IRBIS changes, effective 6:00 PM, July 2, 2019

IRBIS 5.11.02.00 Update:

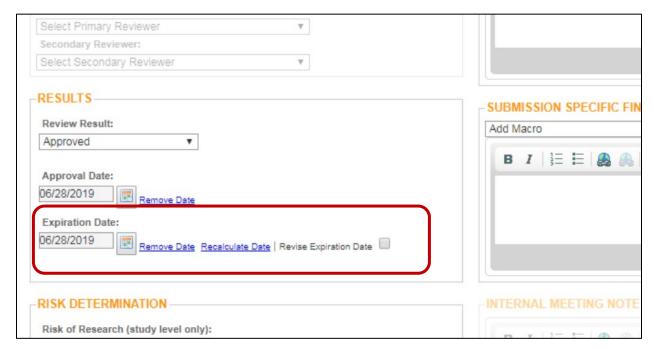| Summary: |
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| • IRBIS transitioning to a new server |
| • General Text Revisions |
| • Updated OHRE Admin Features and Requirements |

IRBIS is being transitioned to a new server. As part of this process, we will merge IRBIS and IRBIS2, and update to Cold Fusion 18, an updated version of the web-application development platform.

Renewal submissions cannot be deleted if a COI disclosure request have already been generated. This applies to submissions created within 45 days of the study expiration date.   If a researcher clicks the delete submission button, the following message will be displayed:

- Submission Reference Id [ReferenceID] cannot be deleted at this time. COI Disclosures have already been created for this submission.

OHRE staff will now have the ability to update the expiration date during a Modification submission. Previously this function did not roll-up properly.   In order to revise the expiration date, this must be completed on the review results screen by select either an Approved or Rely On review result. Next enter your Expiration Date and click the Revised Expiration Date check box **prior** to clicking Save.

Update to NSI Non-Reportable Swimlanes to include specific details rather than displaying "Non-Reportable"

User instructions provided when editing existing Research Project Personnel have been updated to better clarify which options are available.

Previous:

You may not use the personnel lookup after the submission has been certified.

You should only update the information saved, revising spelling or correcting data (e.g., phone number, email address, etc.). If the wrong person has been entered, "remove" the record and add new personnel.

Revised:

You may not use the personnel lookup after the submission has been certified.

Last name cannot be edited. To edit names or remove entries, click "remove" to delete the person and being the process again. You may update the entry to reflect revising spelling of the first name or update data for that individual (e.g., phone number, email address, etc.). To change someone from Internal personnel to an External affiliation, please click "remove" to delete the person and being the process again.

Research users with read-only access to IRBIS will now be blocked from responding to stipulations. Previously they were able to enter stipulation responses, but not able to resubmit.

For Exempt / Not Full Board review letter templates, a hard stop has been added on the admin view which prevents letters from being drafted if no Exempt/Expedited categories have been designated on the Review Results screen. The hardstop will be displayed if:

- A Not Full Board study (review result: Approved) does not have any Expedited Categories selected
- An Exempt study (review result: Exempt) does not have any Exempt Categories selected

The hardstop message displayed says: **Please select a review category before drafting letter.**

Studies that rely on an external IRB now have the ability to set the expiration date to be greater than one year from the date of review. This is to align with the external IRBs policy requirements.

For Annual COI disclosure submissions displayed on the admin screen prior to a renewal submission being created, IRB Chair will no longer auto populate if an IRB Chair navigates to the study history page.

A scheduled task has been added which will sync submissions to the correct administrative review bucket categories in the even a server problem disrupts the normal process. This will run every 20 minutes between the hours of 7AM to 7PM Daily (Weekdays) and at Noon daily on Saturday and Sunday.

 Study submissions are now prevented from being added to a full board committee agenda date after the meeting has already occurred. In the event a submission needs to be added on the day of the meeting due to extenuating circumstances, please contact IRBIS Helpdesk at IRBIS@unc.edu

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The IRBIS Admin timestamp log now captures which OHRE staff person created an Administrative Closure submission and the date and time it was generated.