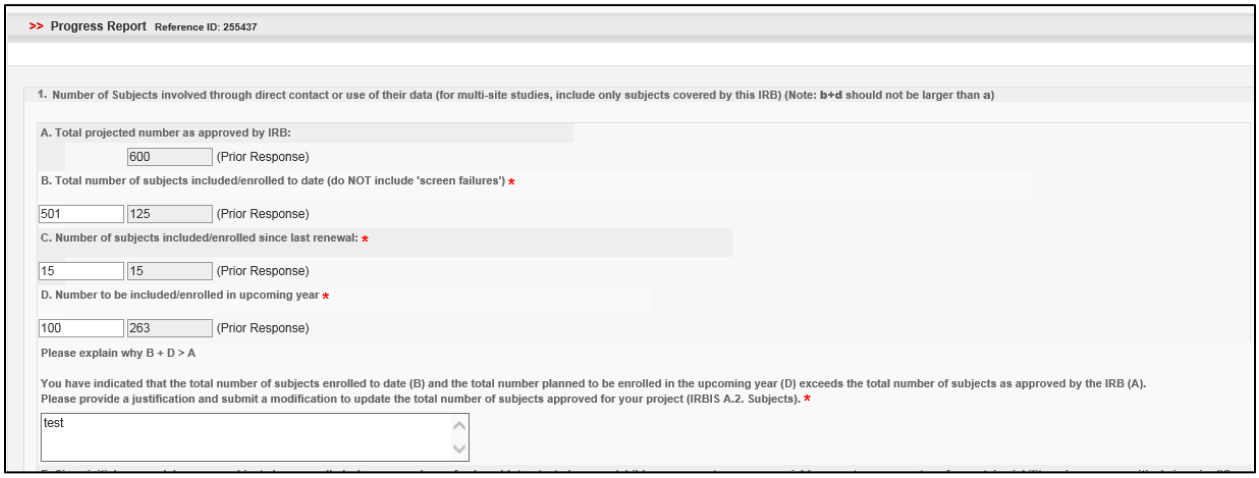
28131 – The IRBIS Progress Report has been updated to better reflect "A. Total projected number as approved by IRB:". Previously this information was being pulled from the prior year's continuing review form question.

The new display will instead have a read-only text box displaying the previously approved answer for A.2.2. "Total number of subjects to be studied by investigators being provided oversight by the UNC IRB. (provide exact number; if unlimited, enter 9999):".

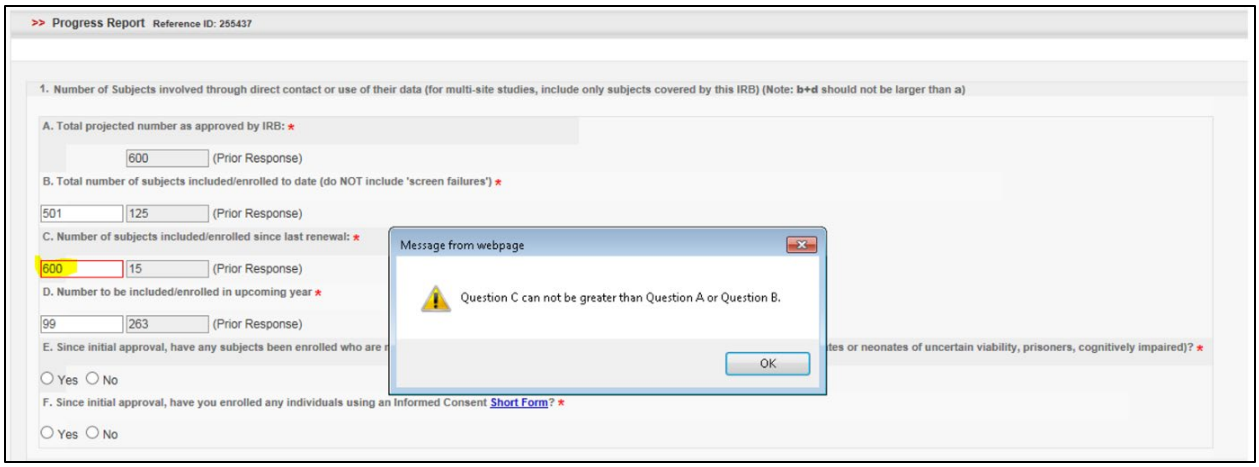
In addition the logic has been revised to better reflect the reporting requirements:

When B + D > A, we now display an open text area requesting an explanation:

> Please explain why B + D > A
>
> You have indicated that the total number of subjects enrolled to date (B) and the total number planned to be enrolled in the upcoming year (D) exceeds the total number of subjects as approved by the IRB (A).
>
> Please provide a justification and submit a modification to update the total number of subjects approved for your project (IRBIS A.2. Subjects). *



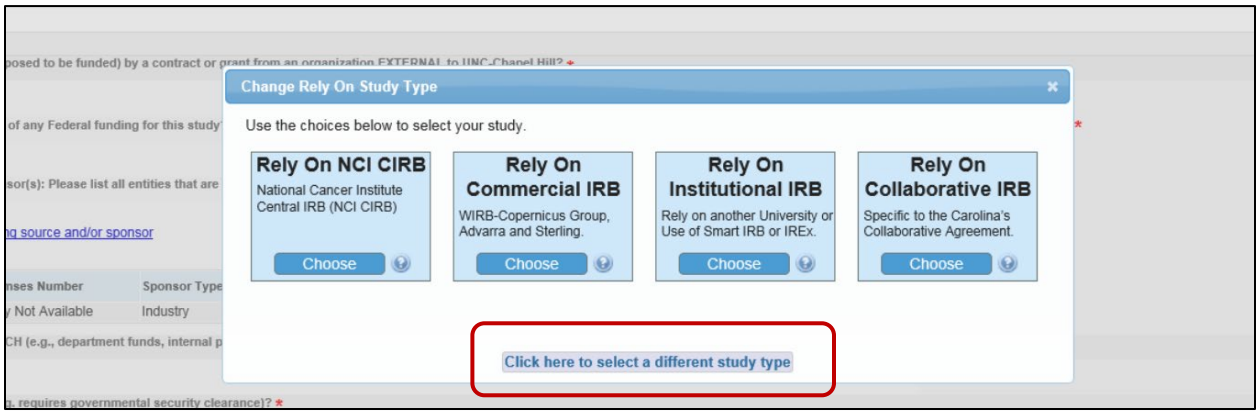
We also display an alert when C > A or B, as the total number of subjects enrolled since the last renewal cannot be greater than the total number approved, nor the total number enrolled.



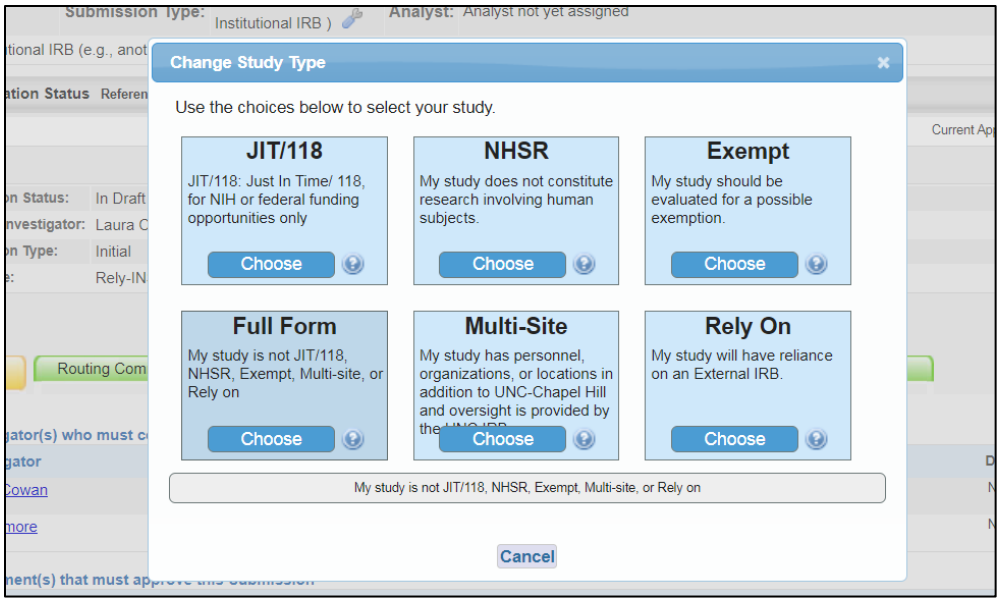
29934 – Rely-On Wrench

This update applies to when the wrench tool is selected to modify your IRBIS submission type. Previously, if you had selected a Rely-On application type and selected one of the four options, it was confusing to switch to a non-Rely-On option as the button as labeled back.

Now, the label will be displayed as 'Click here to select a different study type':

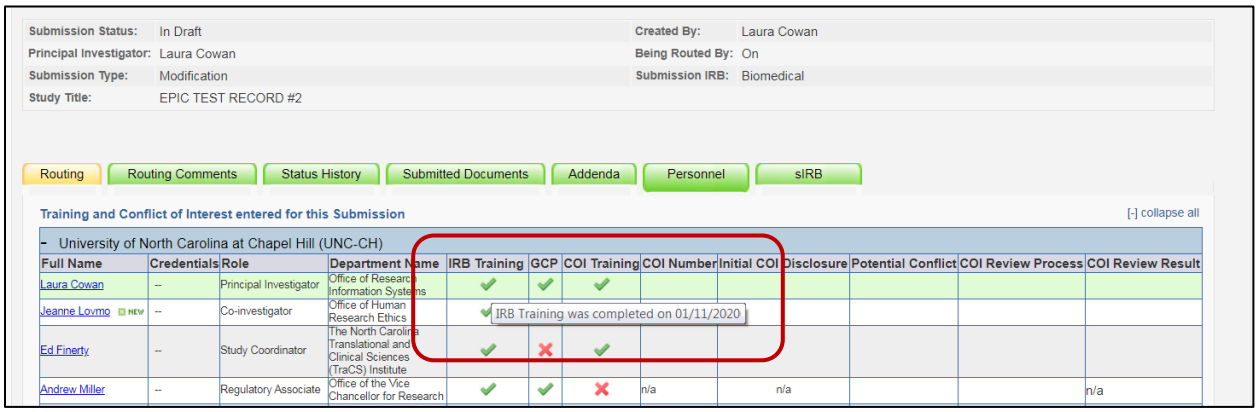


When clicked, you will be presented with the option to select a different type of submission:



29726 – CITI Date of Completion

IRBIS has been updated to reflect the completion date of CITI Human Subjects Protection (HSP) Core Refresher course and Good Clinical Practice (GCP) related dates. This is phase one of a two-part update. Phase two is expected in June 2020. To view, you should hover over the icon in the IRB Training or GCP training column on the Personnel table on the Application Status screen:



29623 – Annual COI update

Presently, if an AR or CR submission was created prior to the 45-day mark when auto creation of Annual COI disclosures is scheduled to occur – the COI disclosures are not being generated for these in draft submissions until they are certified by the Principal Investigator (PI). This can cause additional delays.

This change will enable COIs to be automatically generated at the 45-day mark, even if the study has not yet been submitted/certified by the PI.

Admin Only Feature Updates:

29755 – ADMIN – AR Sequence Issue

This fix will resolve an issue where submissions (usually modifications) fail to roll-up to the study level, when an AR submission is under review at the same time. This is due to a an out of order processing sequence where staff need to be removed from a project, but the AR us already under review by OHRE.

29883 – ADMIN – Macros UI Fix

this fix will enable Macros to be created and updated via the IRBIS user interface.
This task was found to be broken but has been restored. Please note that this task requires additional IRBIS permissions and is not available to Analysts.

29234 – ADMIN – OHRE Minutes/Agenda Fix

this fix will enable OHRE Administrative staff to delete multiple versions of Agendas, Minutes, and Vote Cards that have been uploaded in error. Previously, only the most recent version of the file was able to be deleted.

29892 – ADMIN – Reporting Bugs

this fixes a bug in the beta new reporting feature regarding submission turn-around times. Previously when columns were added or removed (Days PI / Days IRB), the data was not displaying properly. Reports will now be required to be re-generated whenever a column (data element) is added or removed. Please note that this task requires additional IRBIS permissions and is not available to Analysts.

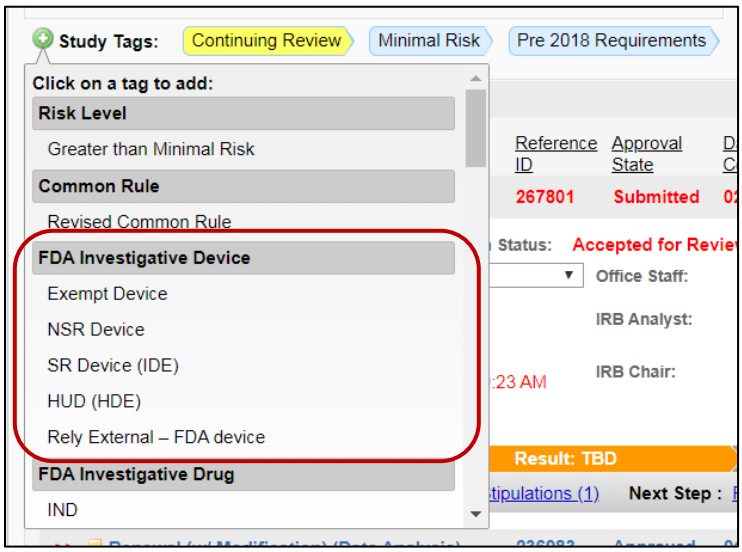
29766 – ADMIN – Analyst/Chair Change Log

This update adds whenever an IRB Analyst or Char is added or removed from a submission to the Timestamp log. This will enable staff to see if a Chair or Analyst had previously been assigned to a particular submission but had since been removed or changed.

29579 – ADMIN – The Risk Determination section, which was previously displayed on the review results screen, has been removed from that location and will instead be indicated via the use of Study Level tags.

Prior options include Risk of Research: ‘Minimal’ or ‘Greater than Minimal’, and Risk of Device (if any): ‘Non-Significant Risk’ or ‘Significant Risk’.

The study level tag options are: ‘Minimal Risk’ or ‘Greater than Minimal Risk’ and the following for an FDA Investigative Device:



29589 – ADMIN – OHRE Attachments and Email Correspondence should now be displayed on the NSI Board view. Previously, only PI Attachments were displayed. This change will enable easier access to these materials of Board members. This is accessed by going to Committee Reviews, selecting an agenda, selecting an NSI submission, and scrolling to the bottom of the pop-up window.