IRBIS changes, effective 6:00 PM, April 9, 2019

IRBIS 5.11.00 Update:

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1) Improved Navigation
The New Safety Information (NSI) submission process has been revised to improve navigation.
To submit an NSI, go to your IRB Study Management page and click: Submit New Safety Information

Next, you will respond to questions about the New Safety Information:
Your responses determine what sections are required. To help researchers navigate the required sections, each section is now displayed on the left-hand item list menu. Completed sections will be indicated with a green check box, and sections requiring additional information are indicated with a yellow triangle:

Until the NSI is submitted, you are able to easily delete and NSI submission by clicking Delete NSI on the left-hand menu:
2) NSI Stipulation Reminders
The IRB will now send you reminders if your responses to NSI stipulations are past the due date indicated in the initial stipulation letter. When the NSI Stipulation letter is sent, reminders will be sent at the following intervals:

- Due date + 3 calendar days
- Due date + 7 calendar days
- Due date + 11 calendar days (final notice)

On day 11, if you have not submitted your response, you will receive a final reminder that states that the IRB will not review any new IRB submissions until the NSI responses are received. Note: This policy does not pertain to NSI submissions.

3) New NSI Stipulations Response Mechanism
The NSI stipulation letter will now contain a link to stipulations rather than listing each stipulation. Click the NSI stipulations link to access your stipulations on the NSI stipulations screen. You no longer need to initiate a follow-up report to respond to stipulations. Respond to each stipulation using the text box provided below.

4) Ability to Update the Initial NSI Report
If the IRB requests that you update the NSI report, it is now possible to revise it. You should use the left-hand menu to navigate to the different sections of the application that have been requested to be revised.
Edit the existing answers to provide additional detail or corrections. Please note that some revisions will trigger new question requirements or sections.

When all changes and responses are complete, please click the yellow Resubmit button, on the left-hand menu. PI certification of NSI responses is still required. Upon resubmission, the NSI will be route to the PI for certification. The PI will continue to receive an email prompting the certification.

To view a comparison of the revised NSI and the prior submission, click the View Revisions button on the left-hand menu. This will display a tracked changes view of the NSI report responses and any attachment revisions.
5) New NSI Stipulation Letters and Responses View
NSI Stipulation responses will now be available to view via the IRB Study Management Screen, Letter icon, similarly to stipulation responses for other submissions.

6) OHRE Initiated NSI Modifications
OHRE now has the ability to administratively initiate an NSI Modification if they are requesting application changes as a result of information submitted in the NSI report. The administrative NSI Modification will not be visible to you when it is in draft. If you attempt to start a submission while the administrative NSI Modification is in draft, you will receive the following hard stop message:
7) Updated Function of the Existing NSI Follow-Up Report
The existing NSI Follow-up report option should now only be used to provide follow-up information after the initial NSI report has been finalized (noted) by the IRB.

To submit a follow-up, choose the Follow-Up option from the NSI management section, or the IRB Study Management screen

To provide feedback or additional suggestions, please contact: IRBIS@unc.edu