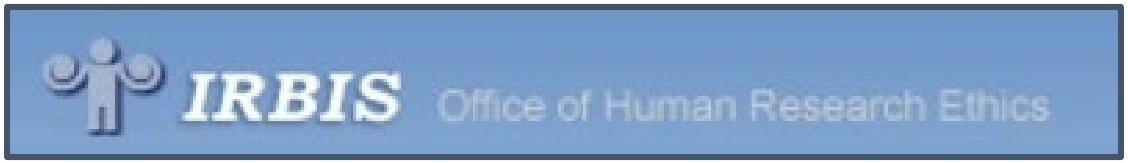


IRB Committee Meeting
IRBIS Agenda

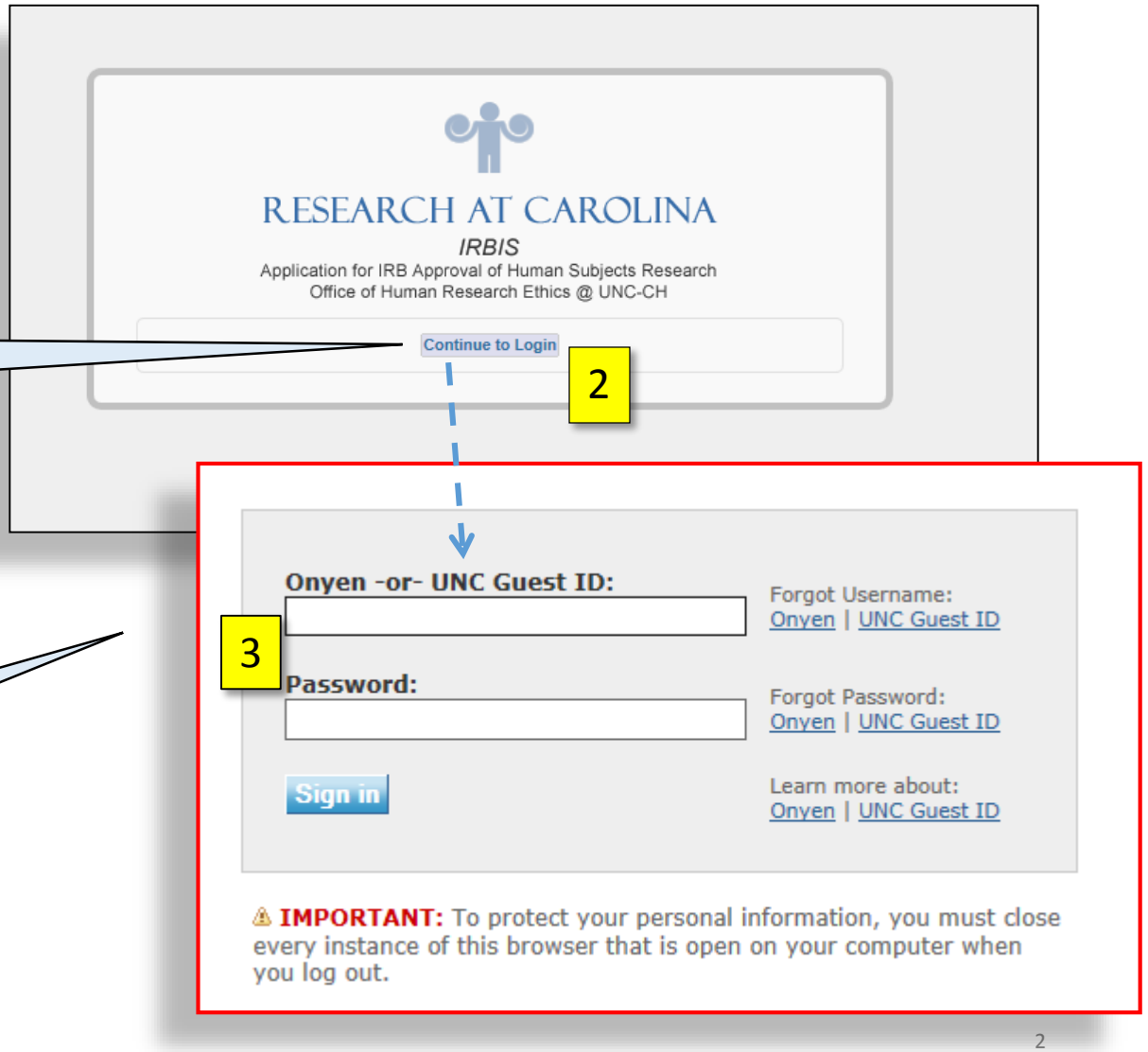
version 2/14/2020

Login to IRBIS

(1) Type irbis.research.unc.edu/irb into your browser (you may use Internet Explorer, Firefox, or Safari, but not Google Chrome).

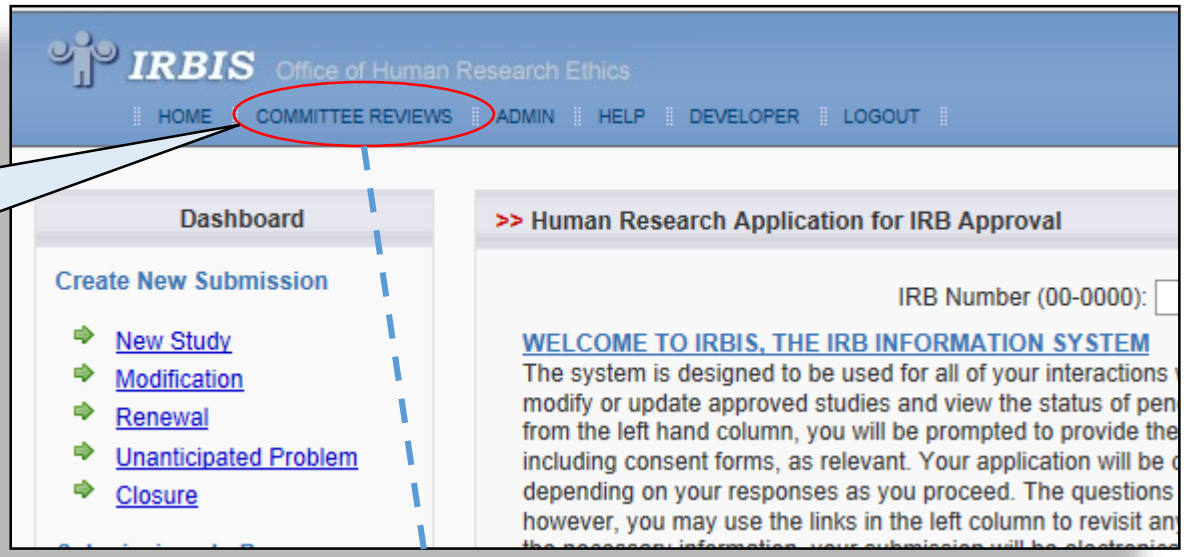
(2) At first login screen, click *Continue to Login* button.

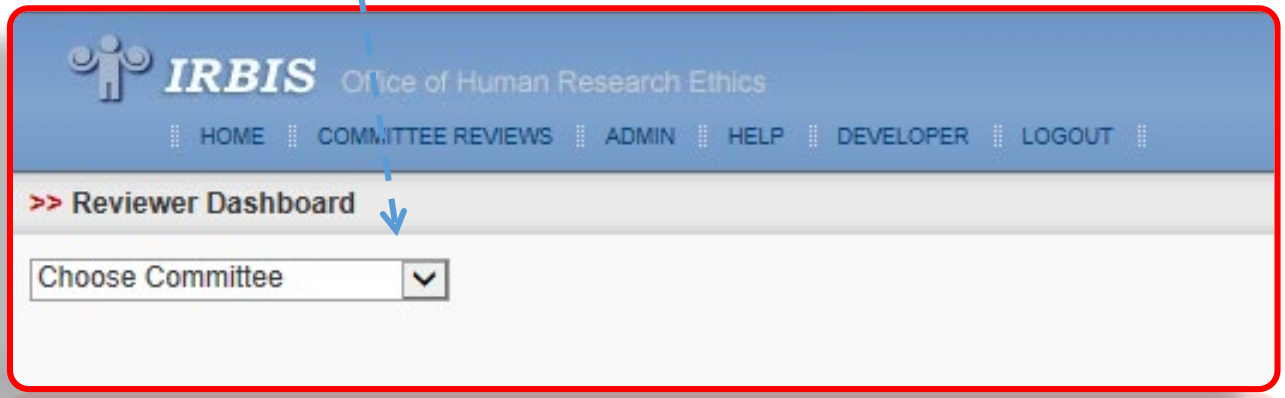
(3) At second login screen, enter UNC **ONYEN** and **Password**, and then click *Sign in* button to access **IRBIS Home** screen.



Access Reviewer Dashboard

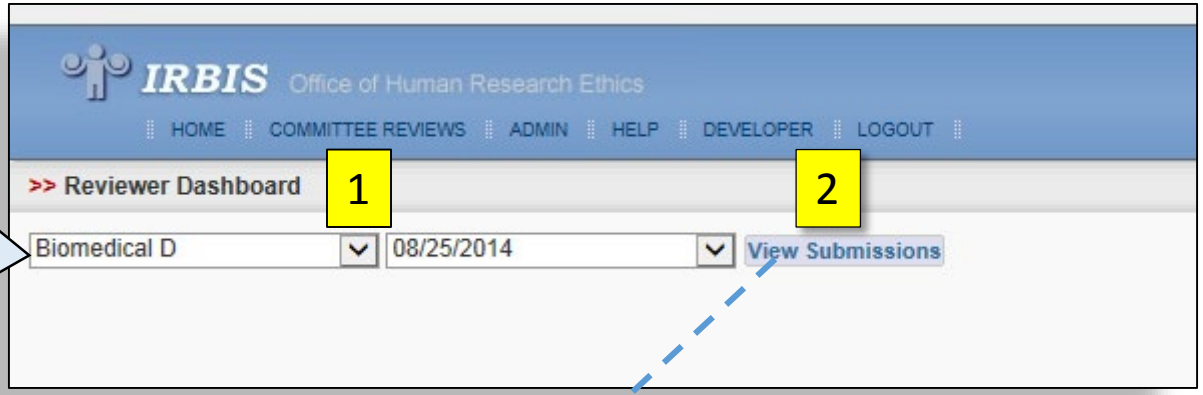
At **IRBIS Home** (your landing screen), click COMMITTEE REVIEWS to access **Reviewer Dashboard**.





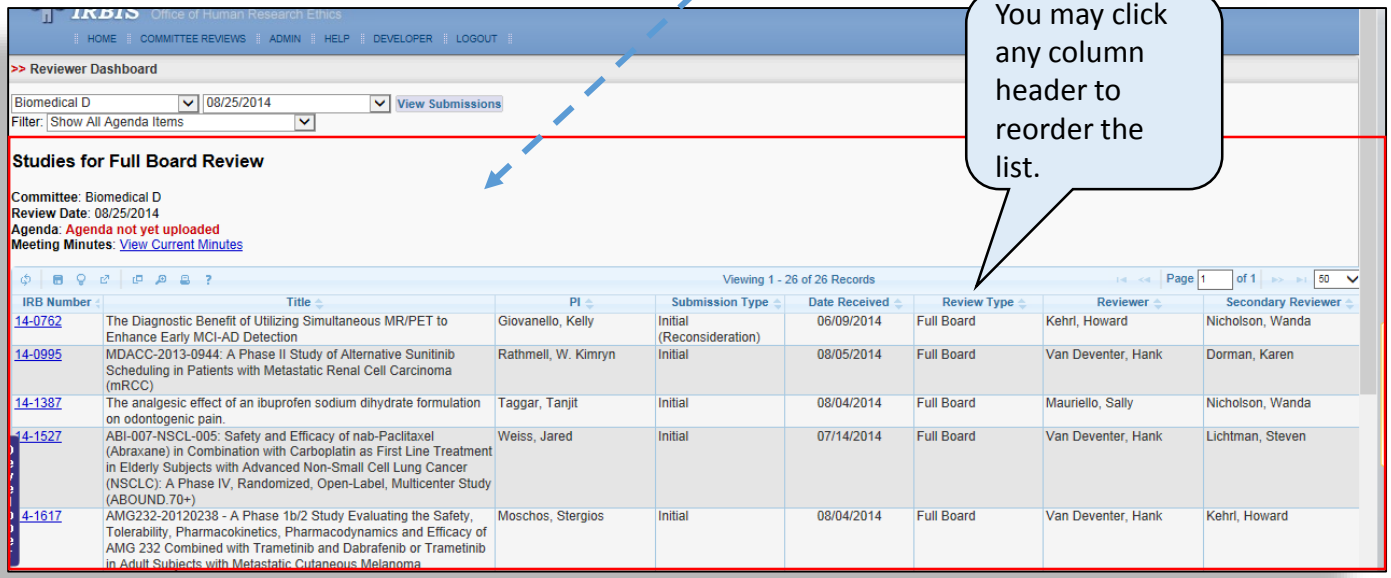
Access Committee Agenda

At **Reviewer Dashboard:**
(1) Choose your assigned committee and select meeting date; then,
(2) Click *View Submissions* button to access meeting agenda (**Studies for Full Board Review**).



As needed**, Filter** to show all agenda items, or just those assigned to you for review.

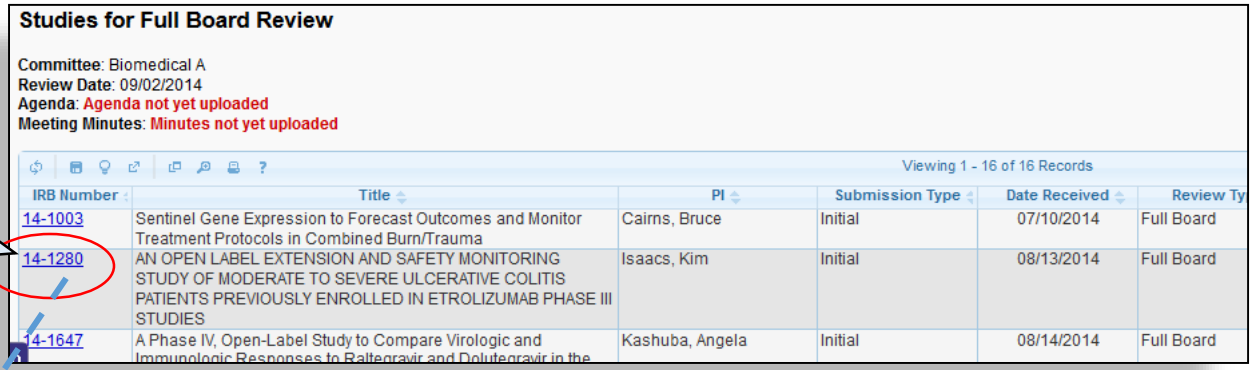
You may click any column header to reorder the list.

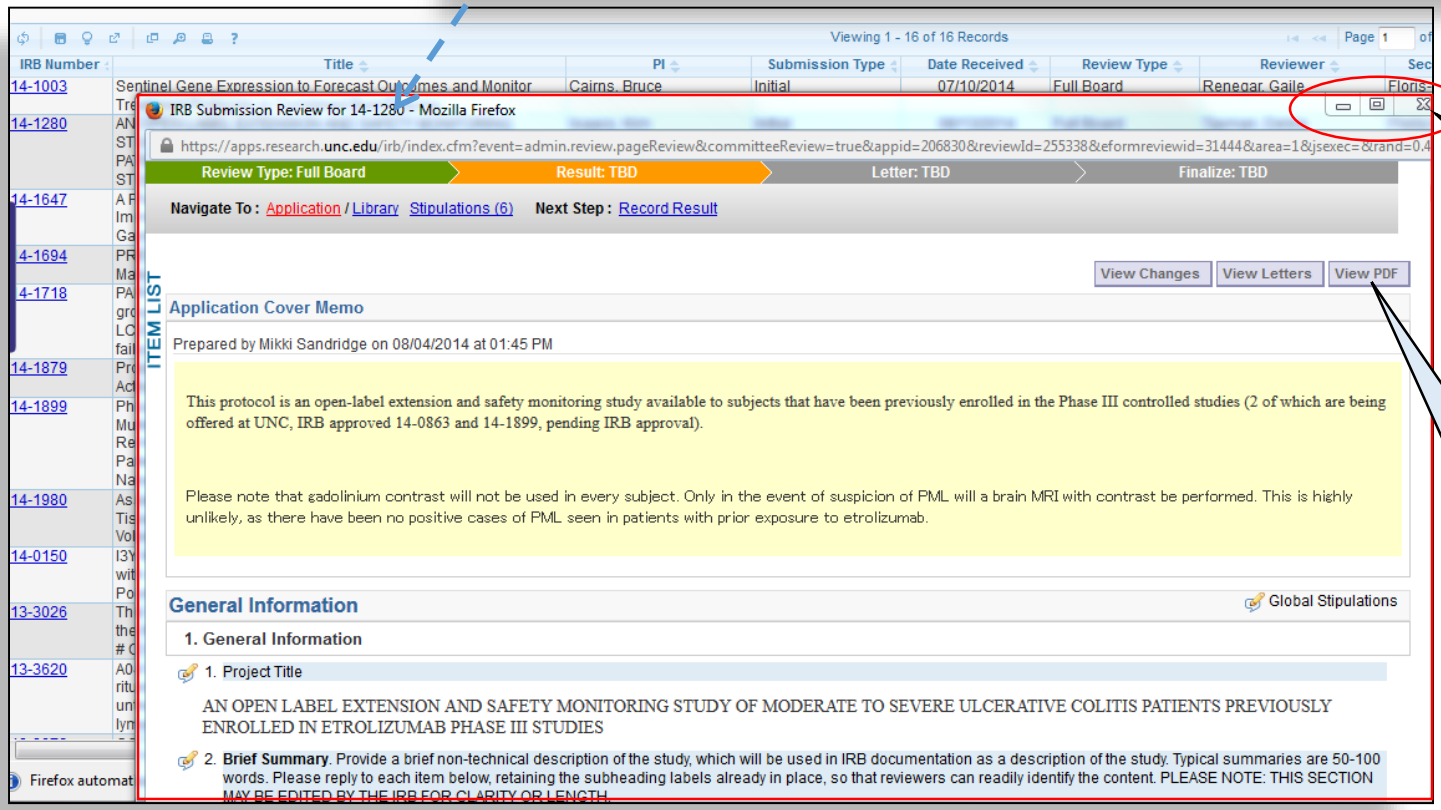


IRB Number	Title	PI	Submission Type	Date Received	Review Type	Reviewer	Secondary Reviewer
14-0762	The Diagnostic Benefit of Utilizing Simultaneous MR/PET to Enhance Early MCI-AD Detection	Giovanello, Kelly	Initial (Reconsideration)	06/09/2014	Full Board	Kehrl, Howard	Nicholson, Wanda
14-0995	MDACC-2013-0944: A Phase II Study of Alternative Sunitinib Scheduling in Patients with Metastatic Renal Cell Carcinoma (mRCC)	Rathmell, W. Kimryn	Initial	08/05/2014	Full Board	Van Deventer, Hank	Dorman, Karen
14-1387	The analgesic effect of an ibuprofen sodium dihydrate formulation on odontogenic pain.	Taggar, Tanjit	Initial	08/04/2014	Full Board	Mauriello, Sally	Nicholson, Wanda
14-1527	ABI-007-NSCL-005: Safety and Efficacy of nab-Paclitaxel (Abraxane) in Combination with Carboplatin as First Line Treatment in Elderly Subjects with Advanced Non-Small Cell Lung Cancer (NSCLC): A Phase IV, Randomized, Open-Label, Multicenter Study (ABOUND.70+)	Weiss, Jared	Initial	07/14/2014	Full Board	Van Deventer, Hank	Lichtman, Steven
14-1617	AMG232-20120238 - A Phase 1b/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Efficacy of AMG 232 Combined with Trametinib and Dabrafenib or Trametinib in Adult Subjects with Metastatic Cutaneous Melanoma	Moschos, Stergios	Initial	08/04/2014	Full Board	Van Deventer, Hank	Kehrl, Howard

Access IRB Application

Click the blue-linked IRB Number to access an interactive version of the IRB application in a pop-up window.

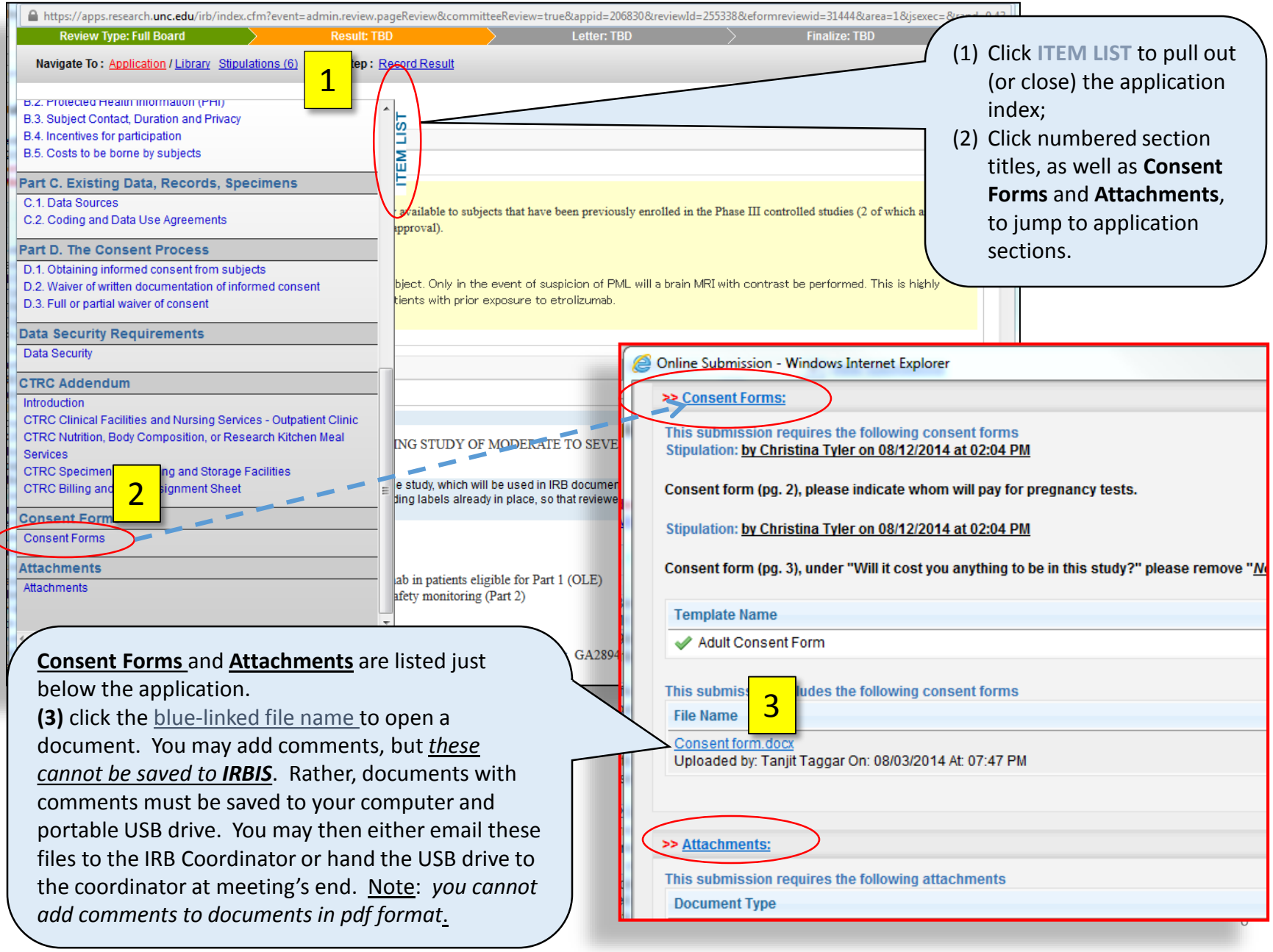




You may expand, minimize, or close the pop-up.

You may view/print a pdf copy of the application.

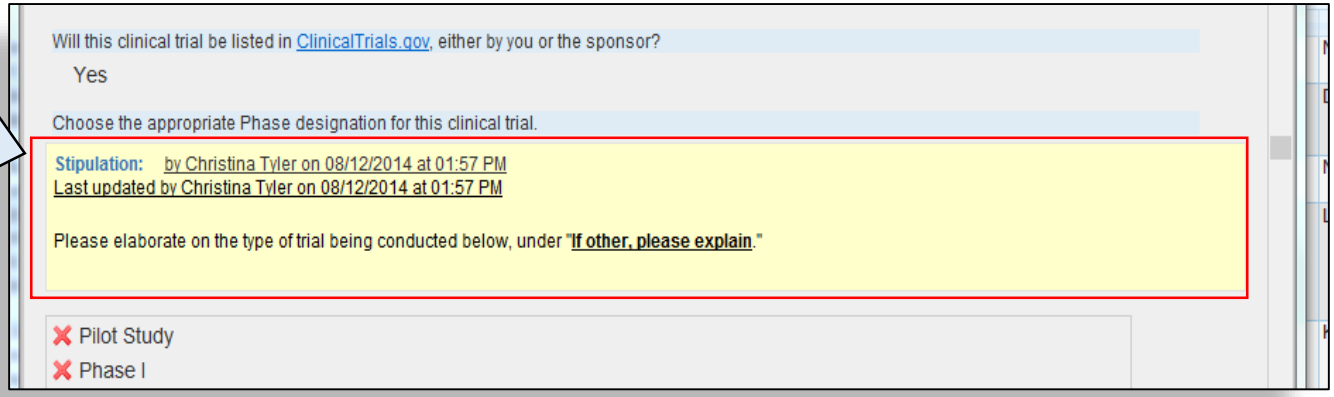
Navigate the IRB Application

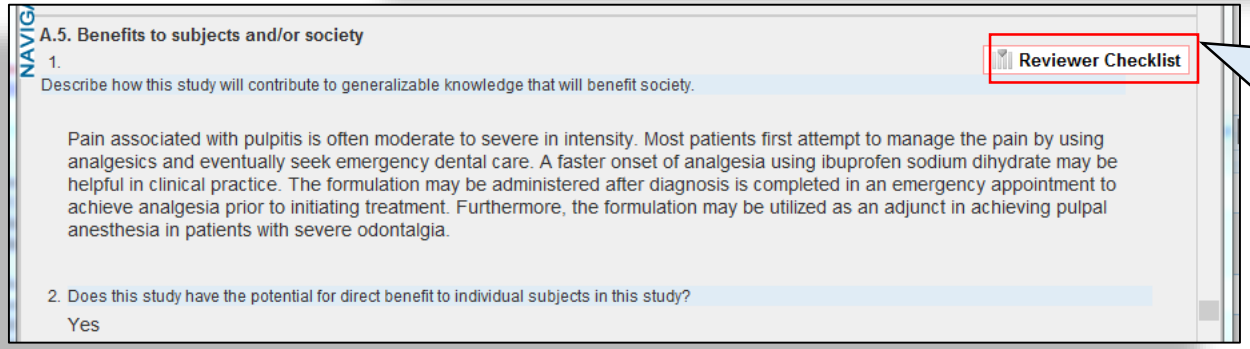


Consent Forms and **Attachments** are listed just below the application.
(3) click the blue-linked file name to open a document. You may add comments, but *these cannot be saved to **IRBIS***. Rather, documents with comments must be saved to your computer and portable USB drive. You may then either email these files to the IRB Coordinator or hand the USB drive to the coordinator at meeting's end. Note: *you cannot add comments to documents in pdf format.*

Navigate the IRB Application (cont'd)

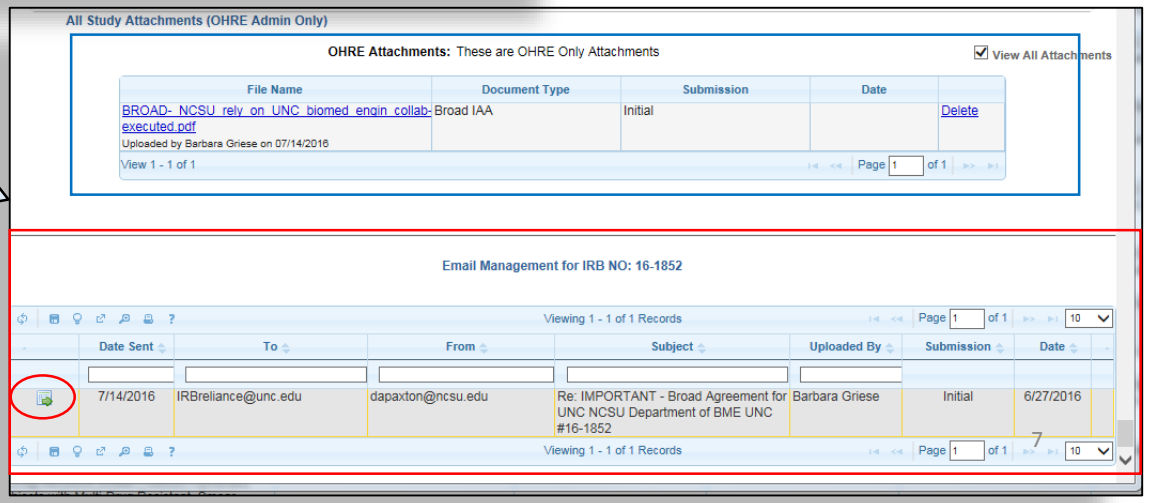
Scroll through the application to find stipulations that were written by the IRB coordinator during pre-review (these appear on a yellow background).





Mouseover **Reviewer Checklist** to see review-questions/criteria embedded at each section of the application; these will help frame/guide your review.
Note: you are no longer required to complete the **Reviewer Checklist** form.

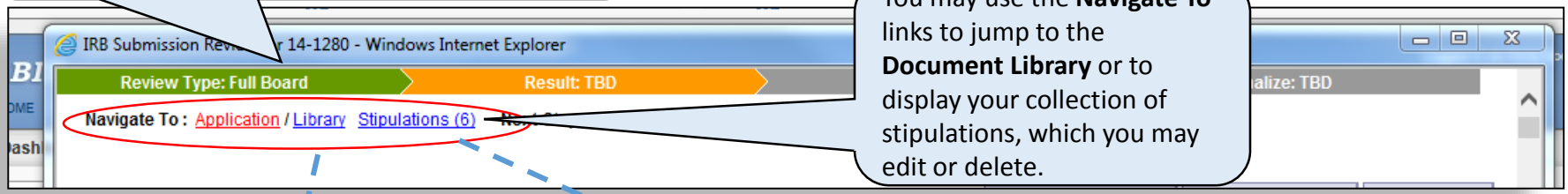
- Documents uploaded by OHRE staff can be accessed at **OHRE Attachments** (below the Application). These may include "compare" versions of PI-revised consent forms or other attachments, as well as PRC reviews completed after the IRB application was submitted.
- Related correspondence is accessible at **Email Management**.

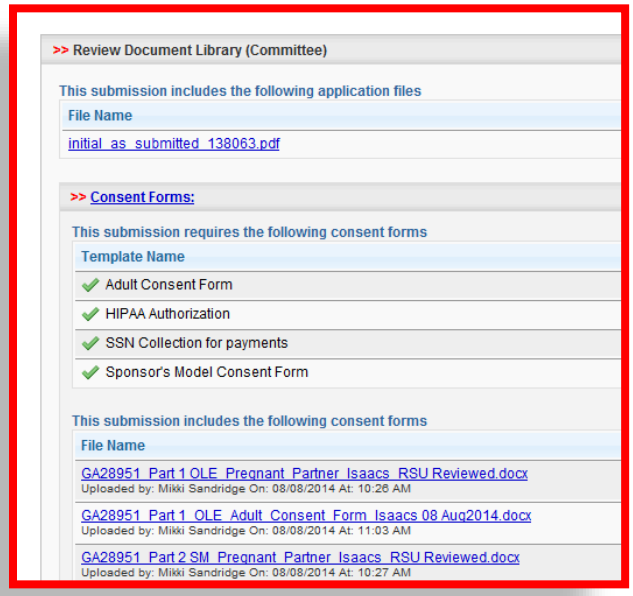


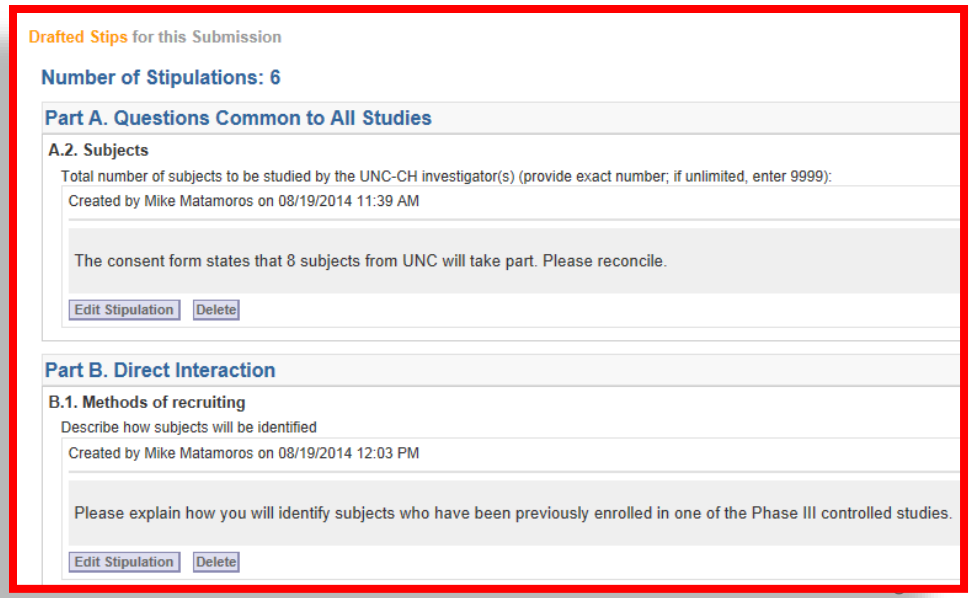
Navigate the IRB Application (cont'd)

The swimlanes at the top of the application track the progress of each review through four steps: **Green** = step completed; **Orange** = next step.

You may use the **Navigate To** links to jump to the **Document Library** or to display your collection of stipulations, which you may edit or delete.



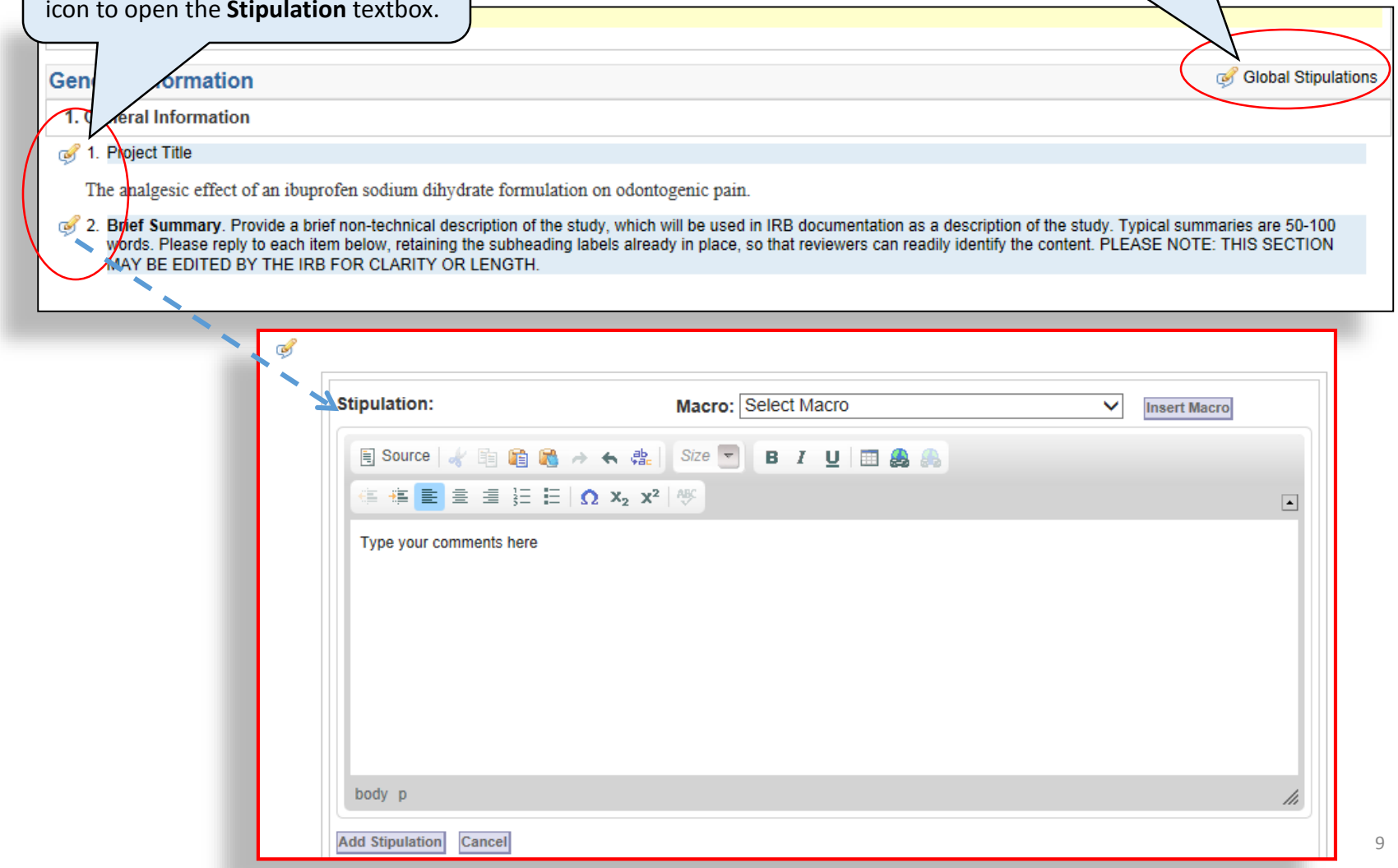




Add Stipulations

Every application question carries an "Add New Stipulation" icon. Click the icon to open the **Stipulation** textbox.

At **Global Stipulations** (top right of application only), you may add general comments that are not question-specific.

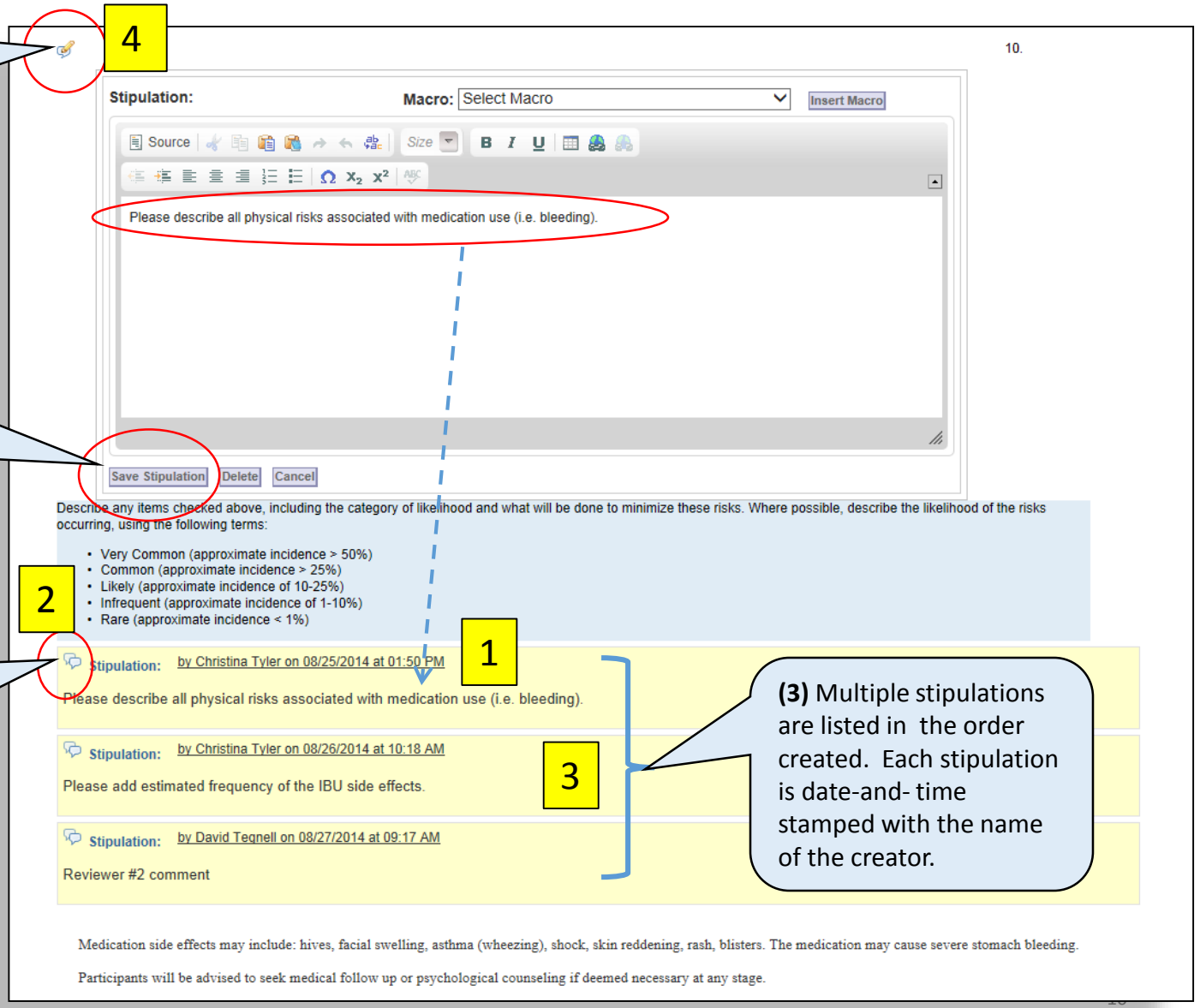


Add Stipulations (cont'd)

(4) Click Add New Stipulation icon to add more stipulations , as needed.

(1) Upon *Save*, stipulations are embedded and displayed against a yellow background.

(2). Click Double-callout icon to re-access and edit or delete.

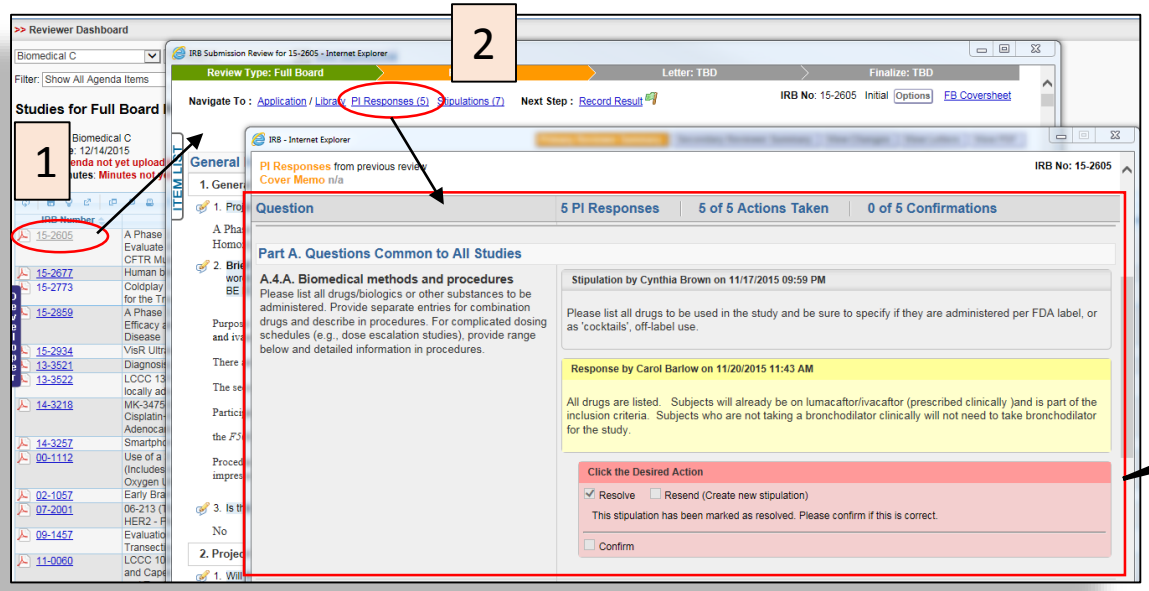


(3) Multiple stipulations are listed in the order created. Each stipulation is date-and- time stamped with the name of the creator.

“Stip Tips”

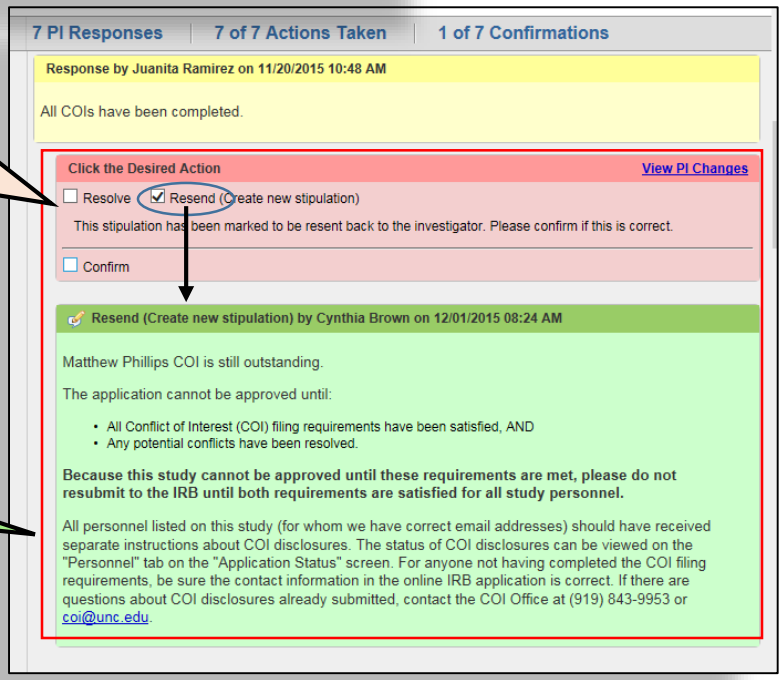
- Any member may write stipulations within the application
- Do not edit or add to another reviewer’s stipulation; rather, write your own stipulation in a separate textbox
- Use complete sentences, and address the investigator respectfully, using the second person pronoun (e.g., “Please add…”)
- Be specific and directive, and briefly explain the rationale for each stipulation
- Make just one point per stipulation
- Do not add stipulations after 8:00 AM, the morning of the meeting
- Do not write or revise stipulations during the meeting (this is the responsibility of the Coordinator and Chair)
- Understand that stipulations may be revised by the convened committee during the meeting, or by the Chair/Coordinator afterward

Review PI's Request for Reconsideration



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).

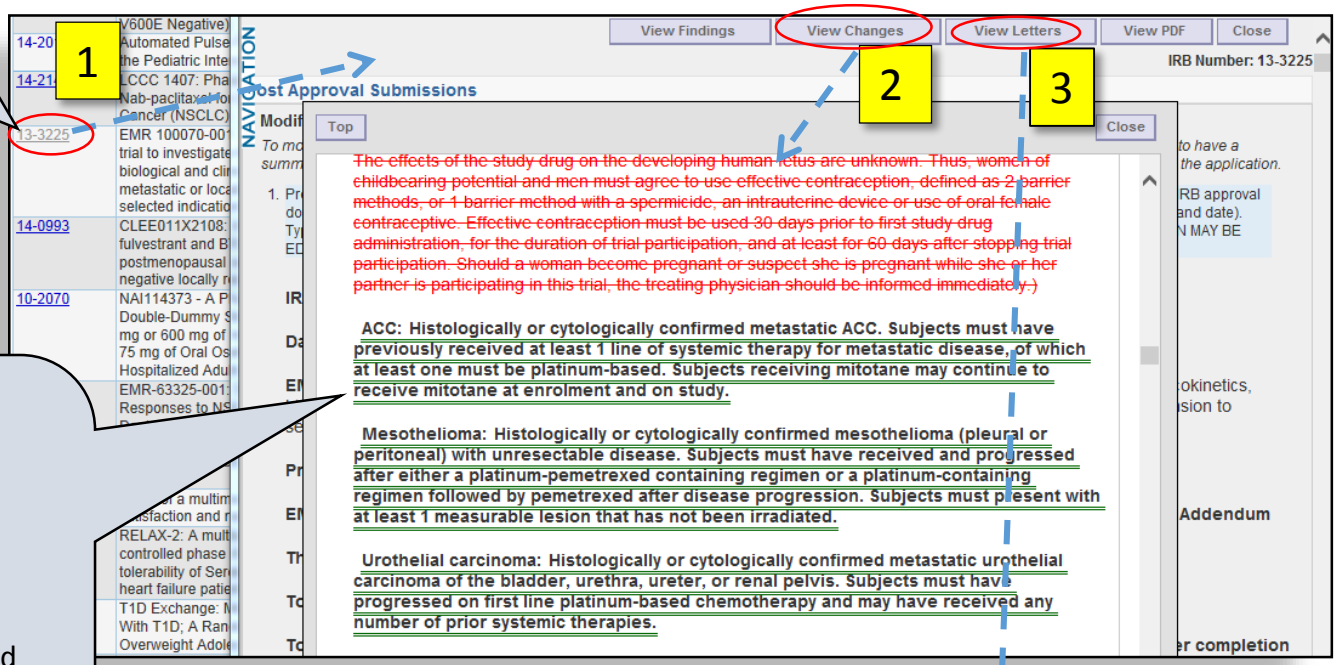
During pre-meeting review, the IRB Coordinator may recommend acceptance (*Resolve*) or rejection (*Resend*) of the PI's Response to the stipulation.



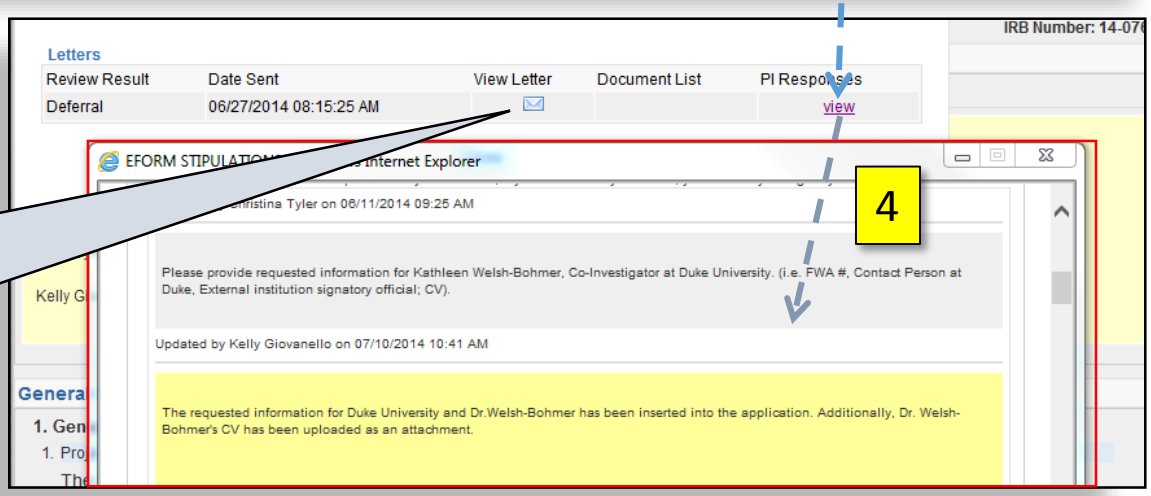
If the Coordinator checks *Resend*, a green text box opens to accommodate composition of a stipulation. Upon the Chair's confirmation (of all actions), the *Resend* is converted to a stipulation.

Review PI's Request for Reconsideration (cont'd)

IRBIS provides a marked version of the application (**View Changes**) that highlights revisions since the board's last review (i.e., since deferral). To access: **(1)** click the IRB Number; then, **(2)** click the *View Changes* button.

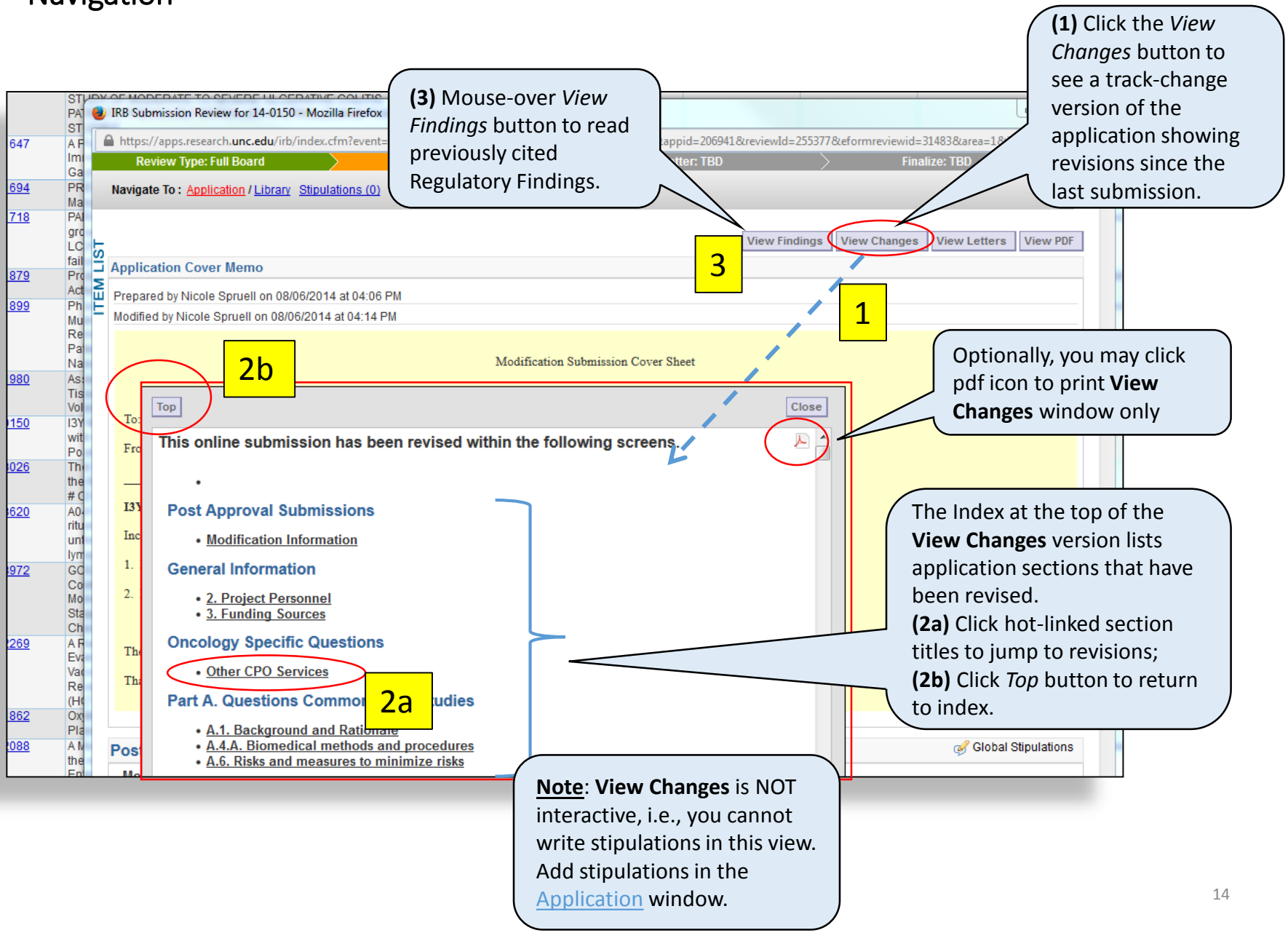


View Changes appears within a secondary (nested) pop-up window. Deletions are **struck through in red**; additions are **double-underlined in green**.
Note: **View Changes** does not display coordinator-added stipulations; neither can you add stipulations in this view. Add stipulations in the application window.



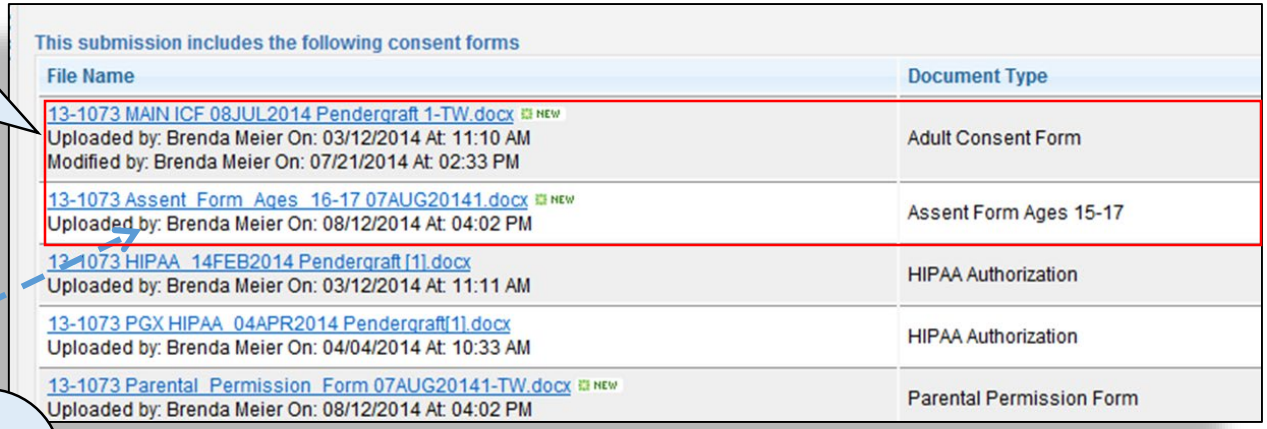
(3) To view the deferral letter: on the application, click the *View Letters* button to open a pop-up, then click the **View Letter** icon.
(4) To display prior stipulations/responses: click **view** under "PI Responses."

Review Modifications (and Renewals with Modifications)
Navigation



Review Modifications (and Renewals with Modifications)
new vs "compare" documents

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

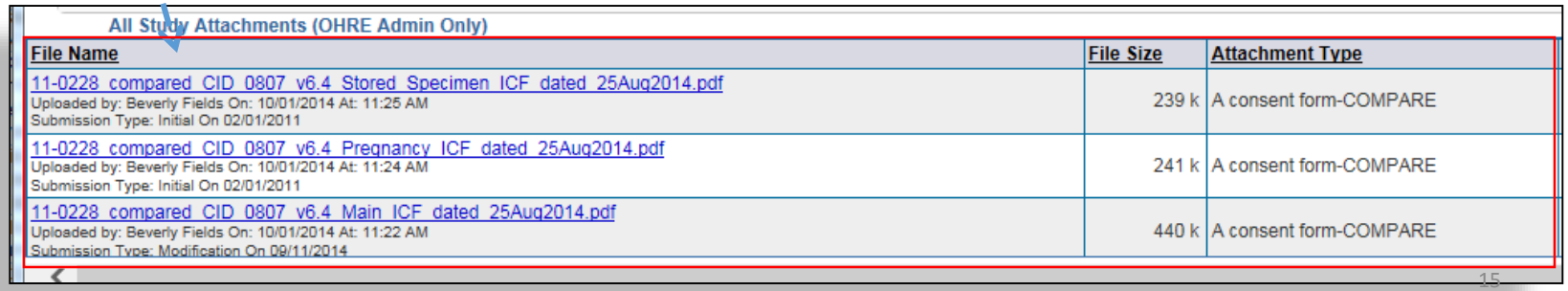


This submission includes the following consent forms

File Name	Document Type
13-1073 MAIN ICF 08JUL2014 Pendergraft 1-TW.docx NEW Uploaded by: Brenda Meier On: 03/12/2014 At: 11:10 AM Modified by: Brenda Meier On: 07/21/2014 At: 02:33 PM	Adult Consent Form
13-1073 Assent_Form_Ages_16-17 07AUG20141.docx NEW Uploaded by: Brenda Meier On: 08/12/2014 At: 04:02 PM	Assent Form Ages 15-17
13-1073 HIPAA_14FEB2014 Pendergraft [1].docx Uploaded by: Brenda Meier On: 03/12/2014 At: 11:11 AM	HIPAA Authorization
13-1073 PGX HIPAA_04APR2014 Pendergraft[1].docx Uploaded by: Brenda Meier On: 04/04/2014 At: 10:33 AM	HIPAA Authorization
13-1073 Parental_Permission_Form 07AUG20141-TW.docx NEW Uploaded by: Brenda Meier On: 08/12/2014 At: 04:02 PM	Parental Permission Form

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).

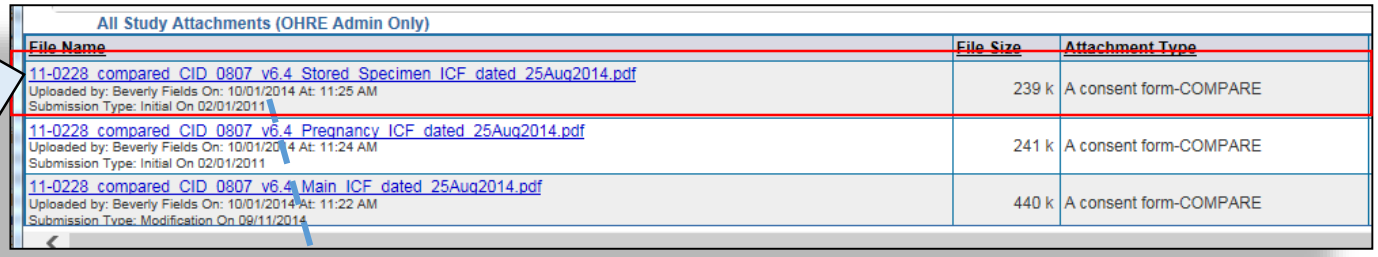


All Study Attachments (OHRE Admin Only)

File Name	File Size	Attachment Type
11-0228_compared_CID_0807_v6.4_Stored_Specimen_ICF_dated_25Aug2014.pdf Uploaded by: Beverly Fields On: 10/01/2014 At: 11:25 AM Submission Type: Initial On 02/01/2011	239 k	A consent form-COMPARE
11-0228_compared_CID_0807_v6.4_Pregnancy_ICF_dated_25Aug2014.pdf Uploaded by: Beverly Fields On: 10/01/2014 At: 11:24 AM Submission Type: Initial On 02/01/2011	241 k	A consent form-COMPARE
11-0228_compared_CID_0807_v6.4_Main_ICF_dated_25Aug2014.pdf Uploaded by: Beverly Fields On: 10/01/2014 At: 11:22 AM Submission Type: Modification On 09/11/2014	440 k	A consent form-COMPARE

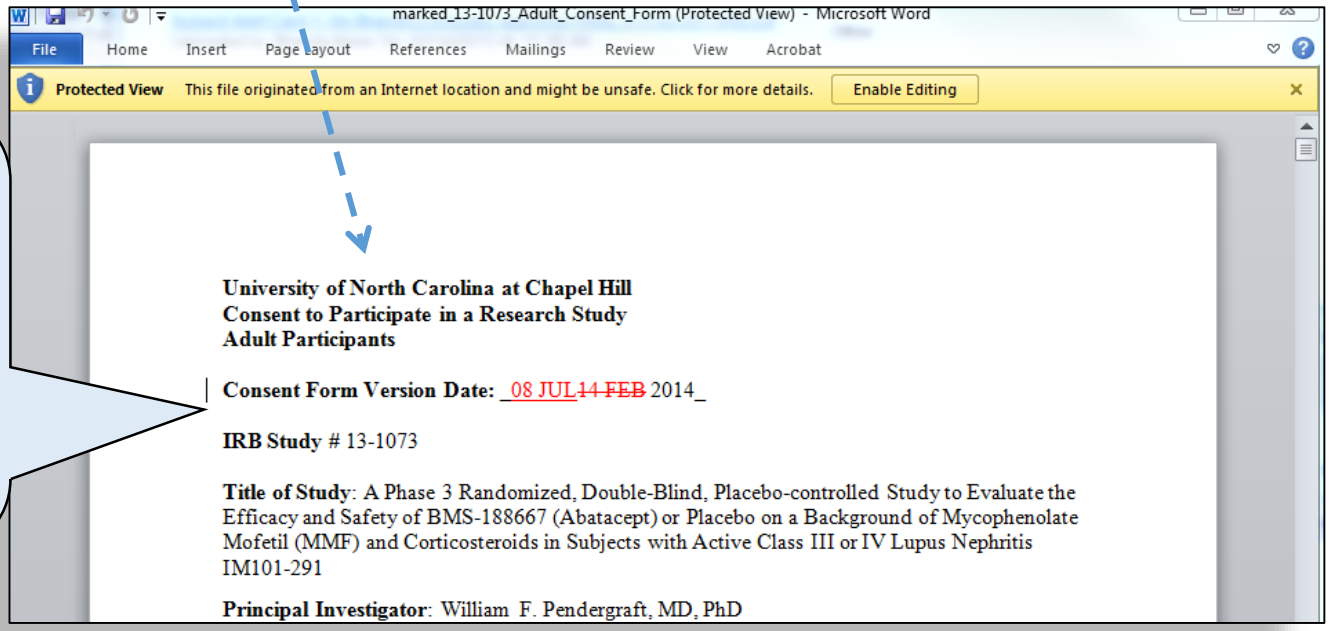
Review Modifications (and Renewals with Modifications)
Reviewing "compare" revised documents at "All Study Attachments"

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).

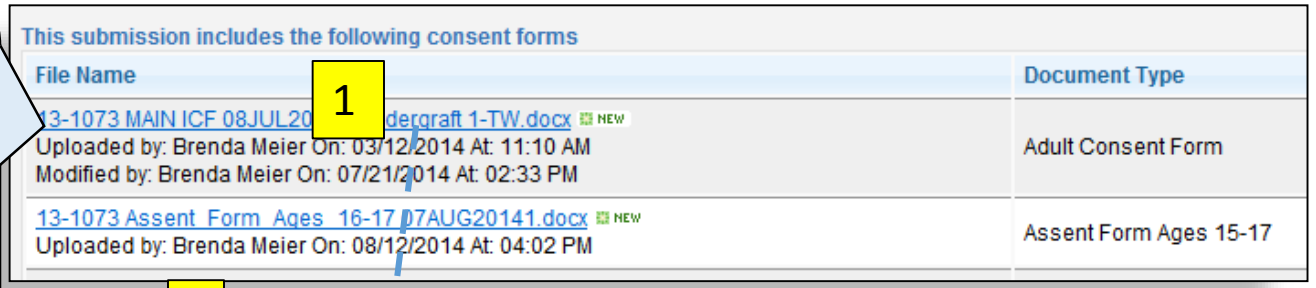


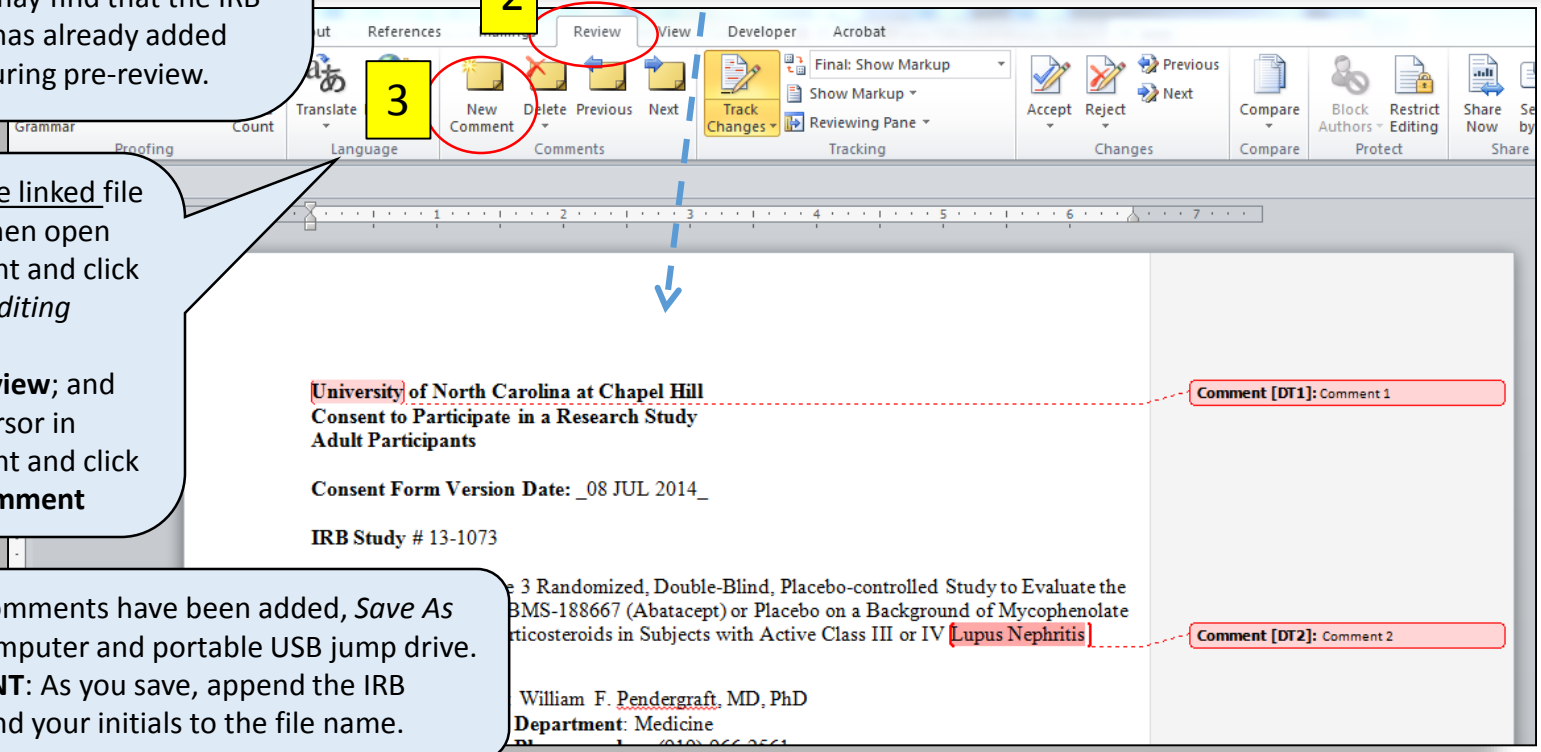
Review Modifications (and Renewals with Modifications)
Adding Comments to new documents

You may "Add New Comments" to **NEW** documents at the **Document Library**: **Consent Forms / Attachments** sections only--NOT **All Study Attachments**.

Note1 : use only the Comments function; do not otherwise edit or mark-up.

Note 2: you may find that the IRB Coordinator has already added comments during pre-review.



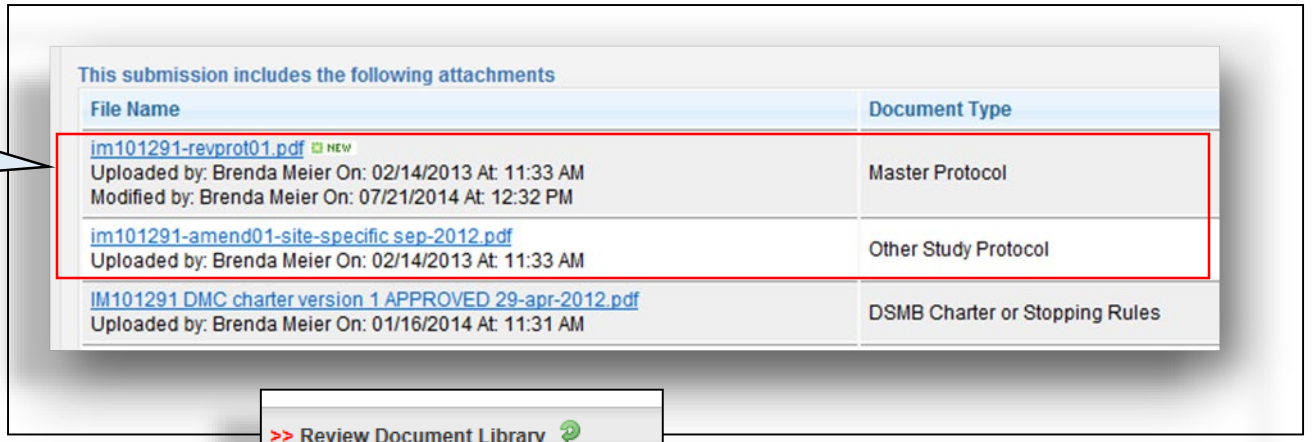


(1) Click blue linked file name; then open document and click *Enable Editing* button;
(2) Click **Review**; and
(3) Place cursor in document and click **New Comment**

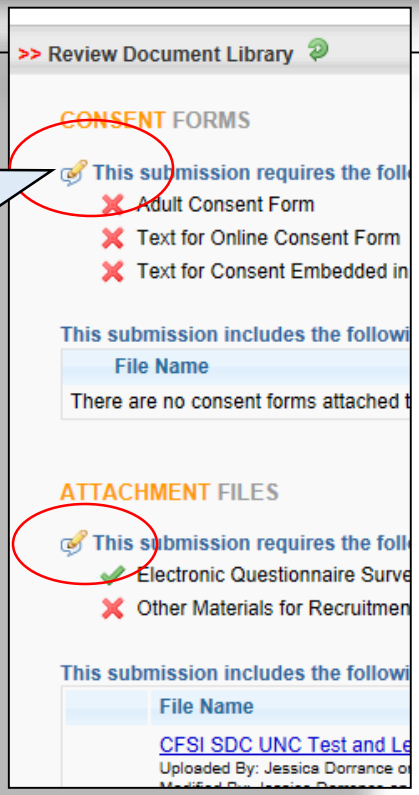
After all comments have been added, *Save As* to your computer and portable USB jump drive. **IMPORTANT**: As you save, append the IRB Number and your initials to the file name.

Review Modifications (and Renewals with Modifications)
Adding Stipulations for pdf documents

Currently, you can neither add comments to pdfs nor compare revised pdf documents to prior versions.

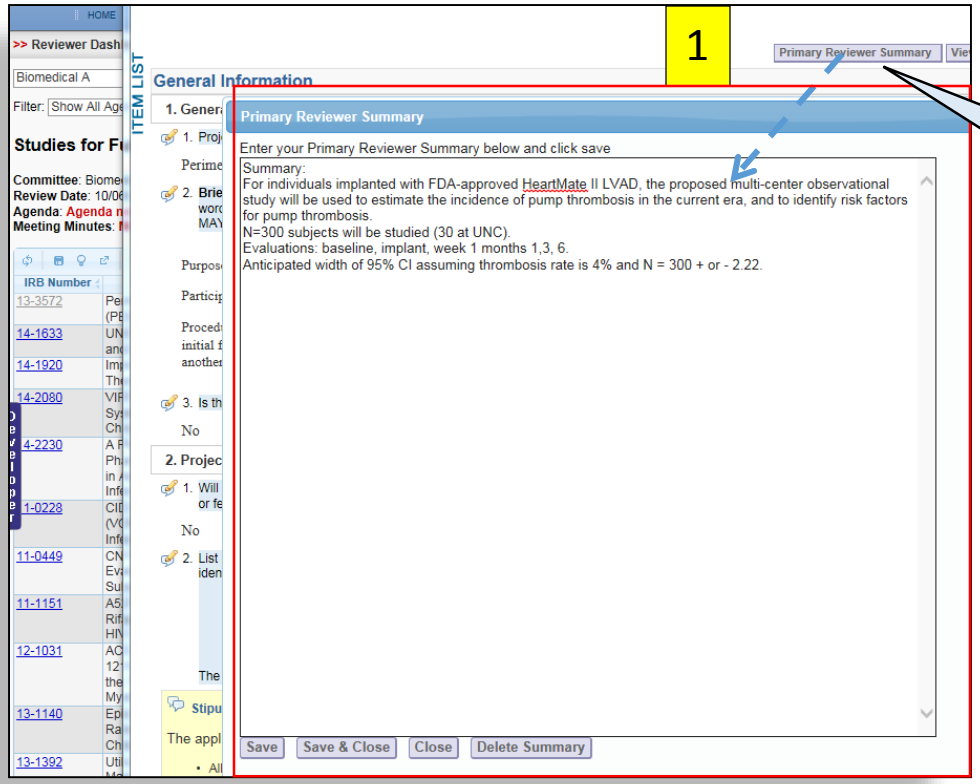


Use the stipulation function to add comments about pdf documents at **Document Library**: **Consent Forms/Attachments** sections (below the application). **Note**: only one stipulation icon is provided at each of these application sections. Create one stipulation (i.e., one set of comments) per document. Preface each set of comments with the complete document file name.



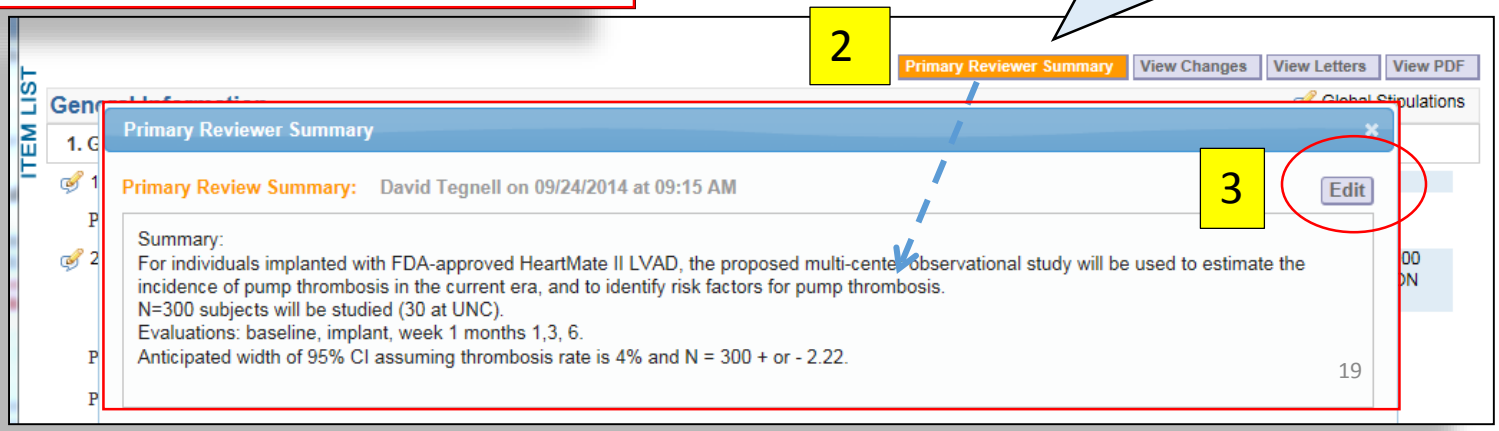
Add/view a primary reviewer summary

A free-text window has been created to facilitate the **Primary Reviewer's** oral presentation. A summary is optional. It is not intended to replace the old Reviewer Checklist; neither is a summary a substitute for writing stipulations.



To Add: Click the *Primary Reviewer Summary* button to open the txt-formatted textbox.
Note: if you paste from a Word document, formatting will not be retained.

To View: Once a review is saved, the *Primary Reviewer Summary* button will turn orange; any member may then click to read the summary.
Note: Only the Primary Reviewer should click the *Edit* button to return to the textbox and revise.



If you have questions

Contact (during business hours):

- Your meeting coordinator (919) 966-3113
- Laura Cowan, IRB Help Desk (919) 966-3685 – irbis@unc.edu