

IRBIS changes, effective 5:00 PM, November 8, 2019

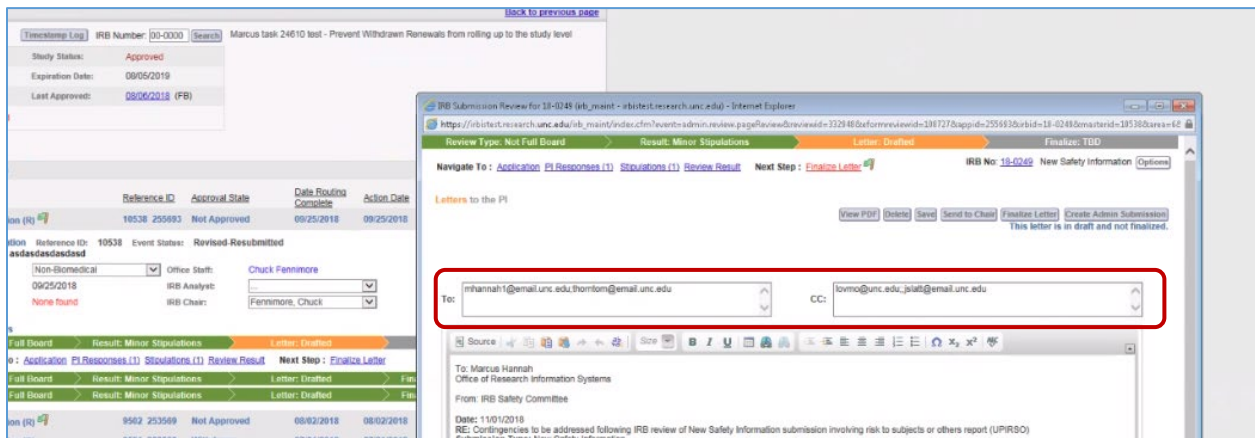
IRBIS 5.09.18 Update:

In 5.3.4, Research Locations, and the Network Entity-Permission to register letter template, the email address for review has been updated to: ORSC@unhealth.unc.edu.

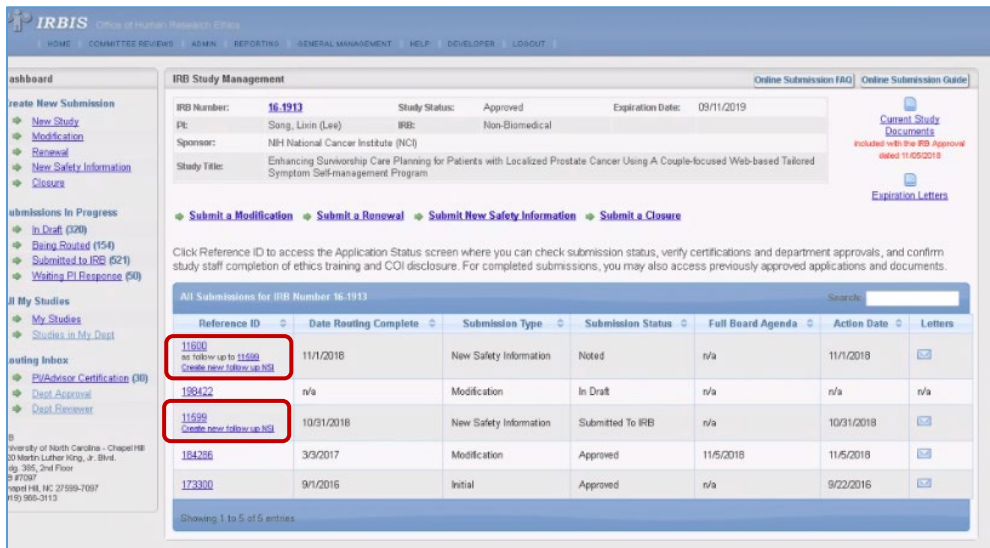
The Network Entity Facility Request form has been updated.

High Point has been removed from the list of HealthCare setting locations.

In the letter draft and finalize views, the email field has been expanded to enable a better view when multiple email addresses are included:

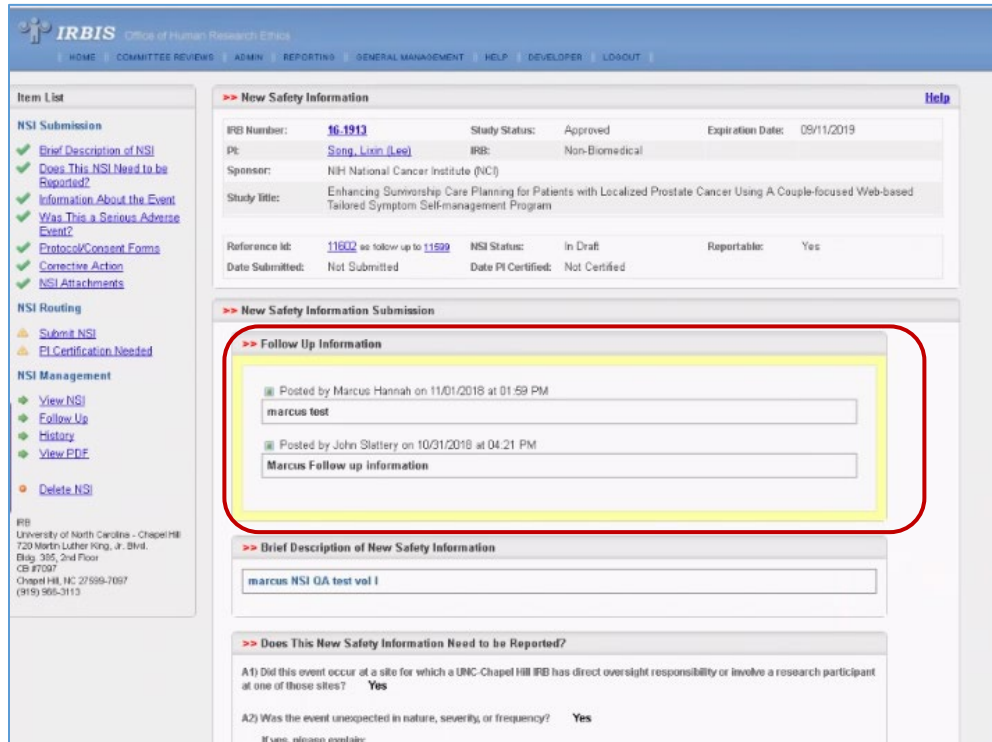


Added a new link to create a follow-up to an existing NSI:



A proposed change of one follow-up submission per ID has been added. If a follow-up has already been submitted to NSI 001, the second follow-up should be a follow-up to NSI 002, rather than a second follow-up to NSI 001. This would prevent multiple conversations about the same topic. This should be fixed in the next update.

The Follow-up box has also been moved to the top of the form:



NSI attachments associated with NSI submissions will now be associated with the submission that they were original attached to. Only new documents will be labeled as new. Currently NSIs do not have the ability to upload revised versions of existing attachments.

NSI Submission – Not Full Board: One the Review Results screen – study specific findings and Risk determination windows are now greyed out. Internal Meeting Notes is now enabled to accept notes in preparation for the SWAG review update.

NSI submission markers are now displayed on all screens to indicate if a Modification or Renewal (with Modification) has answered Yes – that the modification is being submitted in response to New Safety Information.

Submission Type	Reference ID
>> Renewal (w/ Modification) (NSI)	231932
Submission Information	
Submission Status: Accepted	

Study Notes: by Shahila Sriskanda on 09/04/2018 at 10:17 AM

Submission Type	Reference ID	Approval State
Modification (NSI)	231915	Approved
Submission Information		
Submission Status: Completed Reference ID: 2319		
IRB:	Biomedical	Office Staff: Darcy Gunn
Accepted By IRB:	09/26/2018	IRB Analyst: Cat Collins

As previously stated, if this is answered as a “Yes”, please notify Jeanne by email as these may be time sensitive, as these need to be triaged to SWAG and should not be processed as a regular modification unless given direction by Jeanne to do so.

Launch of Study Tags: ready to go, but feature is turned off. We will schedule a special announcement/training session for this item next week.