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

IRBIS 5.11.00 Update:

Summary:

- **Research Dashboard Category Revisions related to Waiting PI Response and Revised/Resubmitted**
- **Annual COI Disclosures**
- **New Safety Information (NSI) Redesign and Stipulations**
  1. Improved Navigation
  2. NSI Stipulation Reminders
     *Admin – PI Response Due Date and Past Due Study Level Tag
  3. New NSI Stipulations Response Mechanism
  4. Ability to Update the Initial NSI Report
  5. New NSI Stipulation Letters and Responses View
  6. OHRE Initiated NSI Modifications
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Research Dashboard Category Revisions related to Waiting PI Response and Revised/Resubmitted

The researcher dashboard has been revised. Waiting PI Response and Revised/Resubmitted has been split into two options:

- Dept Waiting PI Response + Revised/Resubmitted to Dept
- IRB Waiting PI Response + Revised/Resubmitted to IRB

We hope that this change will better clarify where in the process revisions are requested --- by the Principal Investigator Faculty Advisor, or Department Reviewer, verses the IRB.
Annual COI Disclosures
Modifications will no longer be allowed to be created within 45 days prior to the expiration date. The following hardstop message will be displayed notifying researchers that only a renewal is required.

The reason for this is that Annual COI disclosures will now be automatically created 45 days prior to the expiration date.
When you click on the Annual COI reference ID, you will be able to see the automatically created Annual COI disclosures and their current status for all staff currently listed on your project:

When you create the renewal submission, the Annual COI submission and reference ID will automatically converted into the Renewal Submission.

In the OHRE Admin view, the Annual COI automatically generated submission will be shown as follows:

If after the automatically generated Annual COI disclosures are created, changes are needed to the Project Personnel section, these can be done by creating the Renewal submission and choosing yes to question 9.
of the Progress Report section to request modification. Upon certification, the addition / removal of the existing COIs will be done automatically.

New Safety Information (NSI) Redesign and Stipulations

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.

*Admin – PI Response Due Date and Past Due Study Level Tag

We have added a new field on the Review Results screen; PI Response Due Date:

This sets that date that the PI response to stipulations is required to be returned by for NSI stipulations. It will also be automatically inserted into NSI Minor Stipulation letters.
To revise an NSI PI Response Due Date, return to the Review Results screen and click the wrench icon. You must have a special user permission to have this ability.

When the final notice is sent, and study level tag is automatically added to the study record advising that additional OHREC consultation is needed before processing any additional 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 * Admin
When finalizing an NSI Report, OHRE now has the option to create an NSI Related Modification. This can be done via the Finalize Letter screen for NSIs where the review result has been selected as Noted and clicking on the Create Modification (NSI) and Finalize Letter.

It is not possible to create a modification if there is already an active submission either in draft or under review. This will display the following hard stop notification.

Administratively created NSI Modifications will be allowed to be created within 45 days of expiration or if the study is already expired with a soft stop notification to review the urgency of the submission vs. creation of a renewal submission.
Administratively created NSI Modifications will be autonomically linked to the related NSI report displayed in the OHRE view as:

![Image of OHRE view with NSI Modification](image)

Stipulations should then be entered on the application screen and then sent to the researcher via the normal modification stipulation process.

If the researcher tries to create a submission while the Administratively created NSI Modification is in draft in the OHRE view, they will be displayed the following hard stop message:

![Image of OHRE view with hard stop message](image)

7) Updated Function of the Exciting 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
*Admin – Additional Notes

A hardstop has been added to prevent finalizing a minor stipulations letter template if no stipulations have been added:

All NSIs and NSI related modifications will automatically be shown in the My Bucket “watching” for Jeanne Lovmo, regardless of the Analyst assigned. The watch is automatically removed when the submission is finalized.
To clean up any remaining NSI reports that have already had follow-up submitted and finalized, we now have the option to choose NSI Submission Closure from the Review Results screen and select the NSI Administrative Closure letter template.

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