IRBIS changes, effective 6:00 PM, July 31, 2018

IRBIS 5.09.14 Update:

Changes to emails Investigators receive re: outdated stipulations have been made. Previously, there were slight differences in the text for the 30 and 60 day messages. These are now the same. As a next step, ORIS will be working on adding additional reminders for every 30 days until stipulations are resolved. This is expected in August 2018.

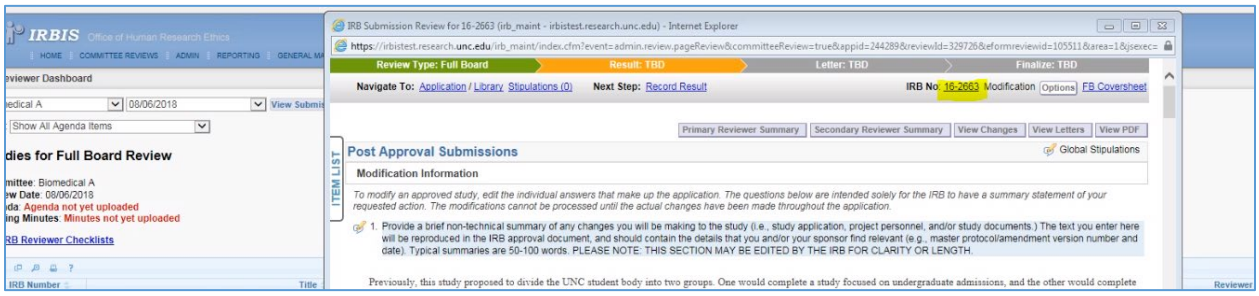
Current:

> IRB records indicate that you have not responded to stipulations relating to study #18-0881. Please respond immediately. Submissions that are not resolved within 90 days from the date listed above will be withdrawn from consideration, unless the IRB has agreed to extend this time. Please contact the IRB Help Desk at 919-966-3685 for help

Revised:

> IRB records indicate that you have not responded to stipulations relating to study #18-0881. Please respond as soon as the issues have been resolved by clicking the link below, responding to each stipulation, and then clicking Proceed to Resubmit.

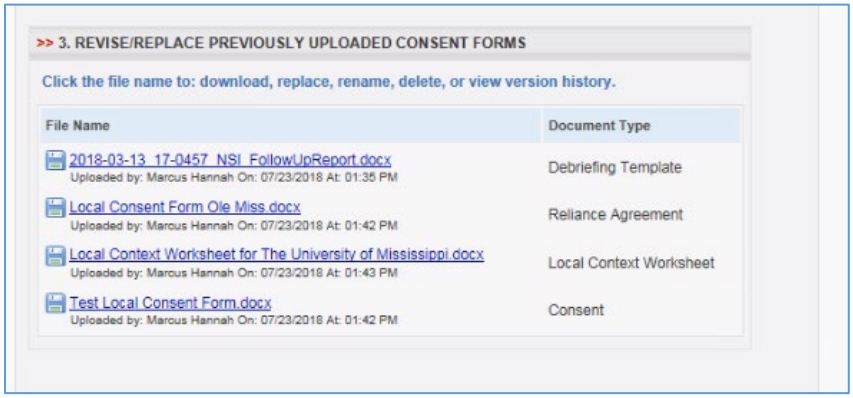
The IRB direct link from the Committee Reviews screen to the Admin full history of the study has been added for all IRBIS Admin roles. Previously, this was only available to Committee Members:



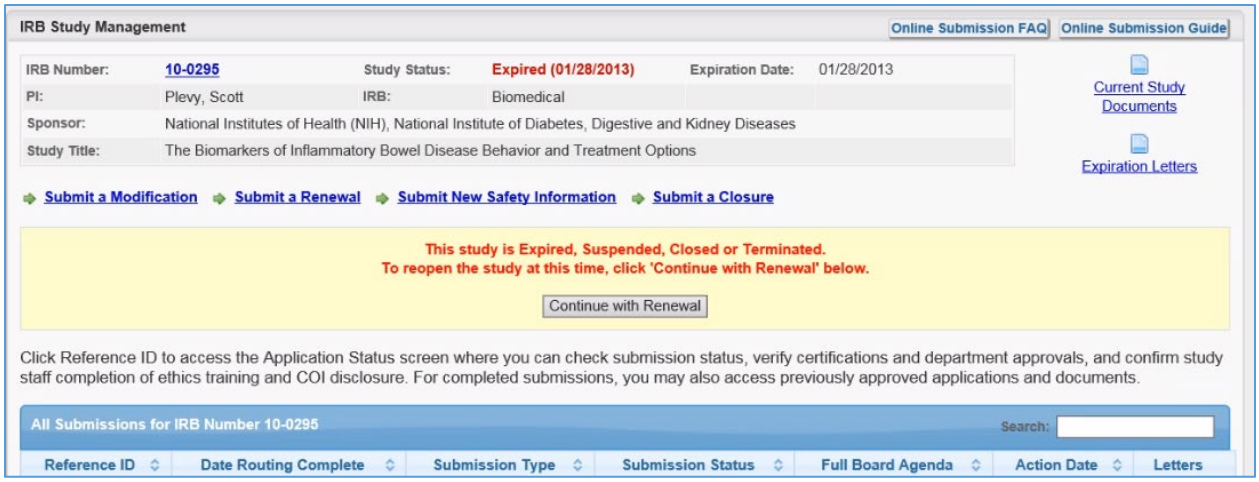
Letter templates have been updated to include both the Principal Investigator and the Faculty advisor in the TO field of the email. Previously, the Faculty Advisor was in the CC field of the email. This will impact all submissions Accepted by the IRB as of August 1, 2018. Submissions accepted prior to August 1 will have the FA remain in the CC field.

The IRB Full Board agenda document has been updated to remove studies with the study status of withdrawn and rely on an external IRB from the list of studies approved by expedited review.

New attachment types of Reliance Agreement, Local Context Worksheet, and Local Consent Form. This is for use on project where UNC is ceding review and relying on an external IRB.



For studies currently expired, we displayed a warning noting that a renewal was recommended, but it was still possible to proceed with a modification. With this update, expired studies will block the creation of modification and force users to instead submit a renewal submission.



Conflict of Interest Disclosures have been revised for projects designated Exempt.

Current:

- NHSR: No COI created or required
- Exempt: Initial submission

Revised:

- NHSR: No COI created or required
- Exempt, Initial submission, any modification where new staff are added

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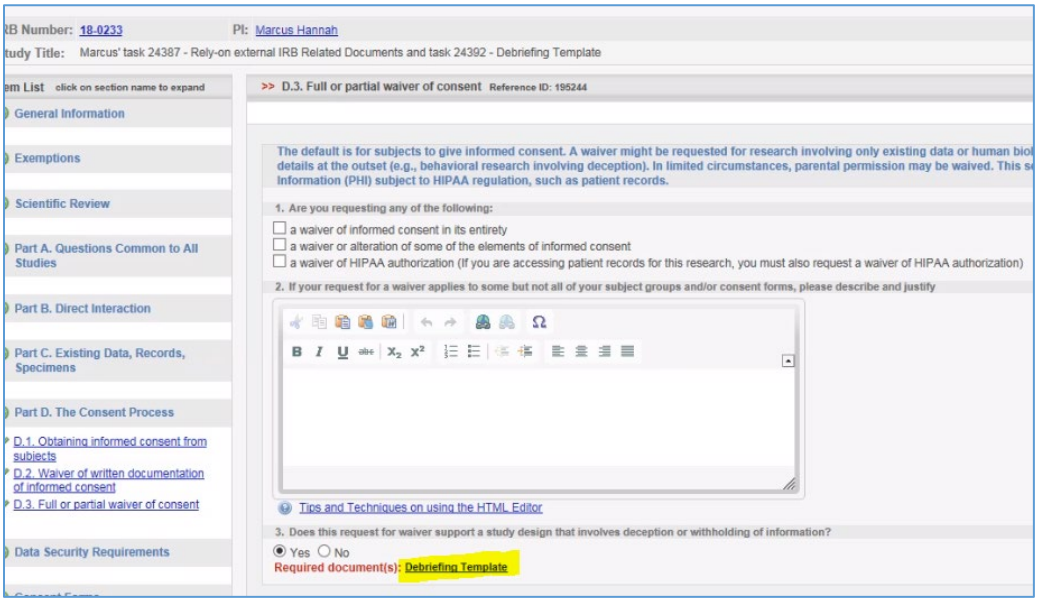
Changes have been made to the Debriefing Template. The document has been relabeled to Debriefing Template and made a required document. It links to an updated form: https://research.unc.edu/files/2018/04/Debriefing-Form-Template.docx



RAMSeS listings of Prime sponsors have been cleaned; previously they would show the prime sponsor name multiple times:

Current:

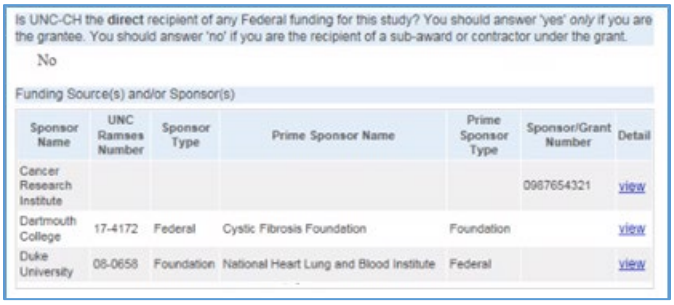
Is UNC-CH the **direct** recipient of any Federal funding for this study? You should answer 'yes' *only* if you are the grantee. You should answer 'no' if you are the recipient of a sub-award or contractor under the grant.

No

Funding Source(s) and/or Sponsor(s)

Sponsor Name	UNC Ramses Number	Sponsor Type	Prime Sponsor Name	Prime Sponsor Type	Sponsor/Grant Number	Detail
Cancer Research Institute					0987654321	view
Dartmouth College	17-4172	Federal	Cystic Fibrosis Foundation,Cystic Fibrosis Foundation,Cystic Fibrosis Foundation,Cystic Fibrosis Foundation,Cystic Fibrosis Foundation,Cystic Fibrosis Foundation,Cystic Fibrosis Foundation			view
Duke University	08-0658	Foundation	National Heart Lung and Blood Institute	Federal		view

Revised:



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