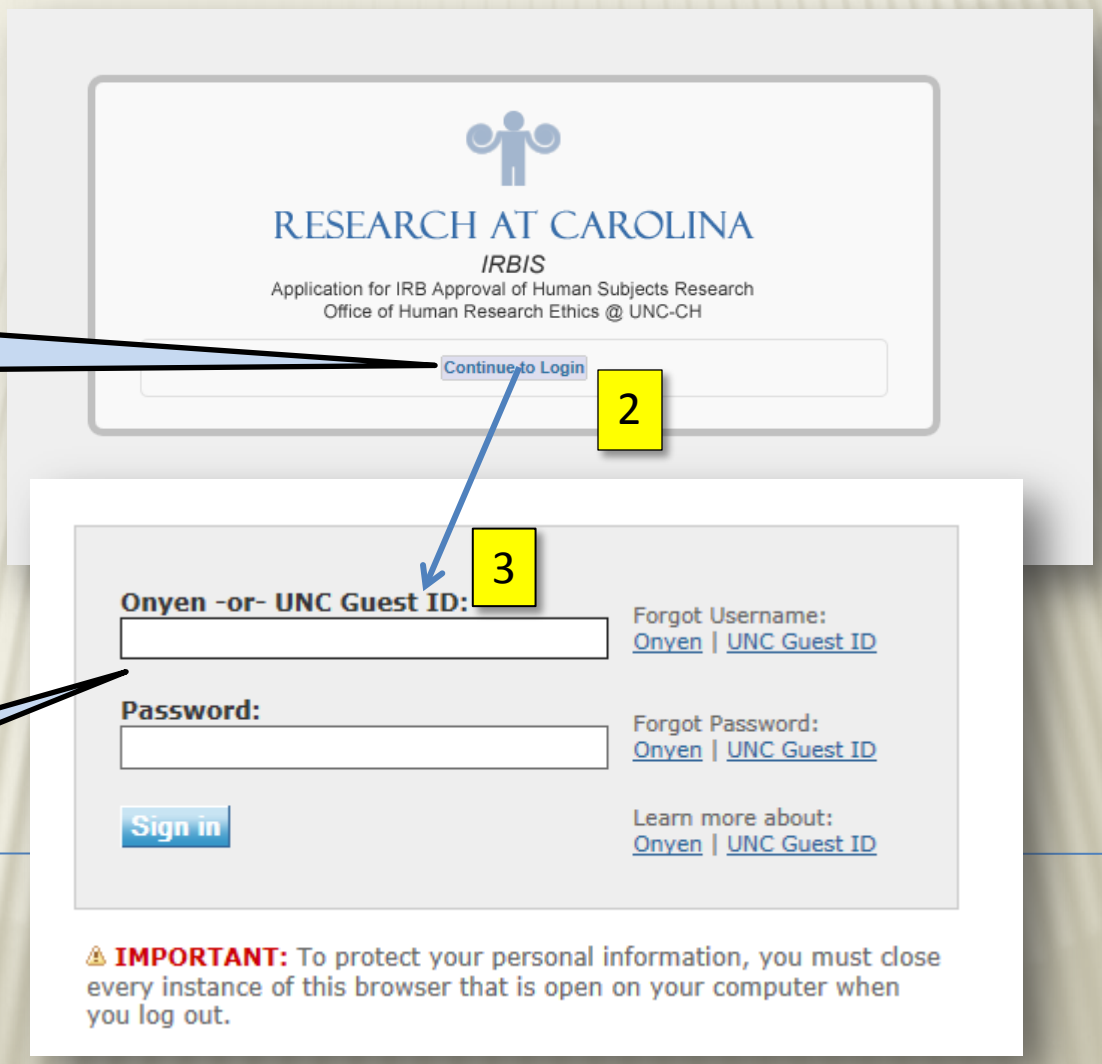
ACCESS ONLINE MEETING AGENDA IN IRBIS

LOGIN TO IRBIS

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

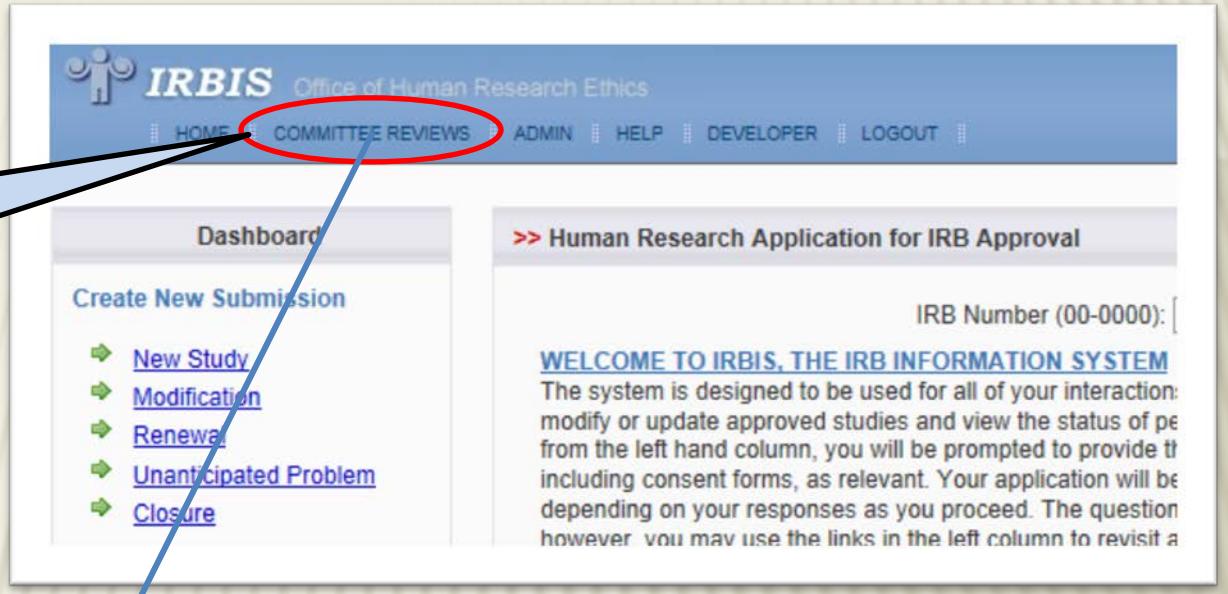
(2) At first login screen, click *Continue to Login* button.

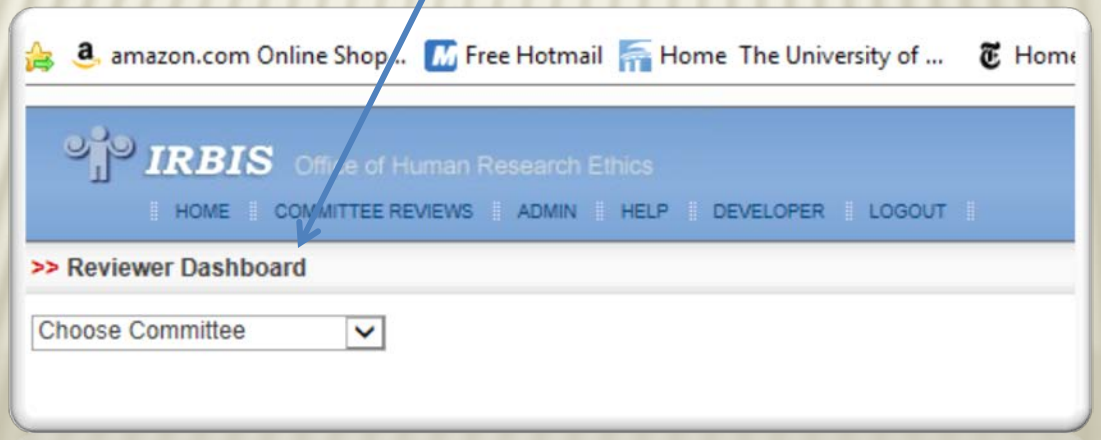
(3) At second login screen, enter UNC **ONYEN** and **Password**, and then click *Sign in* button to access **IRBIS Home** screen.



ACCESS REVIEWER DASHBOARD

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



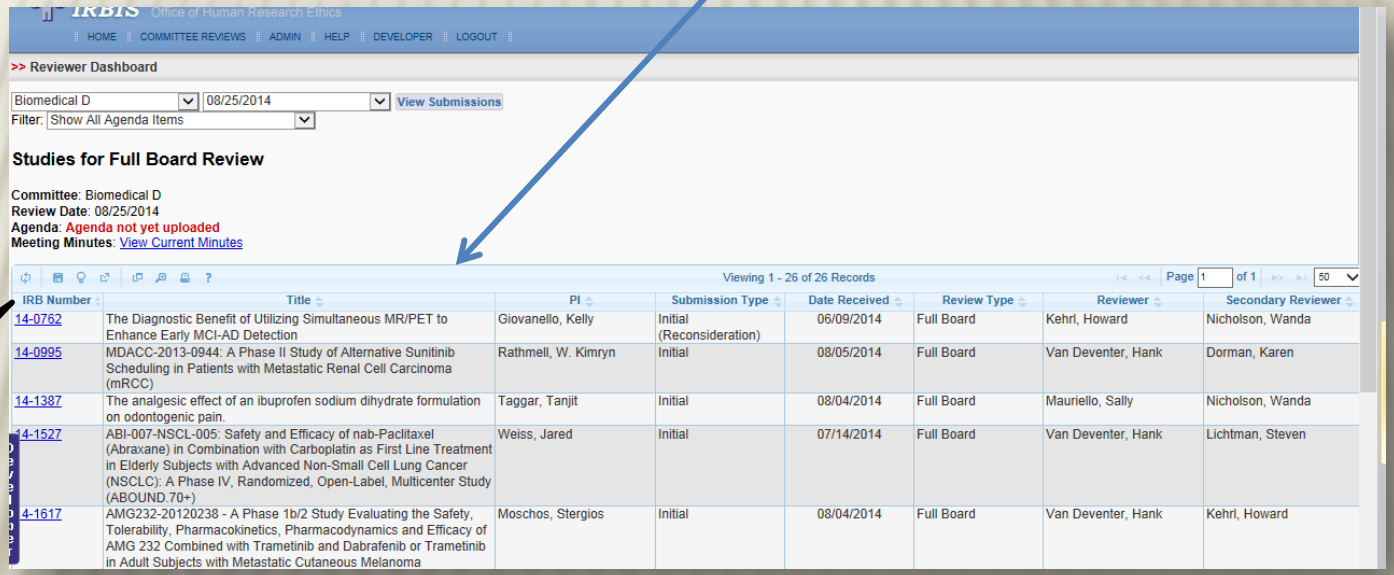


ACCESS COMMITTEE AGENDA

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.

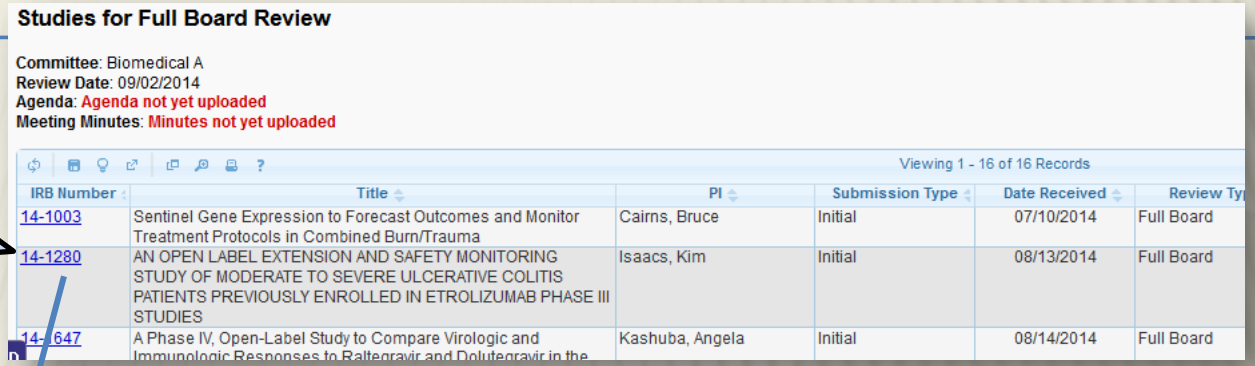
You may click any column header to reorder the list.

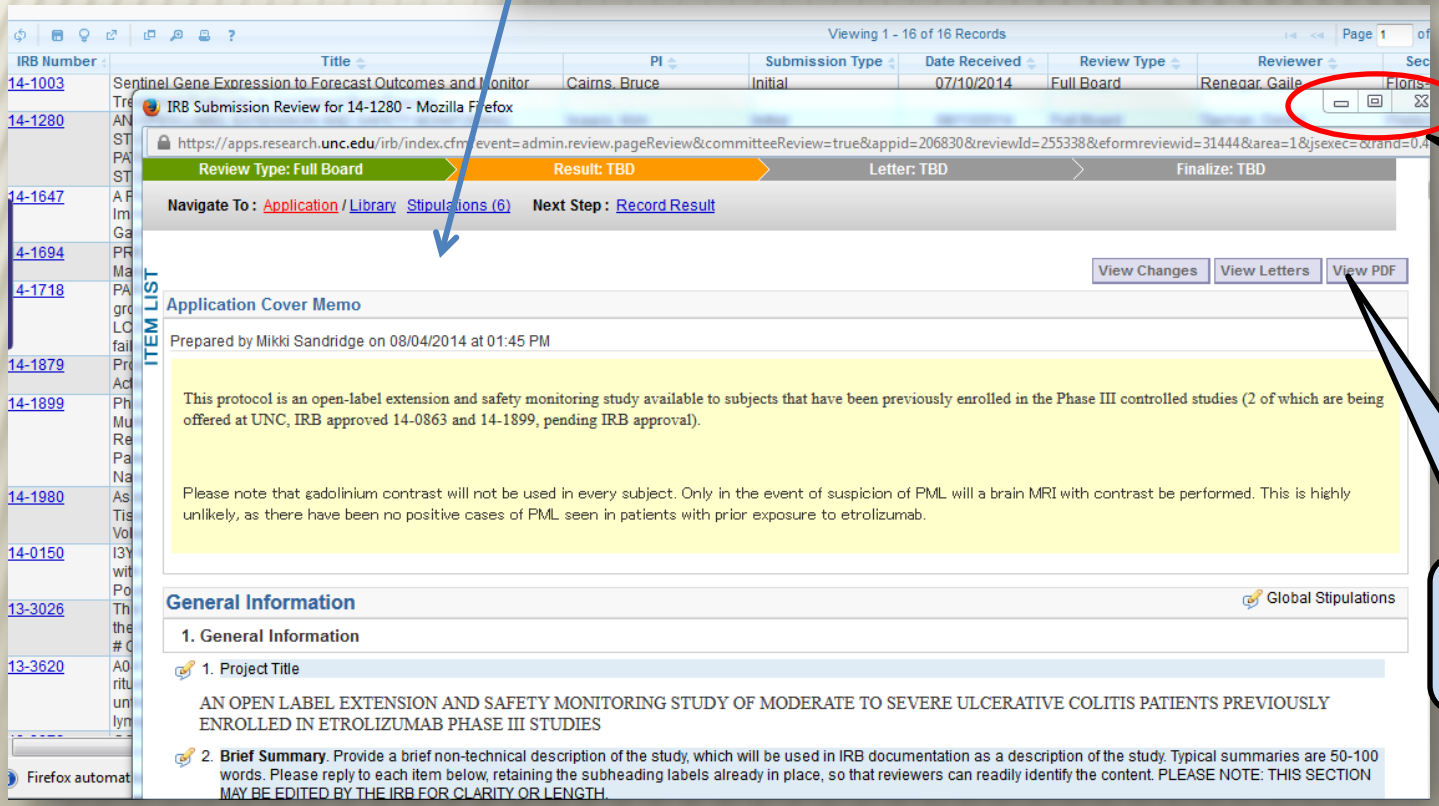


IRB Number	Title	PI	Submission Type	Date Received	Review Type	Reviewer	Secondary Reviewer
14-0762	The Diagnostic Benefit of Utilizing Simultaneous MR/PET to Enhance Early MCI-AD Detection	Giovanello, Kelly	Initial (Reconsideration)	06/09/2014	Full Board	Kehrl, Howard	Nicholson, Wanda
14-0995	MDACC-2013-0944: 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.

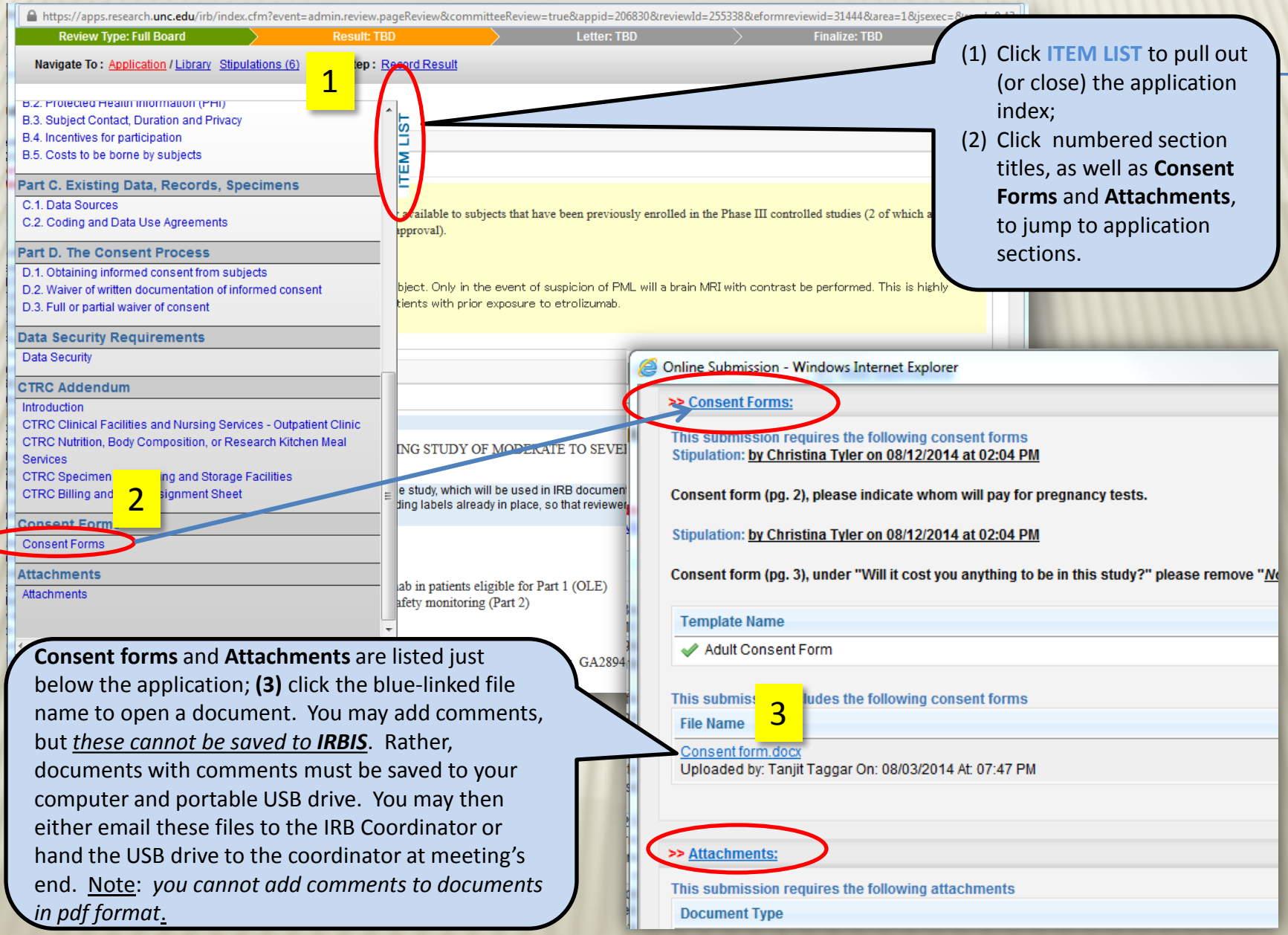




You may expand, minimize, or close the pop-up.

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

NAVIGATE THE IRB APPLICATION

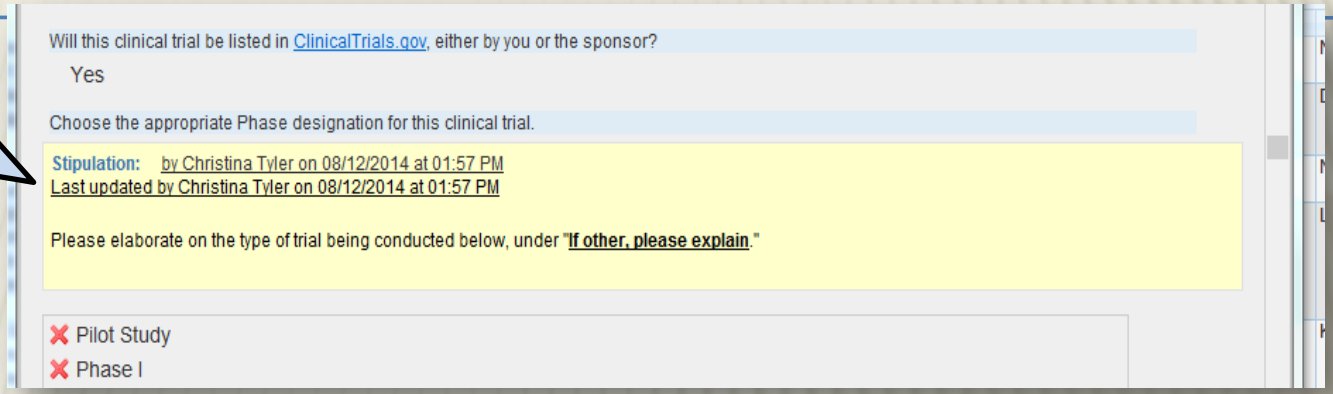


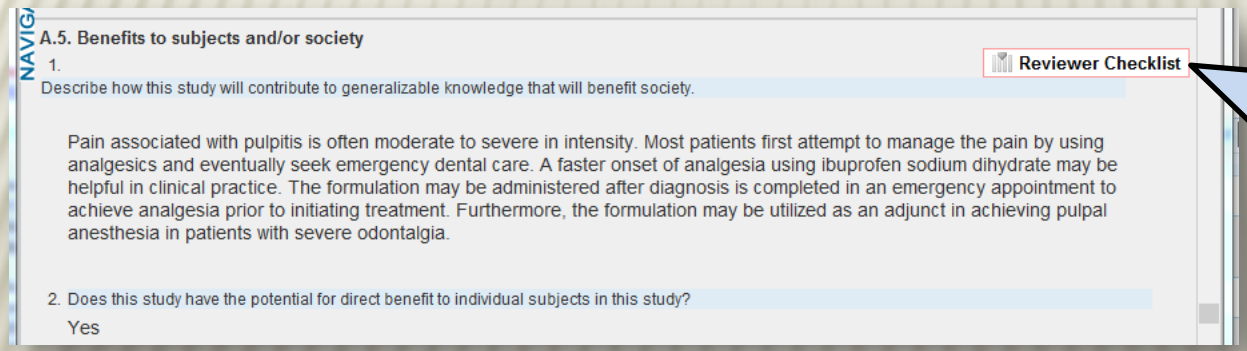
(1) Click **ITEM LIST** to pull out (or close) the application index;
(2) Click numbered section titles, as well as **Consent Forms** and **Attachments**, to jump to application sections.

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)

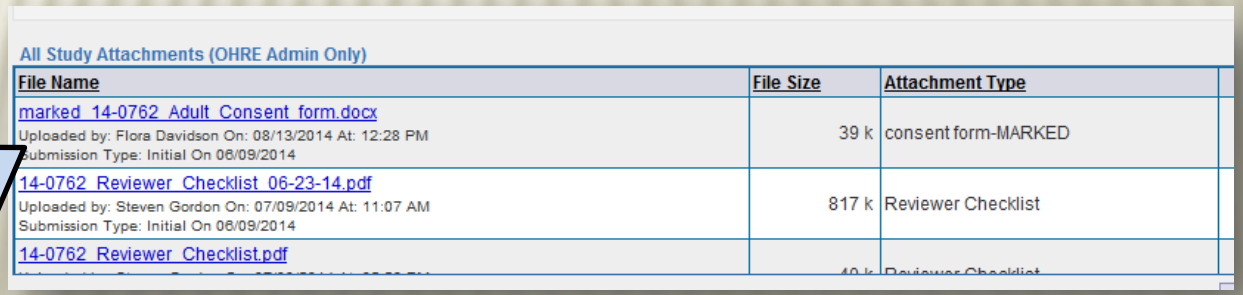
Scroll through the application to find stipulations that were written by the IRB coordinator during pre-review (these appear on a yellow background).





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.

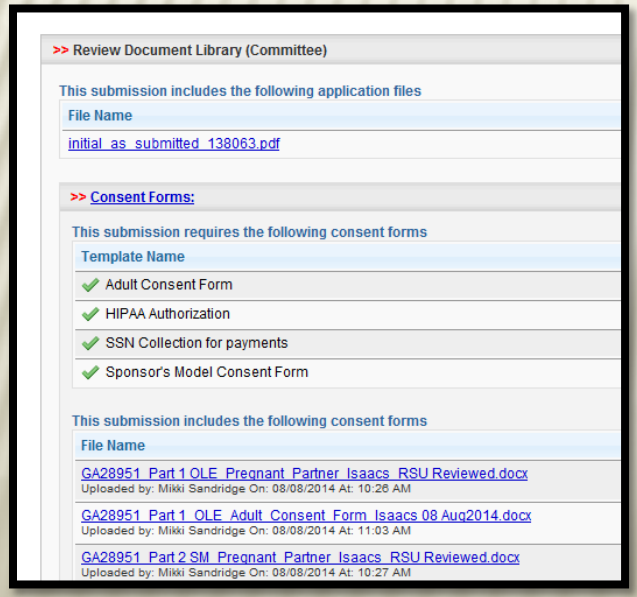
Documents uploaded by OHRE staff can be accessed at **All Study Attachments** (at the bottom of the application). These may include "marked" consent forms or other attachments and PRC reviews completed after the IRB application was submitted.

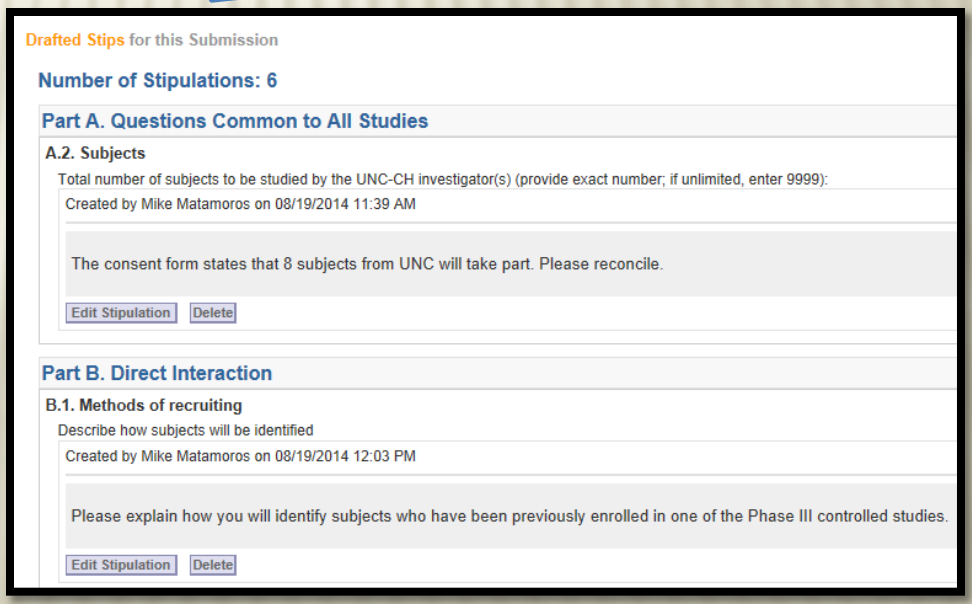


NAVIGATE THE IRB APPLICATION (CONT'D)

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.

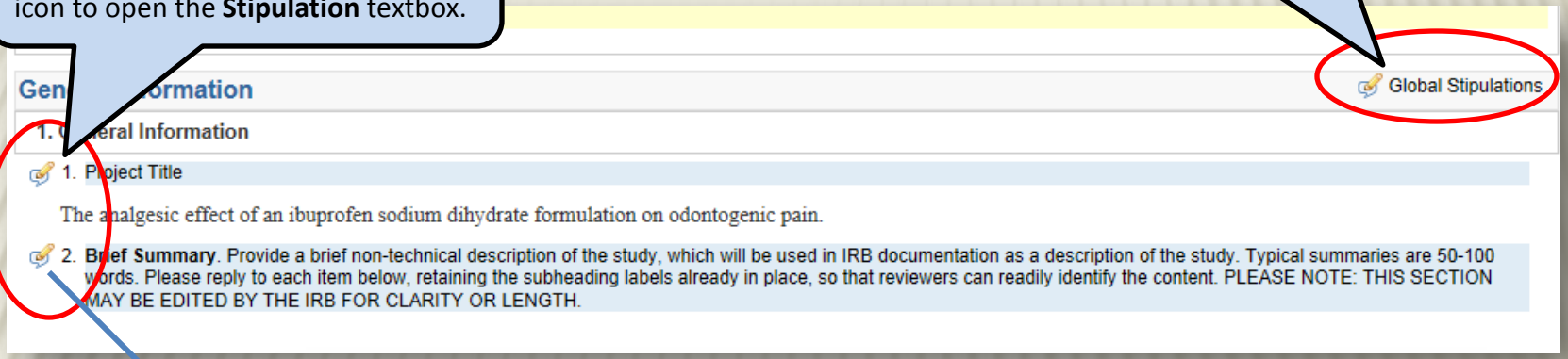


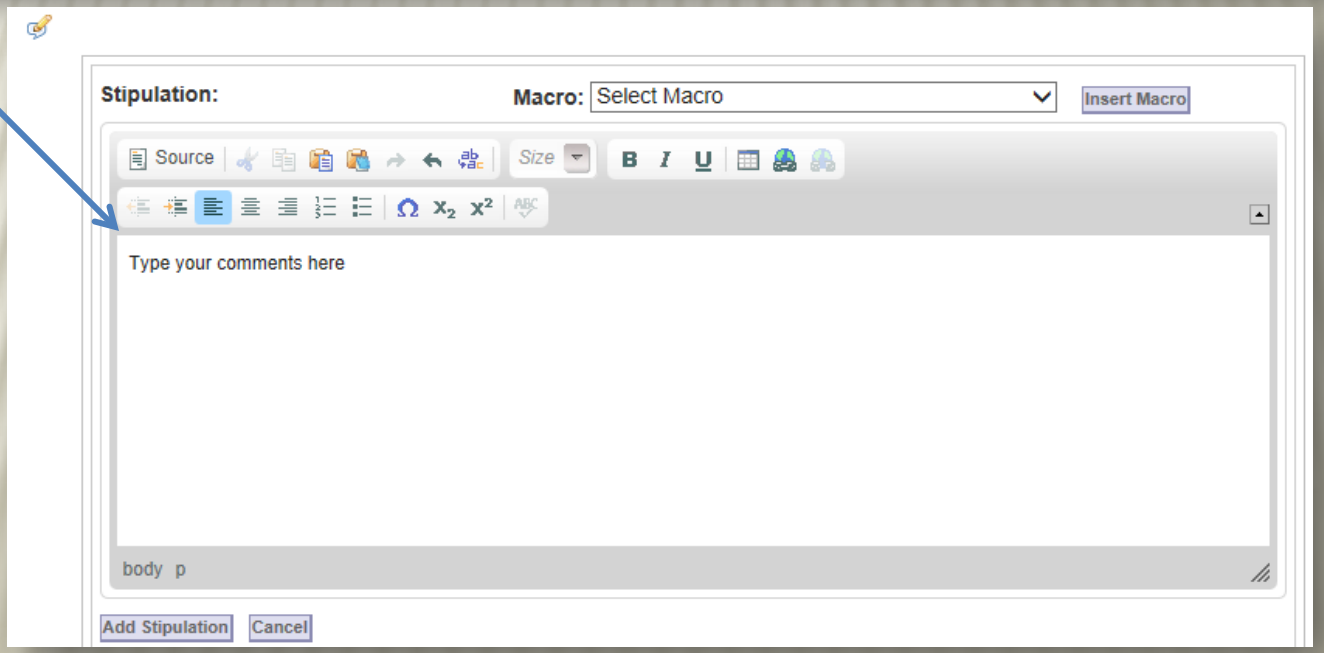


ADD STIPULATIONS

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.



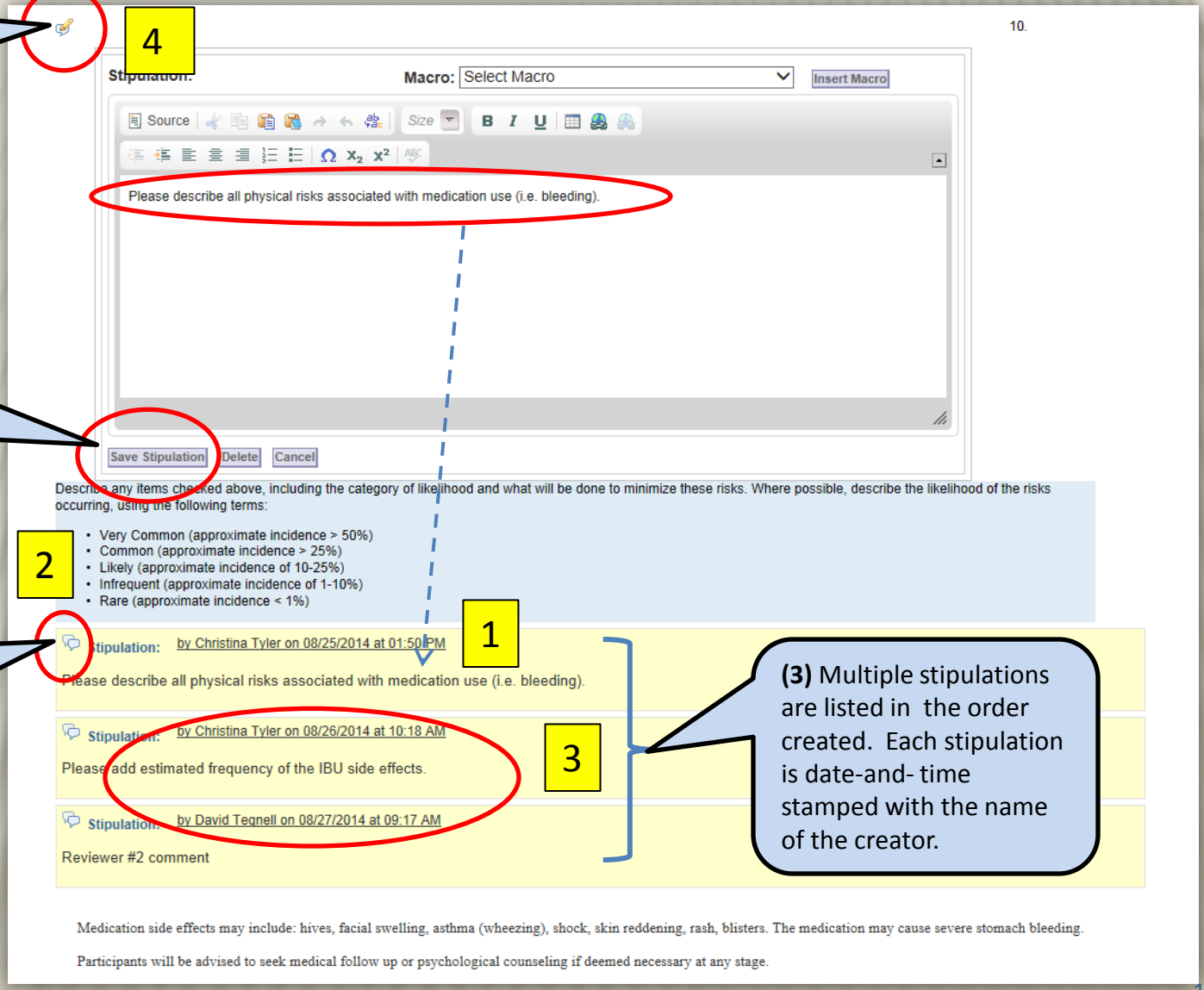


ADD STIPULATIONS (CONT'D)

(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.



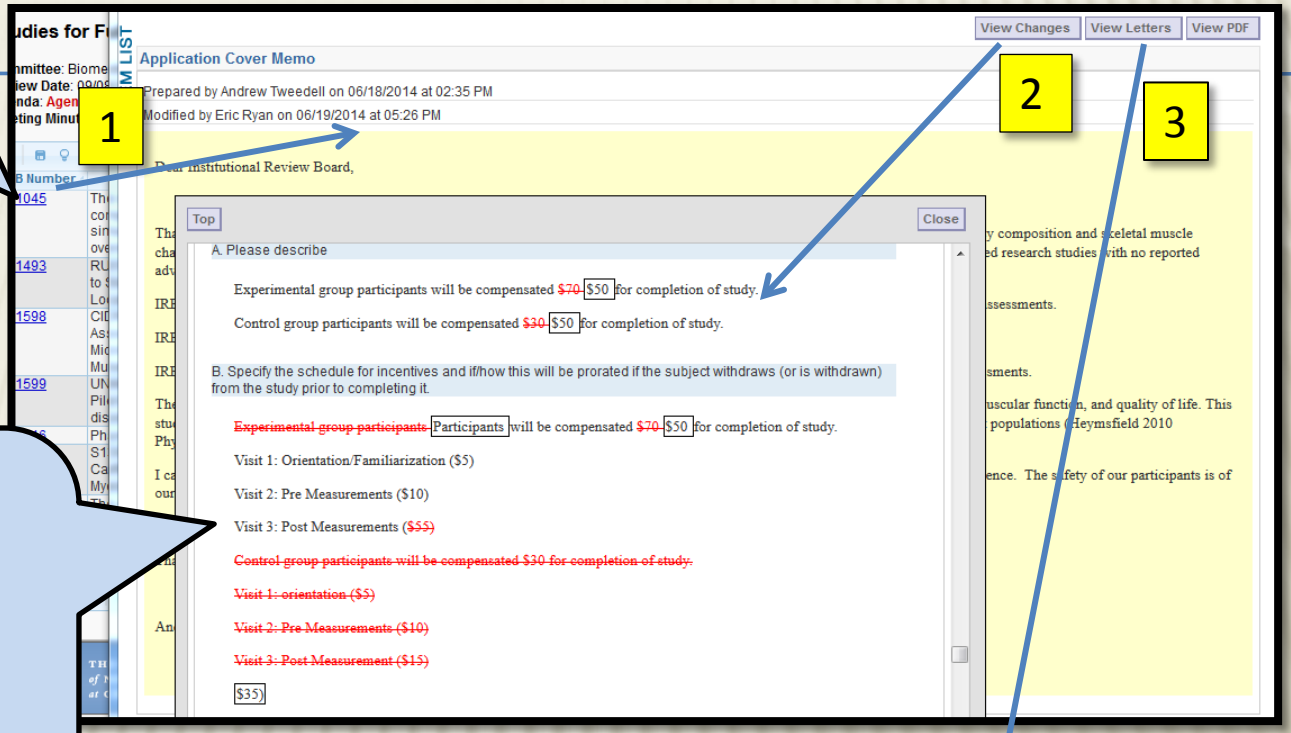
(3) Multiple stipulations are listed in the order created. Each stipulation is date-and- time stamped with the name of the creator.

"STIP TIPS"

- Only Primary and Secondary Reviewers should write stipulations within the application
- Each reviewer should add his/her own stipulations in separate Stipulation textboxes (do not edit or add to each other's)
- 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 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

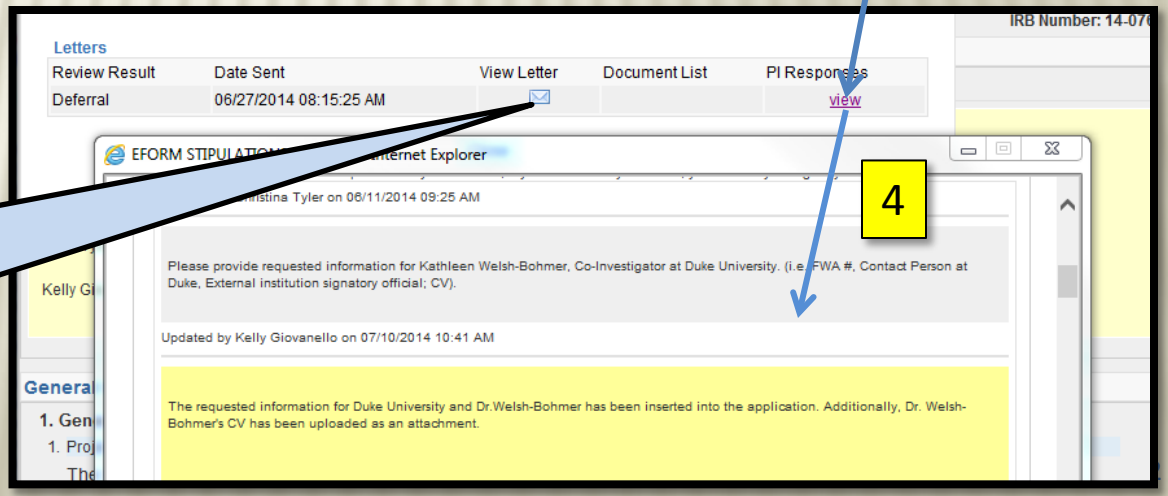
REVIEW REQUEST FOR RECONSIDERATION

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.

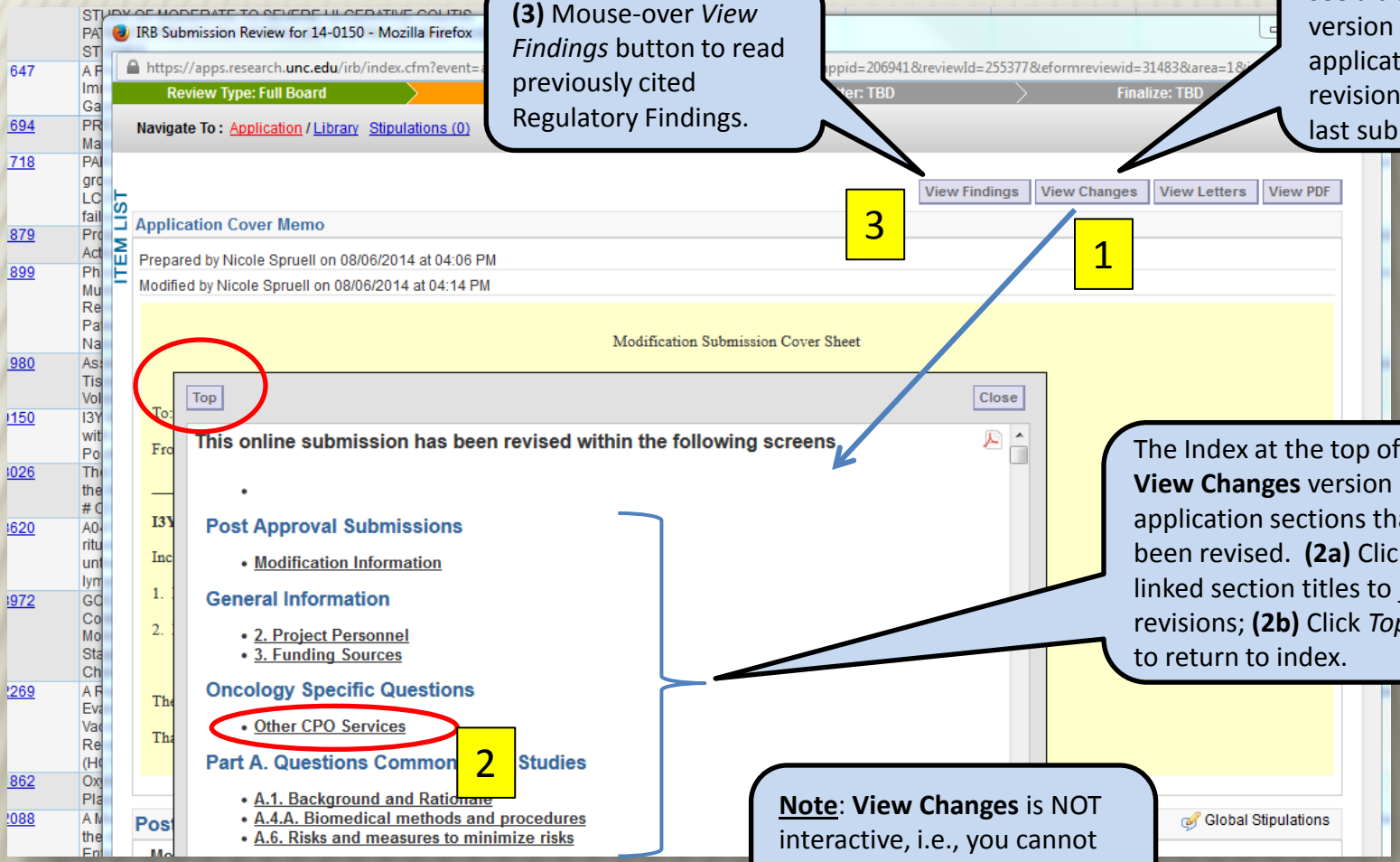


View Changes appears within a secondary (nested) pop-up window. Deletions are struck through in red; additions are displayed within boxes.
Note: **View Changes** does not display coordinator-added stipulations; neither can you add stipulations in this view. Add stipulations in the application window.

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



REVIEW MODIFICATIONS (AND RENEWALS WITH MODIFICATIONS) NAVIGATION



(1) Click the *View Changes* button to see a track-change version of the application showing revisions since the last submission.

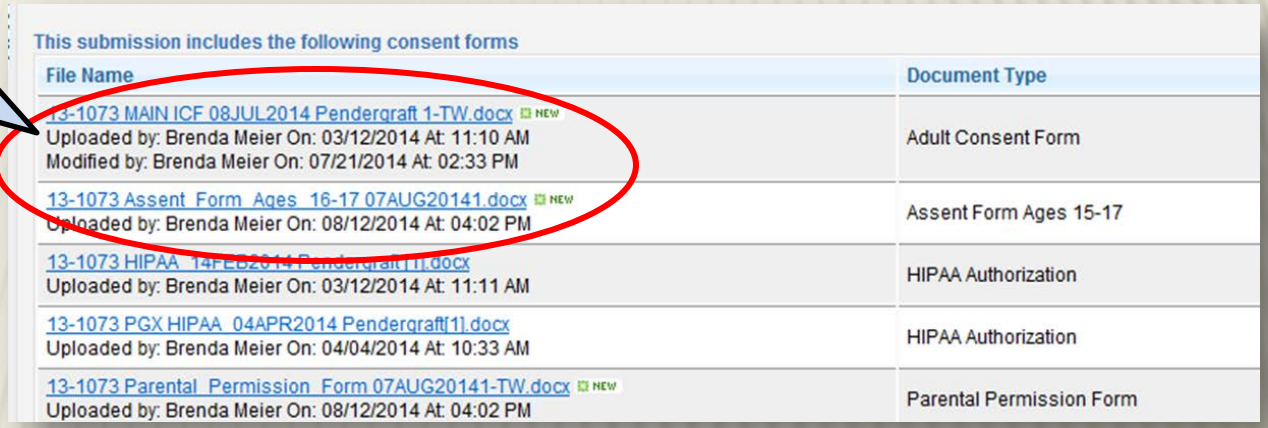
(3) Mouse-over *View Findings* button to read previously cited Regulatory Findings.

The Index at the top of the **View Changes** version lists application sections that have been revised. **(2a)** Click hot-linked section titles to jump to revisions; **(2b)** Click *Top* button to return to index.

Note: **View Changes** is NOT interactive, i.e., you cannot write stipulations in this view. Add stipulations in the application window.

REVIEW MODIFICATIONS (AND RENEWALS WITH MODIFICATIONS)
PI-REVISED VS NEWLY ADDED 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

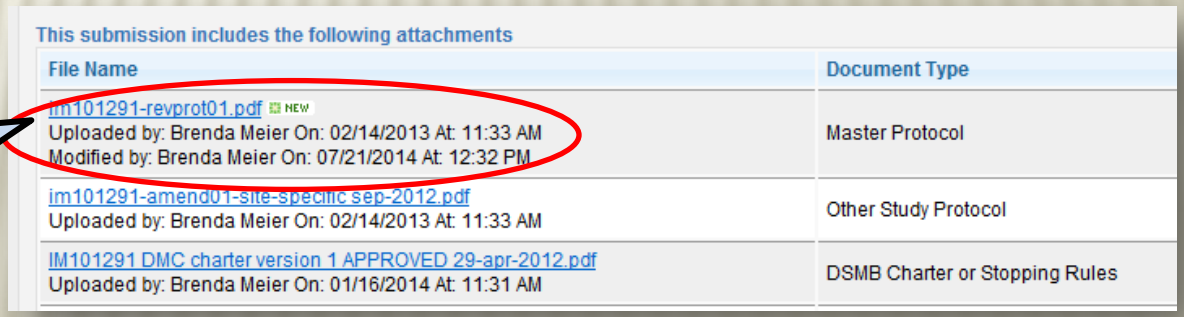
File Name	Document Type
13-1073 MAIN ICF 08JUL2014 Pendergraft 1-TW.docx NEW Uploaded by: Brenda Meier On: 03/12/2014 At: 11:10 AM Modified by: Brenda Meier On: 07/21/2014 At: 02:33 PM	Adult Consent Form
13-1073 Assent_Form_Ages_16-17 07AUG20141.docx NEW Uploaded by: Brenda Meier On: 08/12/2014 At: 04:02 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 NEWLY ADDED docs at the **Consent Forms** and **Attachments** sections (only).
- Access marked review copies of PI-REVISED docs submitted in Word at **All Study Attachments.**

Note: the original (unmarked) PI-REVISED documents are additionally found at **Consent Forms** and **Attachments.**

Access PI-REVISED documents in pdf format only at the **Consent Forms** and **Attachments** sections.
Note: Pdf documents will never be marked up or added to **All Study Attachments**.

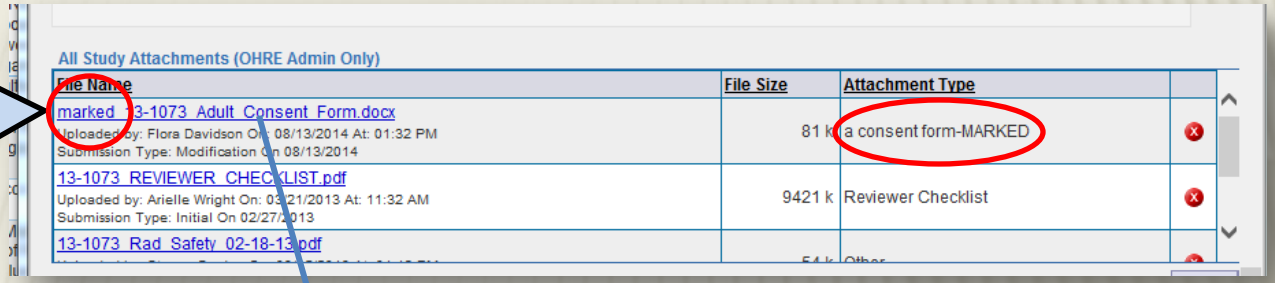


This submission includes the following attachments

File Name	Document Type
im101291-revprot01.pdf NEW Uploaded by: Brenda Meier On: 02/14/2013 At: 11:33 AM Modified by: Brenda Meier On: 07/21/2014 At: 12:32 PM	Master Protocol
im101291-amend01-site-specific sep-2012.pdf Uploaded by: Brenda Meier On: 02/14/2013 At: 11:33 AM	Other Study Protocol
IM101291 DMC charter version 1 APPROVED 29-apr-2012.pdf Uploaded by: Brenda Meier On: 01/16/2014 At: 11:31 AM	DSMB Charter or Stopping Rules

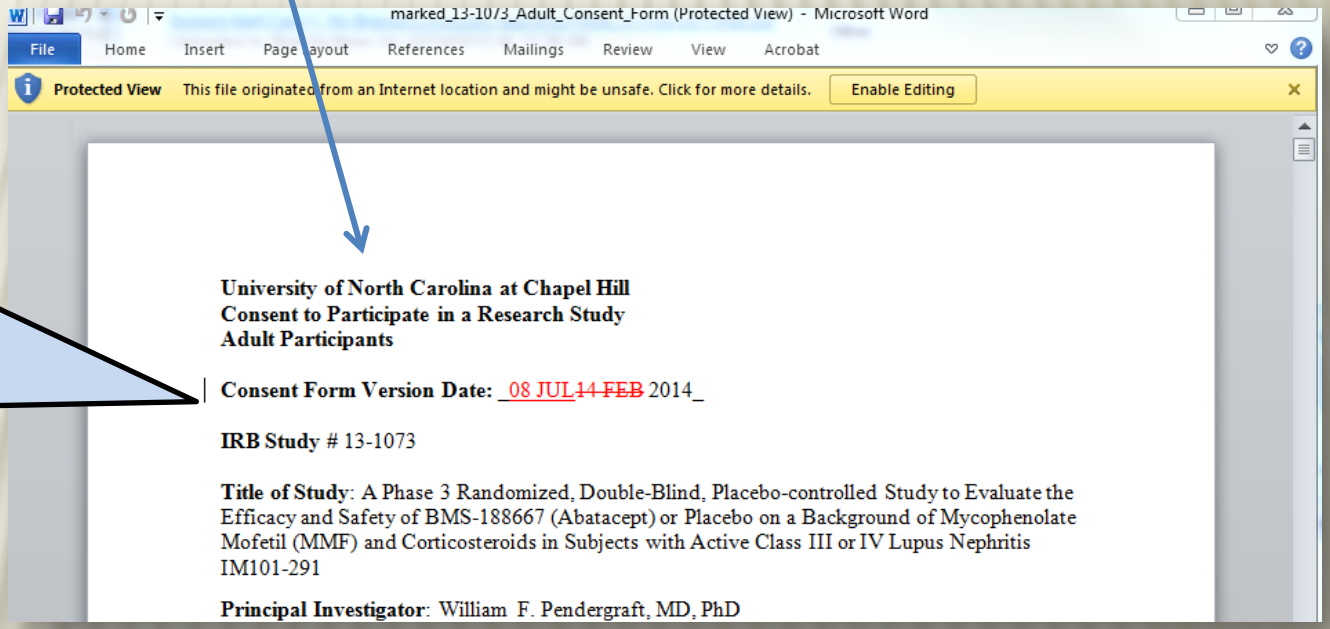
REVIEW MODIFICATIONS (AND RENEWALS WITH MODIFICATIONS)
REVIEWING REVISED DOCUMENTS AT "ALL STUDY ATTACHMENTS"

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



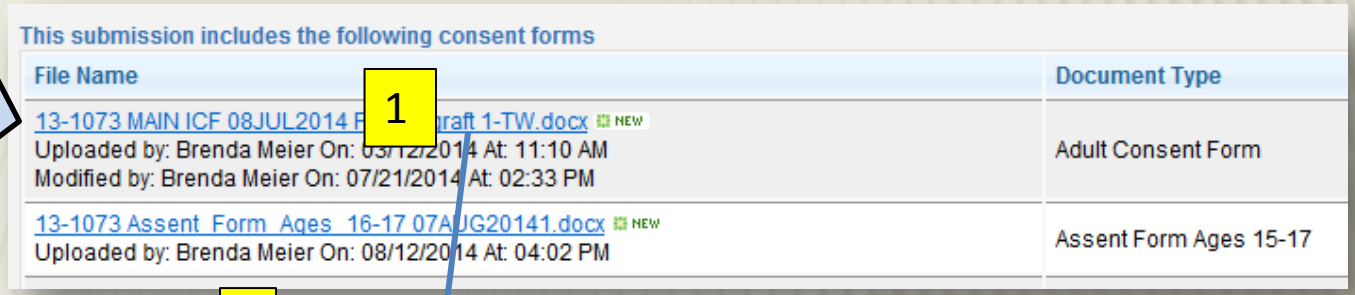
Marked versions are read-only review copies--you cannot add comments.

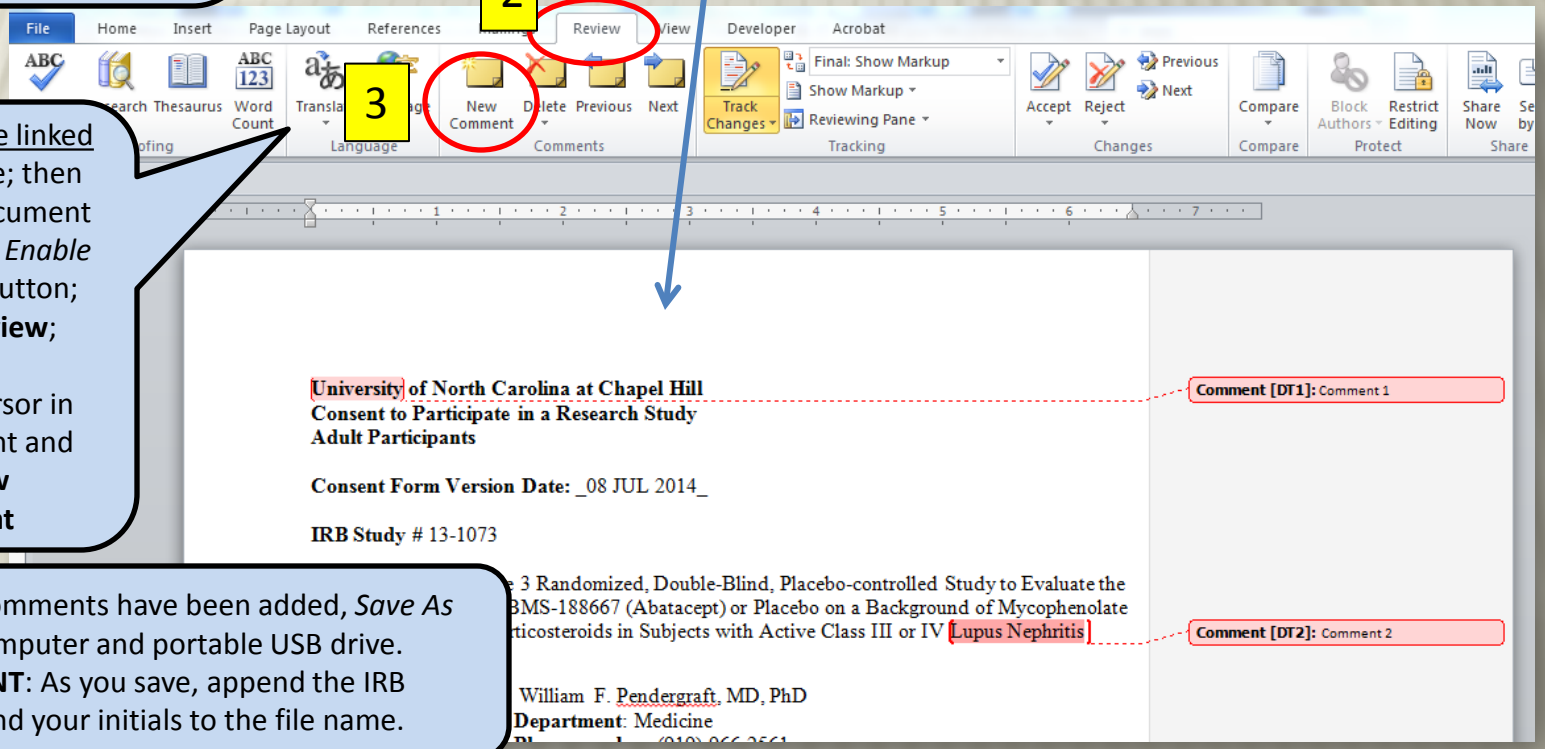
Note: Add your comments to the corresponding original (unmarked) documents at **Consent Forms** or **Attachments** (see next slide).



REVIEW MODIFICATIONS (AND RENEWALS WITH MODIFICATIONS) ADDING DOCUMENT COMMENTS

You may add new comments to unmarked documents at **Consent Forms** or **Attachments** sections (NOT at **All Study Attachments**).
Note: use only the Comments function; do not otherwise edit or mark-up.



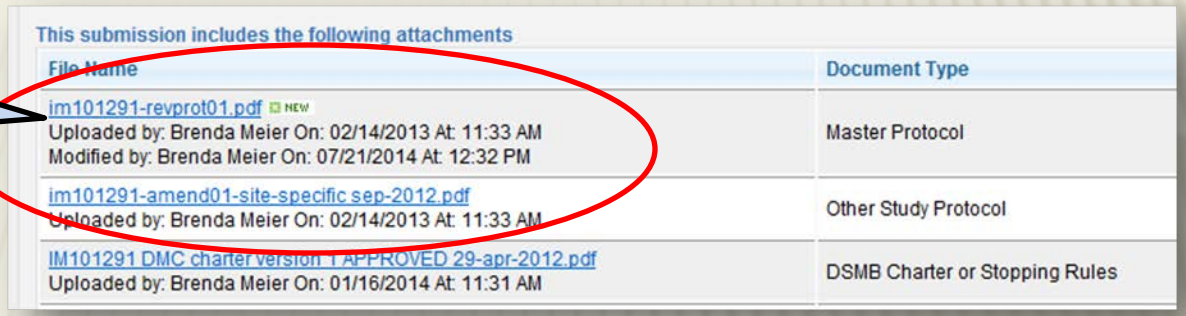


(1) Click blue linked file name; then open document and click *Enable Editing* button;
(2) Click **Review**; and
(3) Place cursor in document and click **New Comment**

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

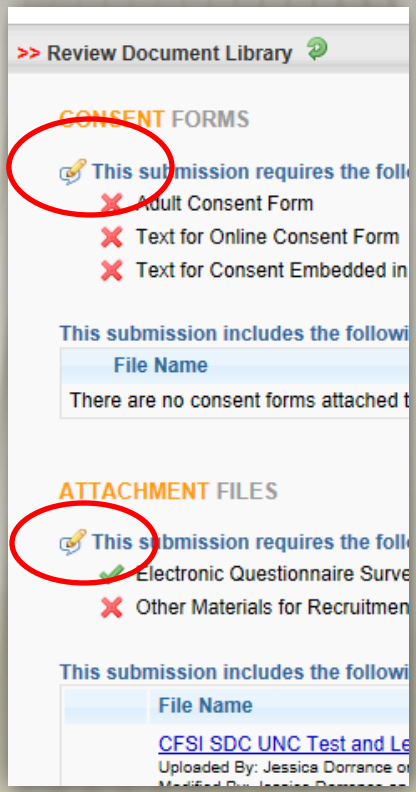
REVIEW MODIFICATIONS (AND RENEWALS WITH MODIFICATIONS) ADDING DOCUMENT STIPULATIONS

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



Add comments about documents in pdf format through stipulations at **Consent Forms** and **Attachments** (within the **Document Library** 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.



IF YOU HAVE QUESTIONS

Contact—during business hours:

- Your meeting coordinator (919) 966-3113
- David Tegnell, IRB Help Desk (919) 966-3685