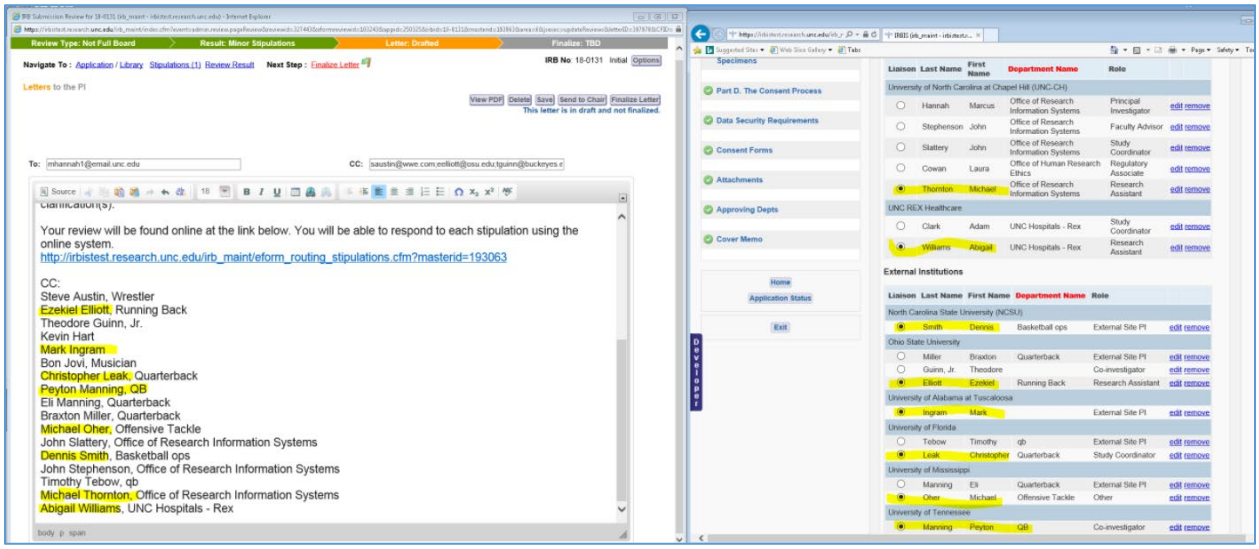
IRBIS 5.09.08 Update:

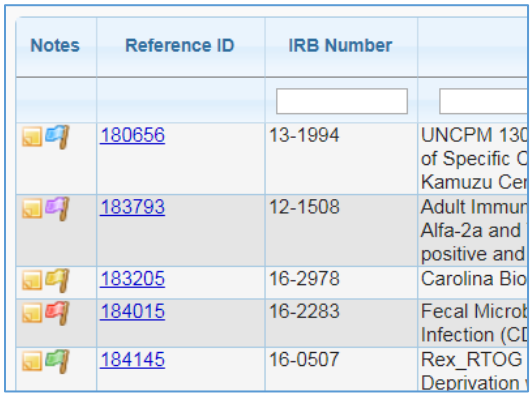
Personnel indicated as Liaison will now receive all IRB Correspondence. This applies to all marked as Liaison from UNC Staff, External Institutions, and Independent Investigators.



The exception to this is that Liaisons from External Institutions, personnel from External Institutions, and Independent Investigators will no longer receive 'non-final' IRB correspondence. They will not receive notices of minor stipulations, minor stipulation reminders, renewal reminders, disapprovals, withdrawn submissions notices.

They will only receive notices of submission approval or study suspension, closure, and expiration.

The revised flag colors from the last update have now been applied to the buckets too:

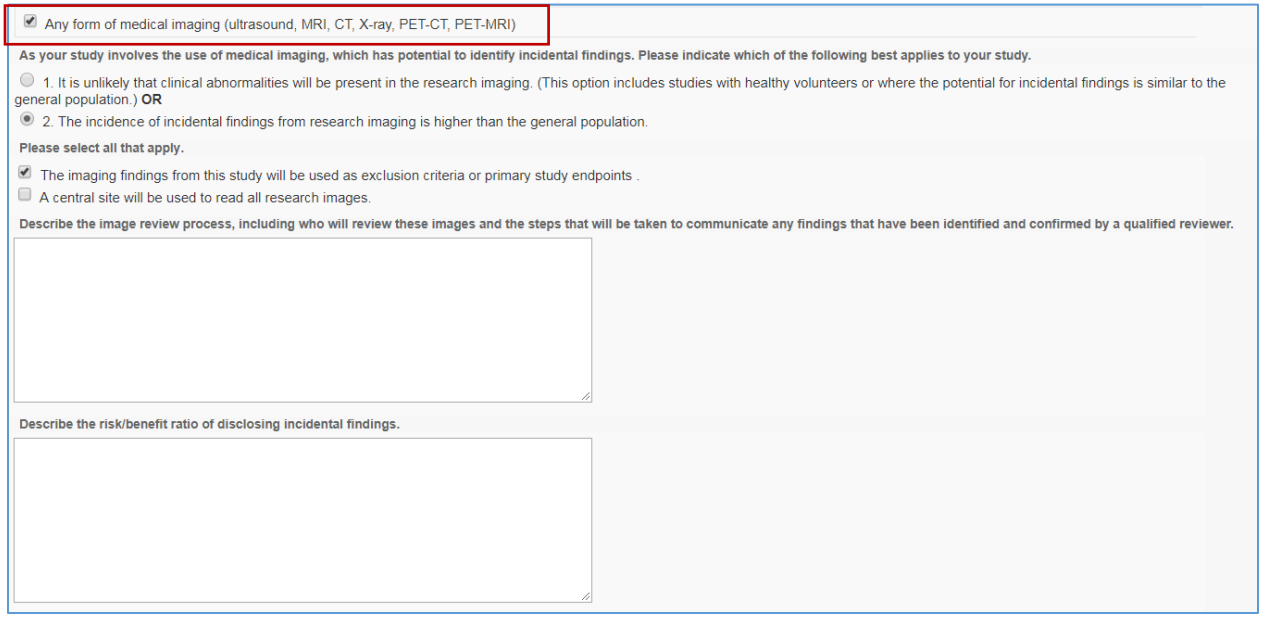


Stipulations that are re-sent should now be displaying the Analyst who wrote the stipulation rather than the name of the chair who sent the letter.

A.4.A, Biomedical methods and procedures has been revsed to update the imaging section.

A new checkbox has been added to the bottom of the question 7 list:

- Any form of medical imaging (ultrasound, MRI, CT, X-ray, PET-CT, PET-MRI)
- If selected options 1 and 2 appear with additional checkboxes and text boxes.



Additionally, specific tags are displayed within the Adult Consent Form and the Parental Permission Consent Form depending on which options are selected.

What will happen if you take part in the study?

Whenever imaging [MRI, CT, X-ray, etc.] is done, there is the chance of finding something unexpected. Unexpected findings can have clinical significance, or no clinical significance. Clinically significant means that the [MRI, CT, X-ray, etc.] shows a problem that may or require further follow up or treatment. The imaging studies in this study will be reviewed by a qualified radiologist. You will be informed of any findings of clinical significance that may be discovered during the imaging procedure.

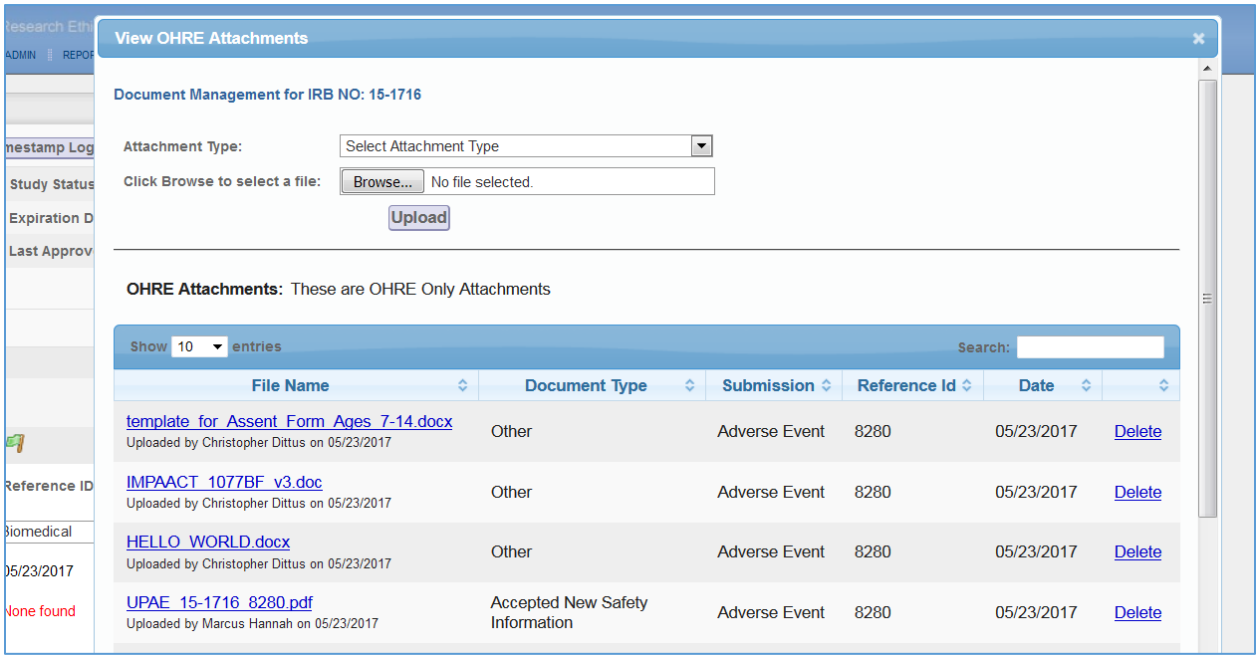
There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate). The [MRI, CT, X-ray, etc.] we are using in this research study is not the same quality as a [MRI, CT, X-ray, etc.] that you may have as part of your health care. If you believe you are having symptoms that may require clinical imaging, you should contact your primary care physician.

If a central site will be used to read research imagines your [MRI, CT, X-ray, etc.] will be conducted here at UNC no UNC physician will review the [MRI, CT, X-ray, etc.]. Rather, your images will be reviewed by a "central reader," a physician designated by the sponsor of this trial to review all of the images. We will inform you of any findings of clinical significance that the central reader tells us about.

Submissions that are given an "NHSR" review result are now blocked from creating/submitting a closure submission form. Modifications and NSI submission types remain.

During the routing process, Department Approval reminders are now sent on Day 0, Day 7, and then daily until completed. This is the same schedule as the Principal Investigator and Faculty Advisors.

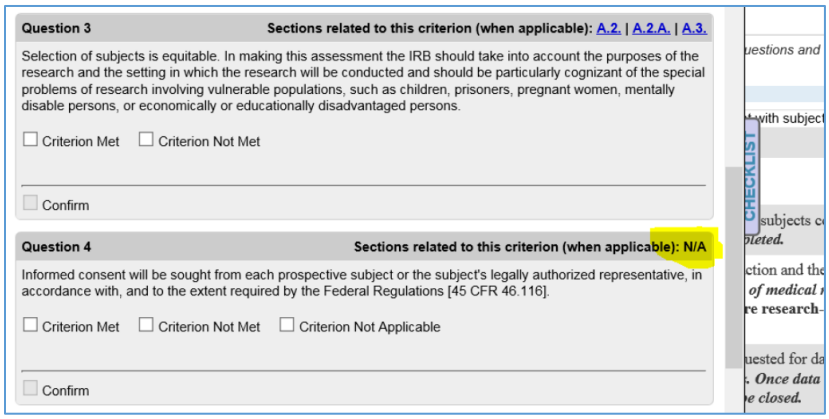
OHRE Attachments have updated to a new file table:



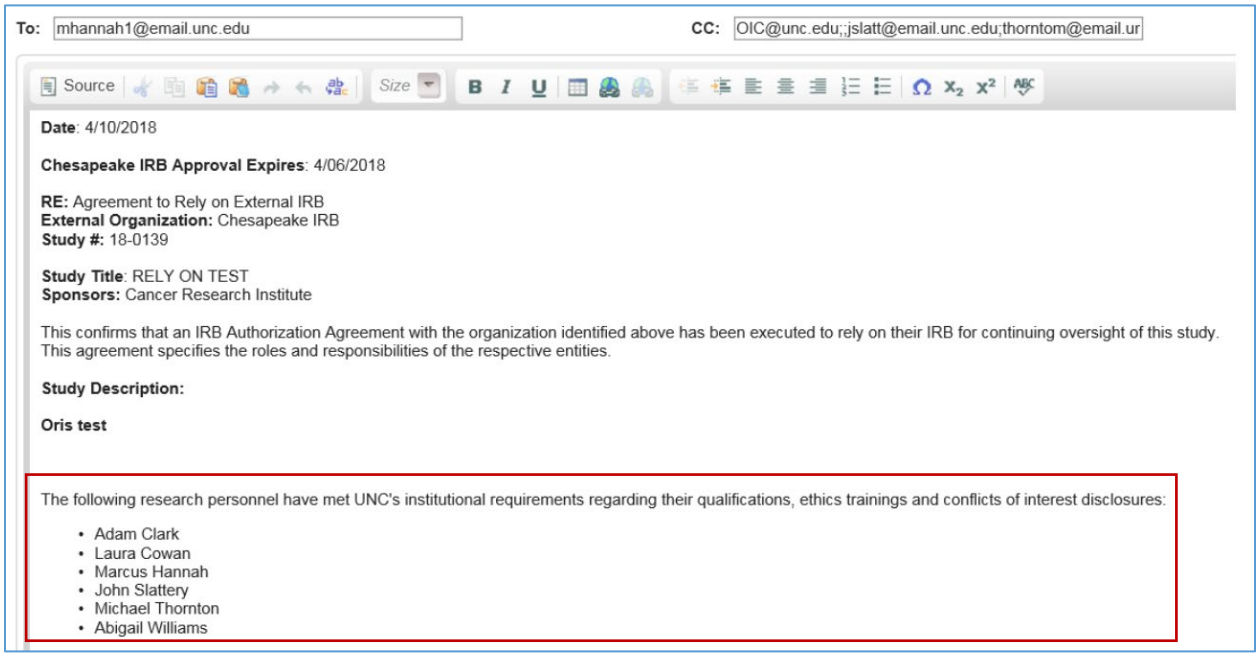
The table sorts by default to the most recently uploaded documents. The Reference ID has been added to help you to better identify documents associated with particular submissions. You can also search by submission type, reference ID, file name, date, or any other content available in the table.

This also appears at the bottom of the Committee Reviews window for use by Committee Members.

The Expedited Checklist now notes N/A when no section of the application is applicable:



Studies that Rely on an External IRB will now have all personnel automatically listed in the drafter letter template:



When an NSI is submitted, the explanatory text has been updated:

Prior:

Are you ready to submit this New Safety Information?
Please review and submit below.
Please upload any attachments using the Attachment tab on the following page.
The final step in this process is to have the new safety information submission certified by the PI; the IRB will not receive this new safety information submission until the PI has certifed.

Revised:

Are you ready to submit this New Safety Information?
Please review and proceed by clicking the Submit button.

You will have the opportunity to upload any attachments by clicking the Attachments tab on the next page.

The New Safety Information submission must be certified by the Faculty Advisor (if applicable) and the Principal Investigator. **The IRB will not receive this New Safety Information submission until the PI has certified.**

Faculty Advisor certification has now been added to NSI submissions. When an NSI report is submitted, the PI and the Faculty Advisor will receive notification that certification is required:

TO: PI Name
PI Department

FROM: Biomedical IRB

DATE: 4/06/2018

STUDY #: 14-0210
STUDY TITLE: EPIC TEST RECORD #1
NSI Report #: [REFERENCE_NUMBER]

A New Safety Information report #[REFERENCE_NUMBER], titled "NSI Test for Laura", has been submitted for your review and certification.

The New Safety Information must be certified by the Faculty Advisor (if applicable) and the Principal Investigator. **The IRB will not receive this New Safety Information submission until the PI has certified:** Click here to certify now.

Thank you.

If the link does not work, you can access the submission directly by going to IRBIS.UNC.EDU and clicking 'PI/Advisor Certification' in the lower left-hand corner of your IRB dashboard or contact IRBIS@unc.edu for assistance.

Certification by both the Principal Investigator and the Faculty Advisor are required for the submission to be accepted by the IRB for review.