IRBIS changes, effective 5:00 PM, January 4, 2018

IRBIS 5.09.03 Update:

New sIRB tab for Researchers to view multisite related documents:

By clicking on the icon, Researchers will be able to view the current approval status of the site, as well as the history if changes have been made. Please note the yellow triangle indicating that the sites have not yet been approved.
New read-only Researcher view of the Personnel tab:

![Image of the Personnel tab]

This revised view includes the CITI Good Clinical Practice (GCP) status as well as the COI policy for external sites.

If Researchers manually enter an external site name (rather than using the lookup), a hard stop for the submission until the data is validated.

External Site COI Policy:

- Undetermined (default)
- TBD
- UNC Policy
- Site Policy

Once changed from Undetermined, it is not possible to return. The Policy must be set by someone with a new role “IRB COI Policy Manager”. Until the policy is set, the submission is not able to be finalized. John Roberts will be responsible for setting this policy for the time being.

If the external site elects to use UNCs COI Policy, UNC COIs will be automatically triggered via AIR and the existing COI hardstop will be applicable.
IRBIS will now auto generate COIs for all internal staff added during a modification submission (UNC, Rex, other Affiliates), per existing UNC policies.

Please note: During the transition, a COI override may be required for certain scenarios. For example: Co-Is (non faculty) who had for one reason or another missed having a COI manually triggered. Please contact IRBIS@unc.edu if you believe your submission is eligible for a modification related COI override. The COI office is aware that this may be the case for a temporary amount of time.

The Review Results screen has been updated so that when a submission is set to ‘Approved’ and External Site Status link appears:
You will be required to review and confirm this screen after entering the review results and clicking Draft Letter:

Sites will be marked as Inactive by default:
When a site is activated, you should indicate this via the toggle:

When active, the sites are automatically included in the approval letter template:

Once approved, please note the green circle icon indicating that each of these external sites have now been approved:
By clicking on the icon, you can see the history of that site’s status:

Under the Options tab, a new sIRB Attachments tab is now available:

Here, Admin users will be able to download copies of sIRB related Attachments, regardless of submission status (e.g. if Barbara or John need to upload a revised copy of the Local Context Worksheet or Agreement). Here you will also be able to easily see the status of the external sites.

Any other changes should be done by the Researcher during a normal modification submission.

Researchers new to the application on the current submission are now flagged for special attention: