IRBIS Tips & Tricks

October 2019 IRB Board Monthly Education

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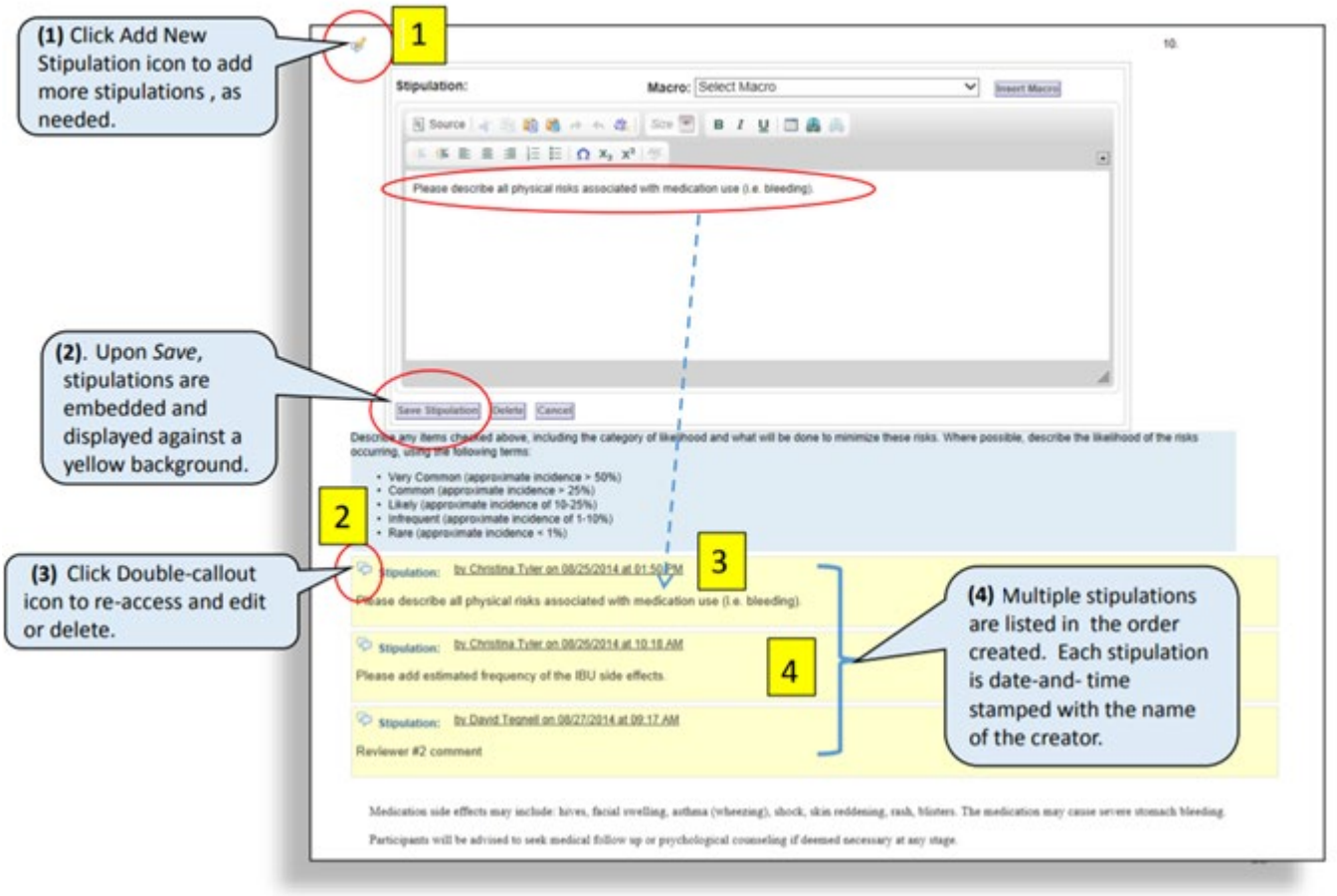
THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

Common Questions

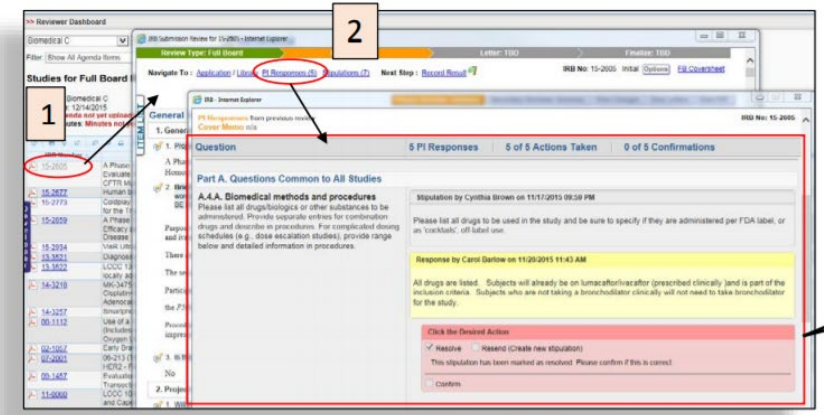
Thank you for responding to the Qualtrics survey and providing details regarding your IRBIS use and training. Major Themes:

- How to enter stipulations
- How to view PI responses to stipulations
- Reviewing Changes to IRB Applications & Consent Forms
- Navigating through all the required attachments
- IRBIS Server Speed Issues

How to enter stipulations:

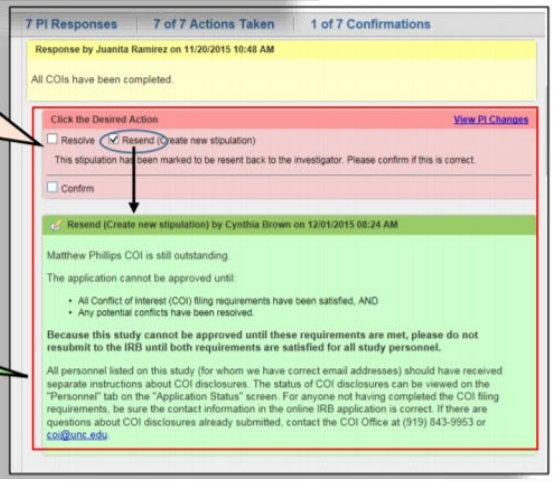


How to view PI responses to stipulations:



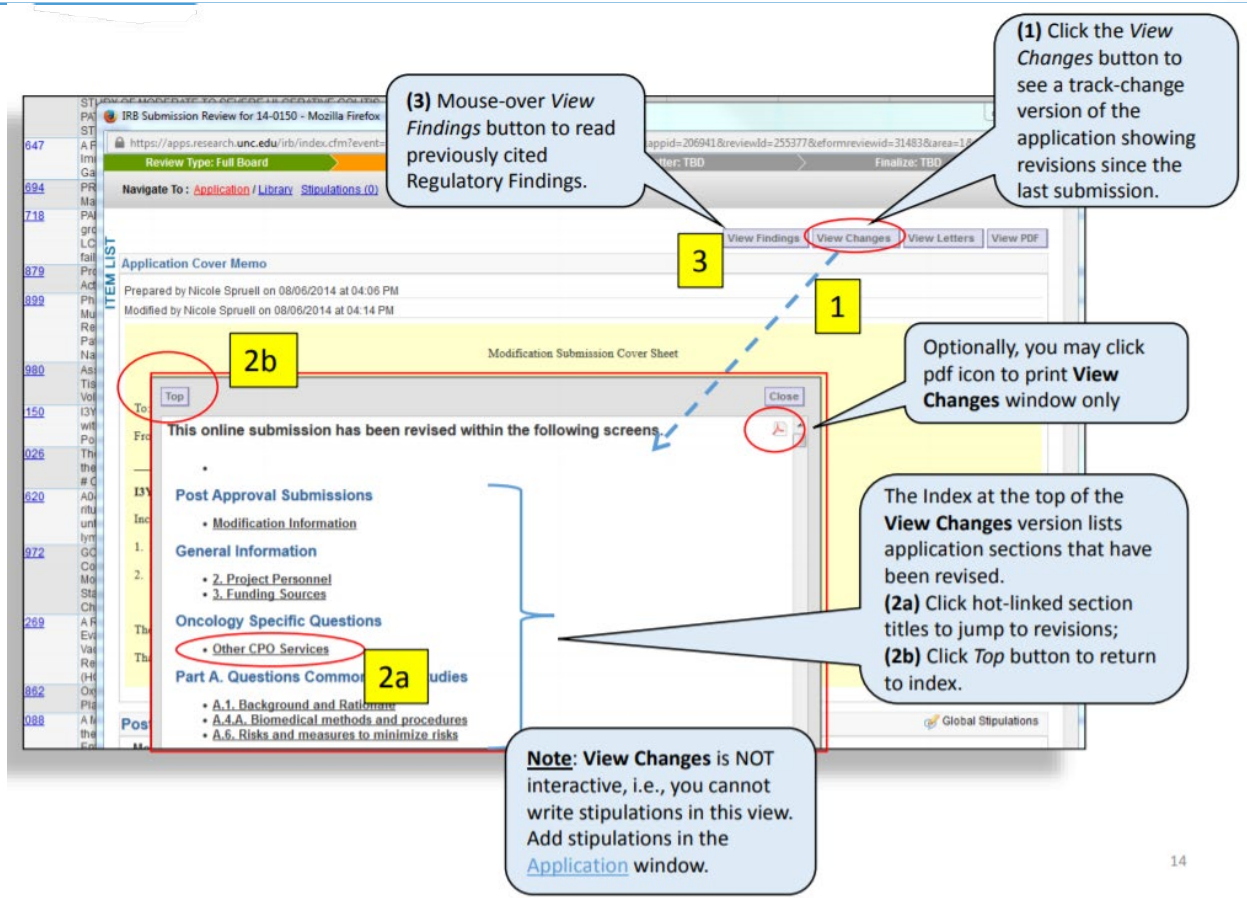
Access list of PI Responses to deferral stipulations -- *with* the IRB Coordinator's pre-meeting review displayed in pink. (**note**: this block is not interactive for board members).

During pre-meeting review, the IRB Coordinator may recommend acceptance (*Resolve*) or rejection (*Resend*) of the PI's Response to the stipulation.



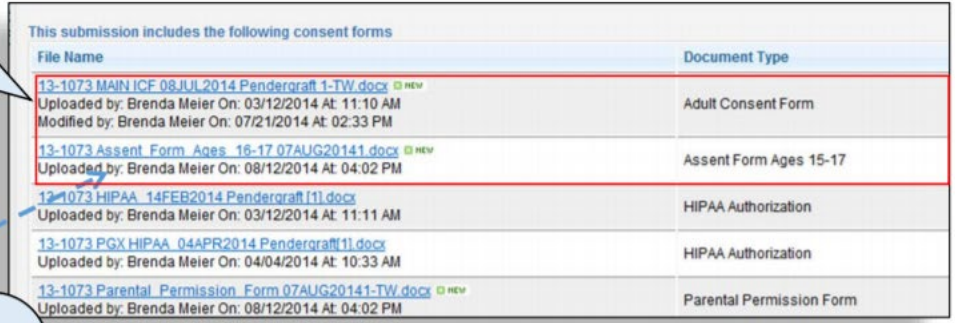
If the Coordinator checks *Resend*, a green text box opens to accommodate composition of a stipulation. Upon the Chair's confirmation (of all actions), the *Resend* is converted to a stipulation.

How to view revisions to the application:



How to view attachment updates:

Both PI-REVISED and NEWLY ADDED consent forms and attachments are designated "NEW". PI-revised documents carry the additional indication: "Modified by."

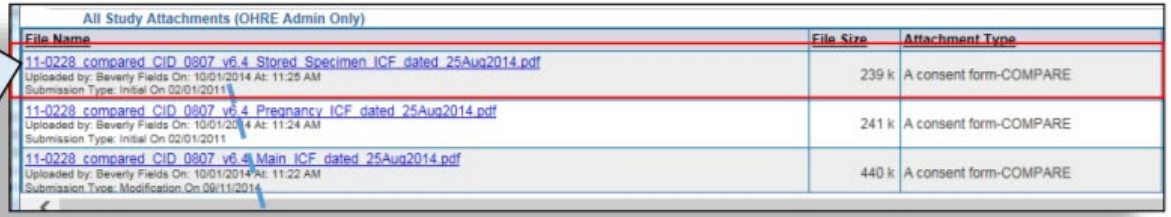


Important

- Access **NEW** docs (NEWLY ADDED and PI-REVISED) at the **Document Library**: **Consent Forms / Attachments** sections (only).
- Access "compare" versions (IRB-created read-only review copies of PI-REVISED docs) submitted in Word at **All Study Attachments** (beneath the application).

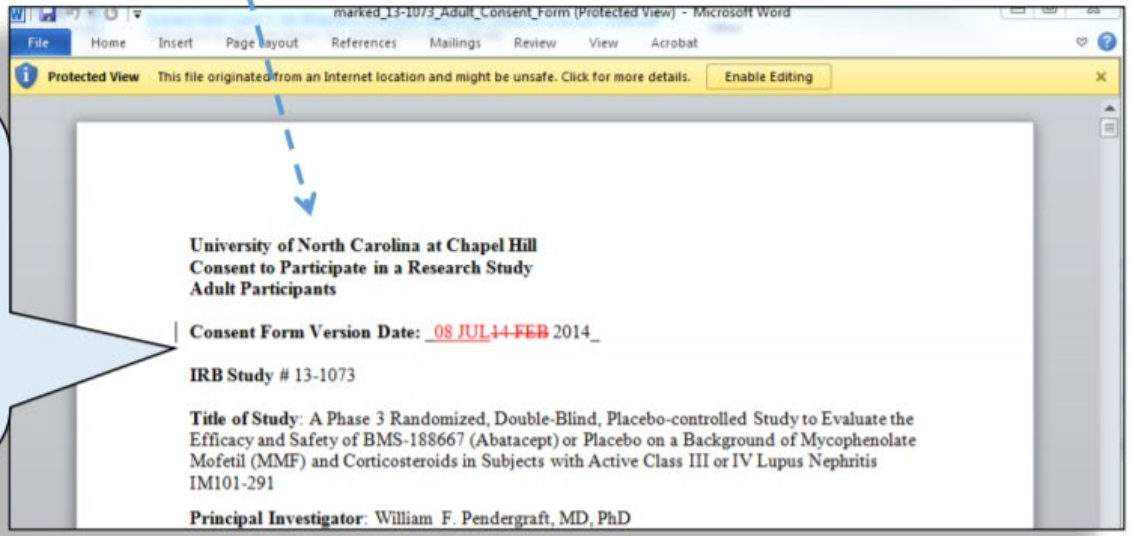
How to view revisions to consent forms:

Access "compare" versions--review copies of PI-REVISED documents submitted in Word--at **All Study Attachments** (below the application). Click blue-linked file name and then open.



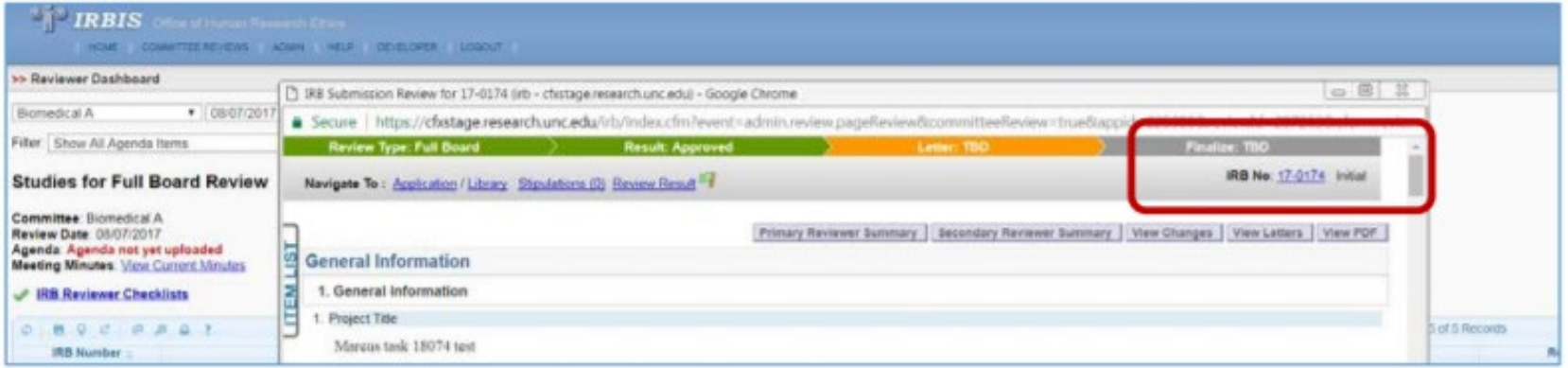
"Compare" versions are read-only review copies, showing what has changed since last approval--you cannot add comments.

Note: Add your comments to the corresponding **NEW** documents at the **Document Library**: **Consent Forms** or **Attachments** (see next slide).



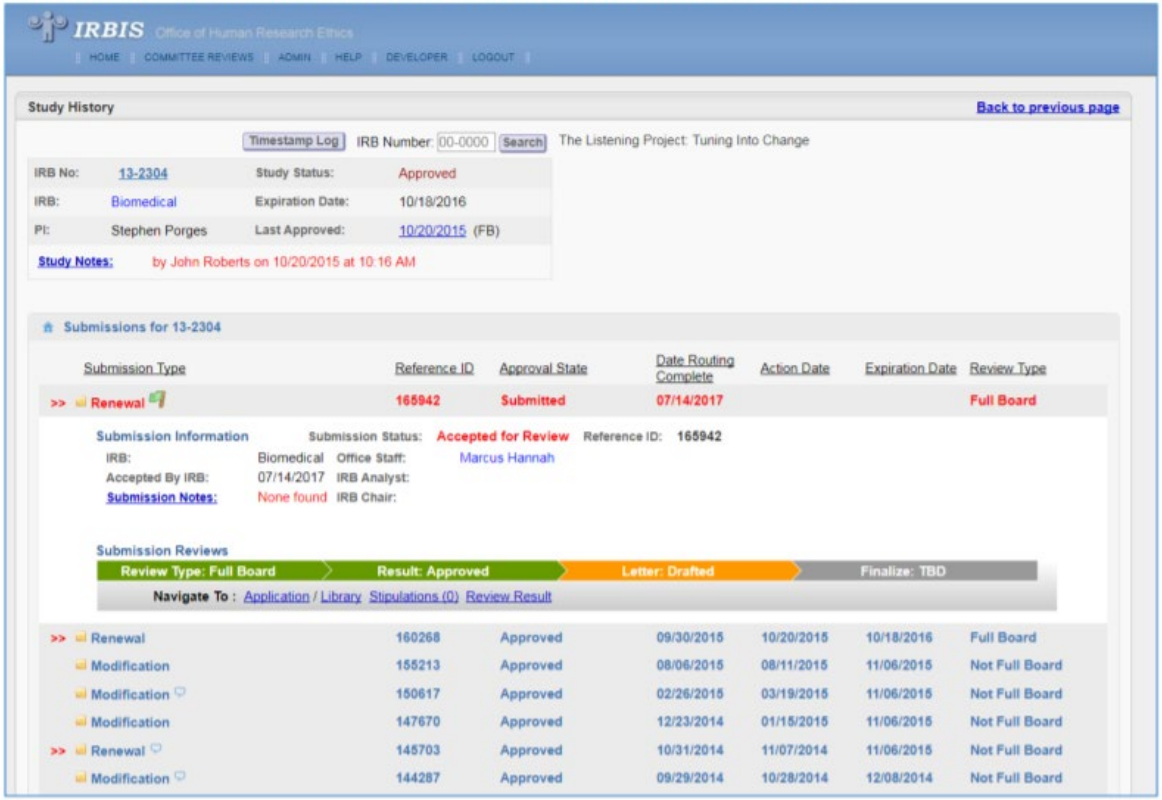
Ability to view past board discussions and findings

From the IRB application screen on the Full Board agenda, you can click the **IRB number** in the top right corner of the window to learn more about the history of the study:



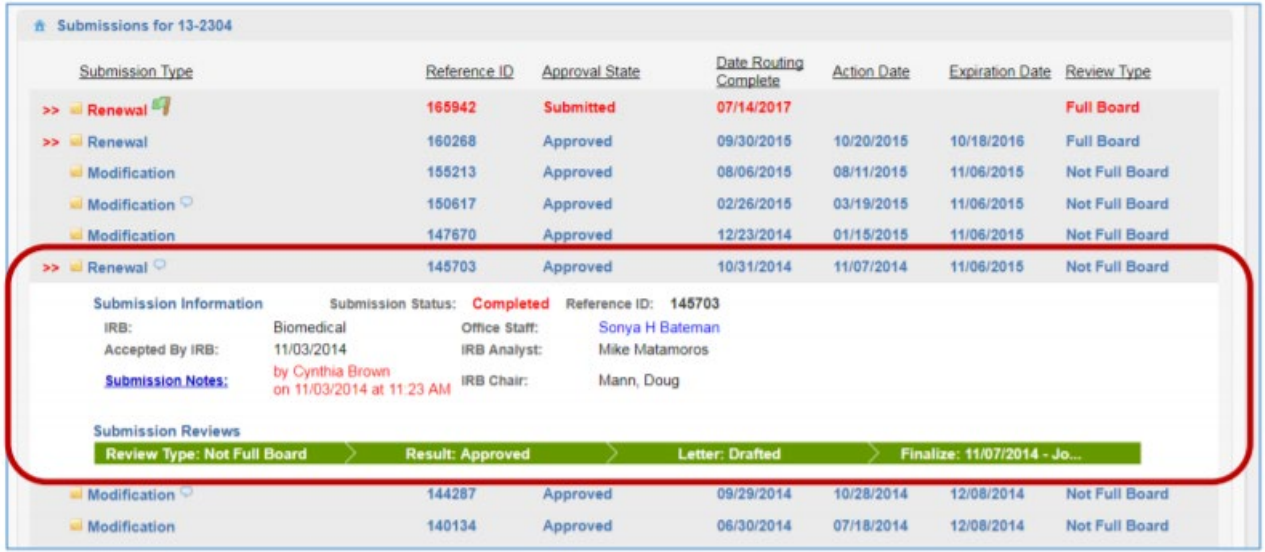
Ability to view past board discussions and findings

A new browser window will open which contains the full history of the study:



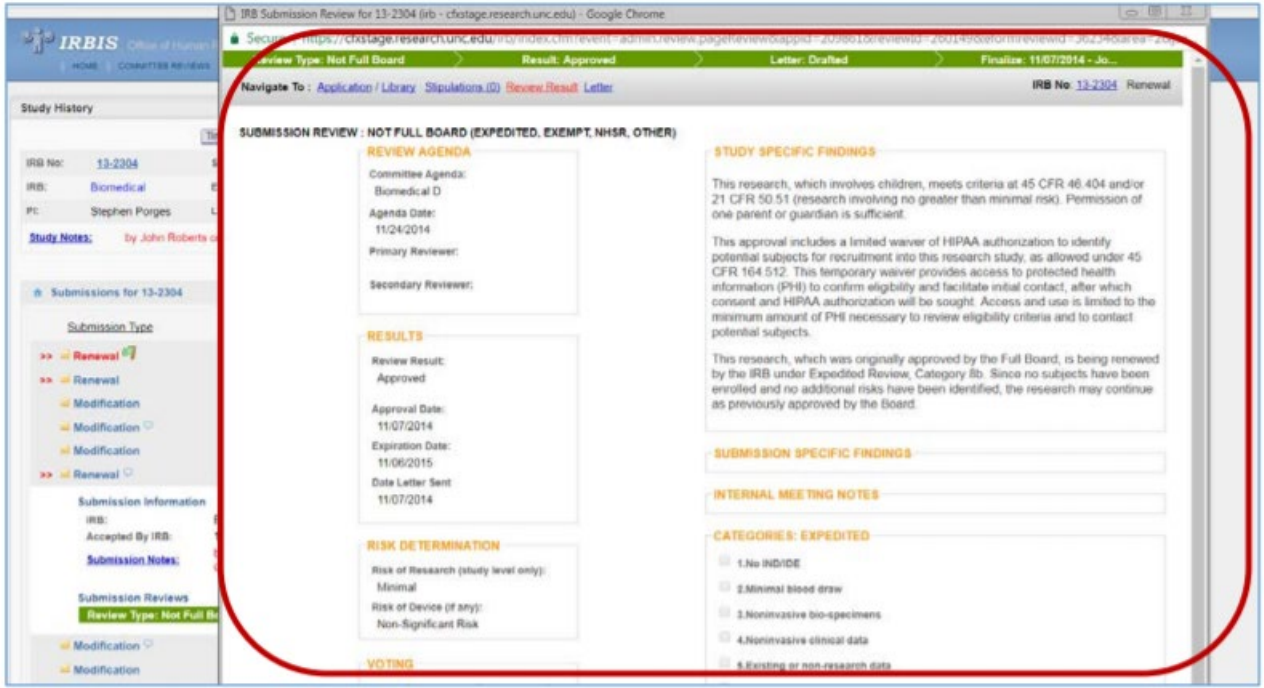
Ability to view past board discussions and findings

You can select a past Renewal, Modification, New Safety Information Report (NSI), or Initial application by clicking on that item. For example, if you wanted to review information provided in the 2014 Renewal submission for this project, click that Renewal and the associated submission information will expand for your review:



Ability to view past board discussions and findings

From there, you can click on the green swim lane to access the documentation, which will open in a pop-up window to the Review Result screen:



Here you can see the Committee that reviewed the renewal, date, risk determination, study and submissions specific findings, internal meeting notes, and voting summary.

IRBIS Server Speed Issues

Since the new server came online in July 2019, the Office of Research Information Systems (ORIS) has been working tirelessly to get the response speed back within our acceptable range. They have run countless tests and have narrowed the problem down to two items for which they are working on a solution.

We hope to have a short term solution available by the end of October, and them will begin work on a long term solution.

We appreciate your patience while we work to solve this issue!

Recommendations from Boards via Survey:

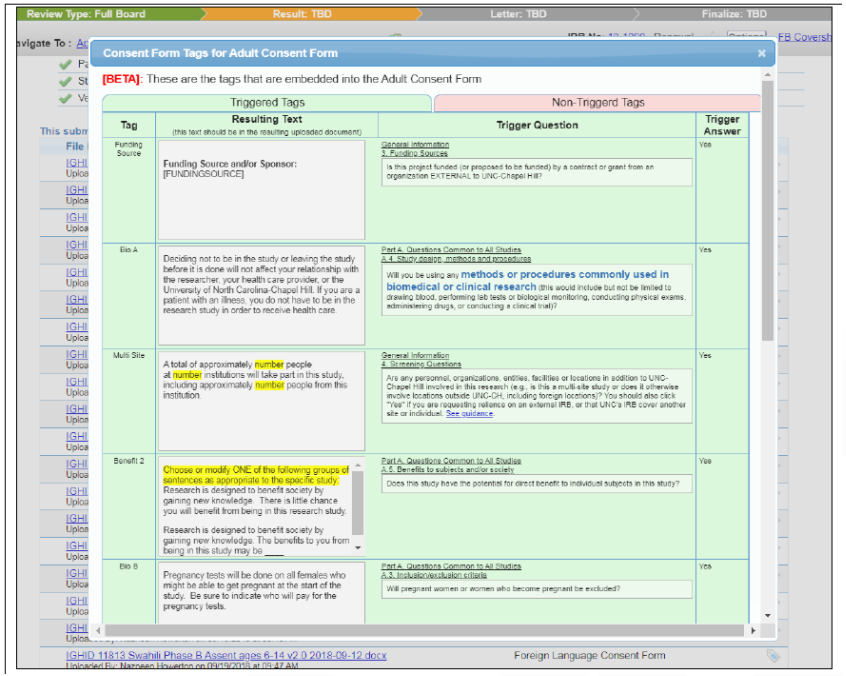
- Comparison of Consent Forms generated as HTML rather than download a file.
- PDF quick view option for attachments rather than having to download a file.
- Substantive areas outside of my expertise
- Too much jargon used at meetings that can make understanding the process challenging.
- Dual monitors and moving application / review documents around the screen / opening multiple documents tips

Additional Recommendations from Boards:

- Distinguish IRB template language from research entered data into the consent form templates
- Eliminate redundancies in IRB application
- Topic specific review checklist templates (e.g. drug study, interventional study, study involving minors)
- Include SRC Reviews and responses, including changes to study
- Integrate Reviewer Checklist into the IRB Application

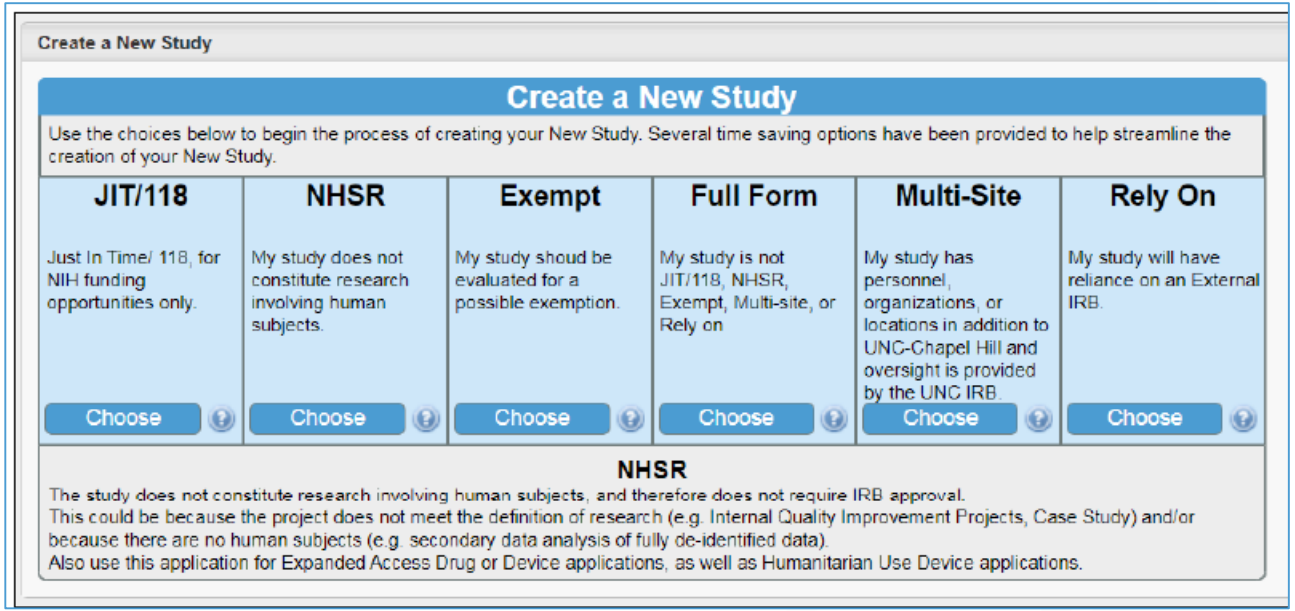
Feature Development currently in progress:

- Distinguish IRB template language from research entered data into the consent form templates



Feature Development currently in progress:

- Eliminate redundancies in IRB application



Who to contact for questions:

- Please provide any IRBIS issues, complaints, recommendations to:

IRBIS@unc.edu

- Please visit IRBMember.web.unc.edu
Member Orientation, 4. IRBIS System Orientation