IRBIS changes, effective 6:00 PM, March 7, 2019

Live on PRODUCTION - HOTFIXED IN 5.10.03.15:

The Chair auto-save is now repaired for all buckets.

NSIs that have been finalized should now be populating out of the buckets into the correct location.

Part C (Was this a serious adverse event?) of the NSI form is no longer populating to the admin view despite having no data entered.

Options > Change Review Type is now properly reflected in the revised buckets.

Exempt Category 3 is now properly allowing an Exempt application to be displayed.

HUD and NHSR application now show N/A for the Hospital Entities RiskManager COIs to align with UNC Policy.

Submitted NSIs (NR) ready to be accepted are now showing up correctly in the buckets

IRBIS 5.10.04 Update:

Going Live on March 7 at 6 PM:

If a letter has sent to the Chair and the Chair deletes the letter, the submission will revert to the previous Full Board or Not Full Board bucket for Analyst review.

MyChart is being added as a checkbox in the B.1. Methods of Recruiting section, just below Join the Conquest. For now, this is only available to a select pilot group of researchers --- and they must have proper approvals in place to use this option.

If MyChart is checked, the following text is displayed:

- Use of MyChart for research recruitment purposes is currently available only to studies which meet specific criteria to participate in a pilot test. Please contact stephanie.deen@unchealth.unc.edu if you would like to see if your study meets the criteria for this use.

A new monthly report listing all researchers listed on an IRB application in the role of Principal Investigator for the first time will be delivered to: chrisnel@email.unc.edu; buchholz@unc.edu; lbcowan@unc.edu; matamoro@email.unc.edu.

Administrative Closure submissions will be added as a pilot project. To start, only the Development Team will have access to create this submission type by clicking a new Admin Study Closure button, but we expect a full launch in late Spring.
Once the Administrative Closure submission has been created, they will be visible in Waiting Triage > Accepted. Once the review type has been added, they will move to the next bucket, as appropriate.

The Development Team will need to review any submissions in routing, in draft, waiting PI responses, or awaiting review prior to the Administrative Closure being finalized. In the next IRBIS update, additional improvements are planned for this process.
**Institutional COI** display has been added in the Principal Investigator COI review result column.

Display of the Institutional Review Results in the COI Review Result column have a few options:

1. If both PI and Institutional are No Conflict - only a single No Conflict result will be displayed
2. If one is No Conflict and the other is a "conflict" - The "conflict" determination will be displayed.
3. If both PI and Institutional have differing conflict results, both conflicts will be displayed (if both the same, only once)

Investigator Review Results:

<table>
<thead>
<tr>
<th>No Conflict</th>
<th>Acknowledged</th>
<th>Admin Considerations</th>
<th>Deferral</th>
<th>FCOI Management</th>
<th>No Evaluation – Declined/Withdrawn</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Funded</td>
<td>Not Manageable</td>
<td>Rely Ext Policy (Manage)</td>
<td>Rely On Ext Policy</td>
<td>Transparency</td>
<td>Unsubmitted</td>
</tr>
</tbody>
</table>

Institutional Review Results:

<table>
<thead>
<tr>
<th>No Conflict</th>
<th>ICOI management</th>
<th>ICOI transparency</th>
<th>UNC Transparency</th>
<th>Blank (in which case the hardstop will request you contact <a href="mailto:COI@unc.edu">COI@unc.edu</a>)</th>
</tr>
</thead>
</table>

If no Institutional Conflict selection has been finalized in AIR, *Blank*, you will encounter a hardstop screen at the time of letter creation which says:

The Principal Investigator has not had their Institutional COI Disclosure reviewed at this time.

In this circumstance, the COI office would need to indicate the appropriate Institutional Review Result or OHRE may choose to override the requirement with proper approval.

The NSI Form, Question E1 has been updated:

**Prior:**

Have you established a corrective action plan to prevent future occurrence of the event? Yes/no
Describe the corrective action plan:

**Revised:**

Please indicate the root cause of the event and provide a Corrective and Preventative Action (CAPA) Plan that addresses the root cause.

When an existing research personnel team member has been promoted to new Principal Investigator of a project, the new icon will now be displayed next to their name.
Additionally, a yellow triangle will indicate they have not yet had the special PI COI disclosure generated. You will still need to contact IRBIS@unc.edu to have the new COI generated, but we are working to get that function opened to all staff in the next few months.

In the Multisite section, the Local Consent Forms document type has been revised to read Local Consent forms and Ads: