

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.

RESEARCH AT CAROLINA
IRBIS
Application for IRB Approval of Human Subjects Research
Office of Human Research Ethics @ UNC-CH

[Continue to Login](#) 2

Onyen -or- UNC Guest ID: 3

Password:

[Sign in](#)

Forgot Username:
[Onyen](#) | [UNC Guest ID](#)

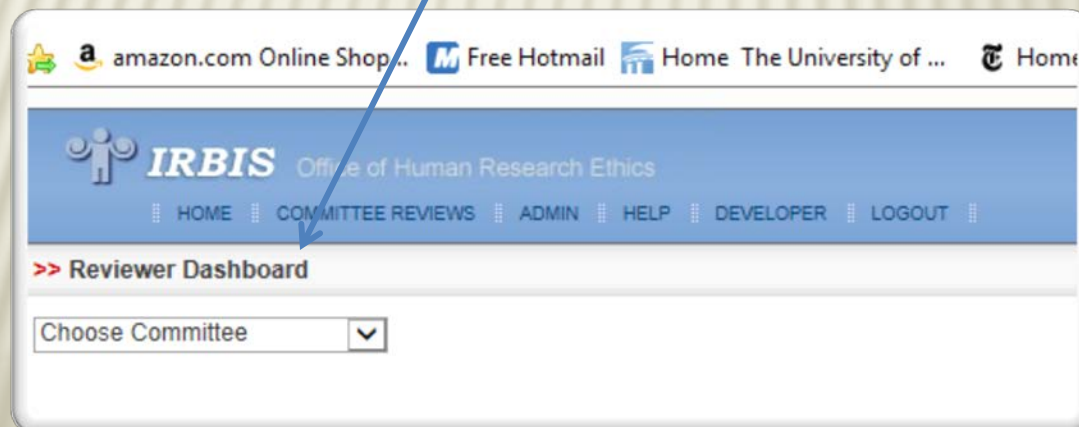
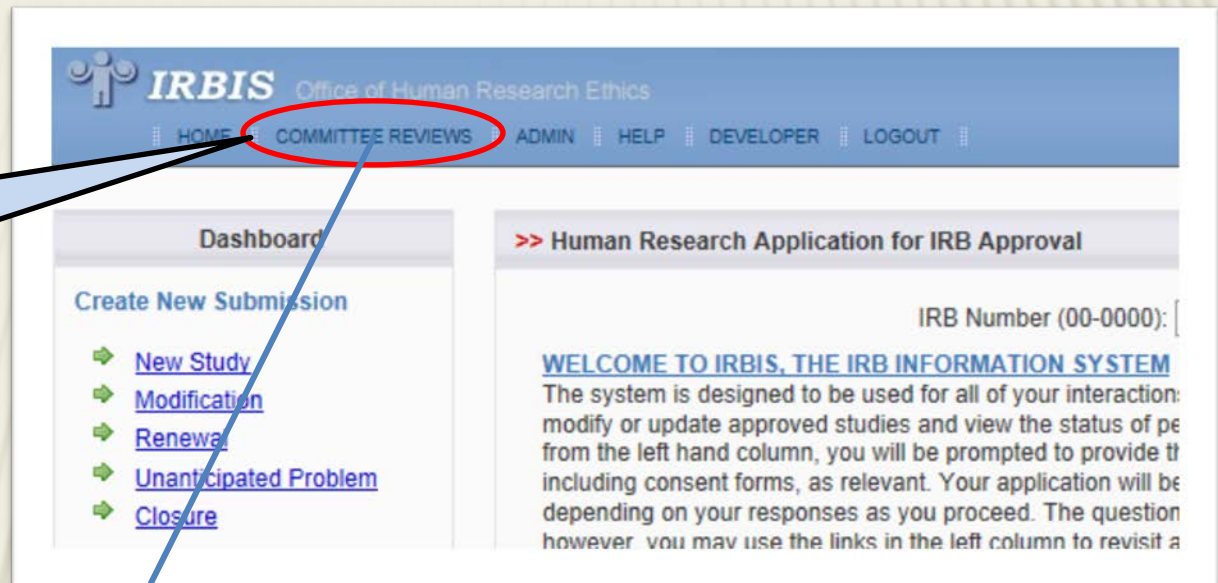
Forgot Password:
[Onyen](#) | [UNC Guest ID](#)

Learn more about:
[Onyen](#) | [UNC Guest ID](#)

⚠ IMPORTANT: To protect your personal information, you must close every instance of this browser that is open on your computer when you log out.

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**).

IRBIS Office of Human Research Ethics

HOME COMMITTEE REVIEWS ADMIN HELP DEVELOPER LOGOUT

>> Reviewer Dashboard

Biomedical D 08/25/2014 View Submissions

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

IRBIS Office of Human Research Ethics

HOME COMMITTEE REVIEWS ADMIN HELP DEVELOPER LOGOUT

>> Reviewer Dashboard

Biomedical D 08/25/2014 View Submissions

Filter: Show All Agenda Items

Studies for Full Board Review

Committee: Biomedical D
Review Date: 08/25/2014
Agenda: **Agenda not yet uploaded**
Meeting Minutes: [View Current Minutes](#)

Viewing 1 - 26 of 26 Records

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

You may click any column header to reorder the list.

ACCESS IRB APPLICATION

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

Studies for Full Board Review

Committee: Biomedical A
 Review Date: 09/02/2014
 Agenda: **Agenda not yet uploaded**
 Meeting Minutes: **Minutes not yet uploaded**

Viewing 1 - 16 of 16 Records

IRB Number	Title	PI	Submission Type	Date Received	Review Type
14-1003	Sentinel Gene Expression to Forecast Outcomes and Monitor Treatment Protocols in Combined Burn/Trauma	Cairns, Bruce	Initial	07/10/2014	Full Board
14-1280	AN OPEN LABEL EXTENSION AND SAFETY MONITORING STUDY OF MODERATE TO SEVERE ULCERATIVE COLITIS PATIENTS PREVIOUSLY ENROLLED IN ETROLIZUMAB PHASE III STUDIES	Isaacs, Kim	Initial	08/13/2014	Full Board
14-1647	A Phase IV, Open-Label Study to Compare Virologic and Immunologic Responses to Baltegravir and Dolutegravir in the	Kashuba, Angela	Initial	08/14/2014	Full Board

Viewing 1 - 16 of 16 Records

IRB Number	Title	PI	Submission Type	Date Received	Review Type	Reviewer	Sec
14-1003	Sentinel Gene Expression to Forecast Outcomes and Monitor	Cairns, Bruce	Initial	07/10/2014	Full Board	Renegar, Galle	Floris
14-1280	IRB Submission Review for 14-1280 - Mozilla Firefox						
14-1647	AN OPEN LABEL EXTENSION AND SAFETY MONITORING STUDY OF MODERATE TO SEVERE ULCERATIVE COLITIS PATIENTS PREVIOUSLY ENROLLED IN ETROLIZUMAB PHASE III STUDIES	Isaacs, Kim	Initial	08/13/2014	Full Board		
14-1694	A Phase IV, Open-Label Study to Compare Virologic and Immunologic Responses to Baltegravir and Dolutegravir in the	Kashuba, Angela	Initial	08/14/2014	Full Board		
14-1718							
14-1879							
14-1899							
14-1980							
14-0150							
13-3026							
13-3620							

Navigation: [Application](#) / [Library](#) / [Stipulations \(6\)](#) / [Next Step: Record Result](#)

View Changes View Letters View PDF

Application Cover Memo

Prepared by Mikki Sandridge on 08/04/2014 at 01:45 PM

This protocol is an open-label extension and safety monitoring study available to subjects that have been previously enrolled in the Phase III controlled studies (2 of which are being offered at UNC, IRB approved 14-0863 and 14-1899, pending IRB approval).

Please note that gadolinium contrast will not be used in every subject. Only in the event of suspicion of PML will a brain MRI with contrast be performed. This is highly unlikely, as there have been no positive cases of PML seen in patients with prior exposure to etrolizumab.

General Information

1. General Information

1. Project Title

AN OPEN LABEL EXTENSION AND SAFETY MONITORING STUDY OF MODERATE TO SEVERE ULCERATIVE COLITIS PATIENTS PREVIOUSLY ENROLLED IN ETROLIZUMAB PHASE III STUDIES

2. Brief Summary. Provide a brief non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

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

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

NAVIGATE THE IRB APPLICATION

https://apps.research.unc.edu/irb/index.cfm?event=admin.review.pageReview&committeeReview=true&appid=206830&reviewId=255338&eformreviewid=31444&area=1&jsexec=Run... 12

Review Type: Full Board Result: TBD Letter: TBD Finalize: TBD

Navigate To: [Application](#) / [Library](#) / [Stipulations \(6\)](#) **1** Step: [Record Result](#)

B.2. Protected Health Information (PHI)
B.3. Subject Contact, Duration and Privacy
B.4. Incentives for participation
B.5. Costs to be borne by subjects

Part C. Existing Data, Records, Specimens
C.1. Data Sources
C.2. Coding and Data Use Agreements

Part D. The Consent Process
D.1. Obtaining informed consent from subjects
D.2. Waiver of written documentation of informed consent
D.3. Full or partial waiver of consent

Data Security Requirements
Data Security

CTRC Addendum
Introduction
CTRC Clinical Facilities and Nursing Services - Outpatient Clinic
CTRC Nutrition, Body Composition, or Research Kitchen Meal Services
CTRC Specimen Banking and Storage Facilities
CTRC Billing and Assignment Sheet

Consent Form **2**
[Consent Forms](#)

Attachments
Attachments

ITEM LIST

Available to subjects that have been previously enrolled in the Phase III controlled studies (2 of which a approval).

subject. Only in the event of suspicion of PML will a brain MRI with contrast be performed. This is highly patients with prior exposure to etrolizumab.

ING STUDY OF MODERATE TO SEVE

e study, which will be used in IRB document ding labels already in place, so that reviewer

lab in patients eligible for Part 1 (OLE) safety monitoring (Part 2)

GA2894

- (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.

Online Submission - Windows Internet Explorer

>> Consent Forms:

This submission requires the following consent forms
Stipulation: **by Christina Tyler on 08/12/2014 at 02:04 PM**

Consent form (pg. 2), please indicate whom will pay for pregnancy tests.

Stipulation: **by Christina Tyler on 08/12/2014 at 02:04 PM**

Consent form (pg. 3), under "Will it cost you anything to be in this study?" please remove "N

Template Name

✓ Adult Consent Form

This submission includes the following consent forms

File Name **3**
[Consent form.docx](#)
Uploaded by: Tanjit Taggar On: 08/03/2014 At: 07:47 PM

>> Attachments:

This submission requires the following attachments

Document Type

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).

Will this clinical trial be listed in ClinicalTrials.gov, either by you or the sponsor?

Yes

Choose the appropriate Phase designation for this clinical trial.

Stipulation: by Christina Tyler on 08/12/2014 at 01:57 PM

Last updated by Christina Tyler on 08/12/2014 at 01:57 PM

Please elaborate on the type of trial being conducted below, under **"If other, please explain."**

☒ Pilot Study

☒ Phase I

NAVIG

A.5. Benefits to subjects and/or society

1.

Describe how this study will contribute to generalizable knowledge that will benefit society.

Pain associated with pulpitis is often moderate to severe in intensity. Most patients first attempt to manage the pain by using analgesics and eventually seek emergency dental care. A faster onset of analgesia using ibuprofen sodium dihydrate may be helpful in clinical practice. The formulation may be administered after diagnosis is completed in an emergency appointment to achieve analgesia prior to initiating treatment. Furthermore, the formulation may be utilized as an adjunct in achieving pulpal anesthesia in patients with severe odontalgia.

2. Does this study have the potential for direct benefit to individual subjects in this study?

Yes

 Reviewer Checklist

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.

All Study Attachments (OHRE Admin Only)

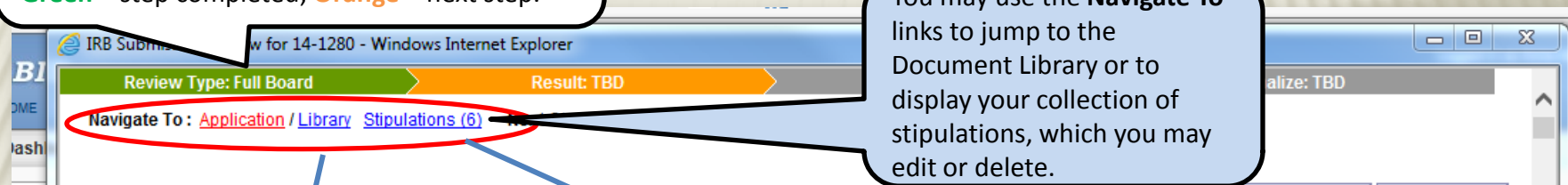
File Name	File Size	Attachment Type
marked_14-0762_Adult_Consent_form.docx Uploaded by: Flora Davidson On: 08/13/2014 At: 12:28 PM Submission Type: Initial On 08/09/2014	39 k	consent form-MARKED
14-0762_Reviewer_Checklist_06-23-14.pdf Uploaded by: Steven Gordon On: 07/09/2014 At: 11:07 AM Submission Type: Initial On 08/09/2014	817 k	Reviewer Checklist
14-0762_Reviewer_Checklist.pdf	40 k	Reviewer Checklist

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.



>> Review Document Library (Committee)

This submission includes the following application files

File Name
initial as submitted 138063.pdf

>> **Consent Forms:**

This submission requires the following consent forms

Template Name
✓ Adult Consent Form
✓ HIPAA Authorization
✓ SSN Collection for payments
✓ Sponsor's Model Consent Form

This submission includes the following consent forms

File Name
GA28951_Part 1 OLE Pregnant Partner Isaacs_RSU Reviewed.docx Uploaded by: Mikki Sandridge On: 08/08/2014 At: 10:28 AM
GA28951_Part 1 OLE Adult Consent Form Isaacs_08 Aug2014.docx Uploaded by: Mikki Sandridge On: 08/08/2014 At: 11:03 AM
GA28951_Part 2 SM Pregnant Partner Isaacs_RSU Reviewed.docx Uploaded by: Mikki Sandridge On: 08/08/2014 At: 10:27 AM

Drafted Stips for this Submission

Number of Stipulations: 6

Part A. Questions Common to All Studies

A.2. Subjects

Total number of subjects to be studied by the UNC-CH investigator(s) (provide exact number, if unlimited, enter 9999):

Created by Mike Matamoros on 08/19/2014 11:39 AM

The consent form states that 8 subjects from UNC will take part. Please reconcile.

[Edit Stipulation](#) [Delete](#)

Part B. Direct Interaction

B.1. Methods of recruiting

Describe how subjects will be identified

Created by Mike Matamoros on 08/19/2014 12:03 PM

Please explain how you will identify subjects who have been previously enrolled in one of the Phase III controlled studies.

[Edit Stipulation](#) [Delete](#)

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.

10.

4

Stipulation: Macro: Select Macro Insert Macro

Source Size **B** *I* U ABC

Please describe all physical risks associated with medication use (i.e. bleeding).

Save Stipulation Delete Cancel

Describe any items checked above, including the category of likelihood and what will be done to minimize these risks. Where possible, describe the likelihood of the risks occurring, using the following terms:

- Very Common (approximate incidence > 50%)
- Common (approximate incidence > 25%)
- Likely (approximate incidence of 10-25%)
- Infrequent (approximate incidence of 1-10%)
- Rare (approximate incidence < 1%)

2

Stipulation: by Christina Tyler on 08/25/2014 at 01:50 PM **1**

Please describe all physical risks associated with medication use (i.e. bleeding).

Stipulation: by Christina Tyler on 08/26/2014 at 10:18 AM **3**

Please add estimated frequency of the IBU side effects.

Stipulation: by David Tegnell on 08/27/2014 at 09:17 AM

Reviewer #2 comment

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

Medication side effects may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters. The medication may cause severe stomach bleeding.

Participants will be advised to seek medical follow up or psychological counseling if deemed necessary at any stage.

“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.

The screenshot shows the IRBIS application interface. The main window displays the 'Application Cover Memo' for IRB Number 14-074. The 'View Changes' button is highlighted with a yellow box labeled '1'. The 'View Letters' button is highlighted with a yellow box labeled '2'. The 'View PDF' button is highlighted with a yellow box labeled '3'. The 'View Changes' pop-up window is open, showing the 'Application Cover Memo' with highlighted changes. The 'View Letters' pop-up window is open, showing the 'Letters' table. The 'View Letter' icon is highlighted with a yellow box labeled '4'. The 'view' link under 'PI Responses' is highlighted with a yellow box labeled '4'.

Application Cover Memo

Prepared by Andrew Tweedell on 06/18/2014 at 02:35 PM
Modified by Eric Ryan on 06/19/2014 at 05:26 PM

Dear Institutional Review Board,

A. Please describe

Experimental group participants will be compensated ~~\$70~~ **\$50** for completion of study.

Control group participants will be compensated ~~\$30~~ **\$50** for completion of study.

B. Specify the schedule for incentives and if/how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completing it.

~~Experimental group participants~~ **Participants** will be compensated ~~\$70~~ **\$50** for completion of study.

Visit 1: Orientation/Familiarization (\$5)

Visit 2: Pre Measurements (\$10)

Visit 3: Post Measurements (~~\$5~~)

~~Control group participants will be compensated \$30 for completion of study.~~

~~Visit 1: orientation (\$5)~~

~~Visit 2: Pre-Measurements (\$10)~~

~~Visit 3: Post-Measurement (\$15)~~

\$35

Letters

Review Result	Date Sent	View Letter	Document List	PI Responses
Deferral	06/27/2014 08:15:25 AM	<input checked="" type="checkbox"/>		view

EFORM STIPULATION

Christina Tyler on 06/11/2014 09:25 AM

Please provide requested information for Kathleen Welsh-Bohmer, Co-Investigator at Duke University. (i.e. FWA #, Contact Person at Duke, External institution signatory official; CV).

Updated by Kelly Giovanello on 07/10/2014 10:41 AM

The requested information for Duke University and Dr. Welsh-Bohmer has been inserted into the application. Additionally, Dr. Welsh-Bohmer's CV has been uploaded as an attachment.

REVIEW MODIFICATIONS (AND RENEWALS WITH MODIFICATIONS) NAVIGATION

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

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

The screenshot displays the IRB Submission Review interface. At the top, the 'Review Type: Full Board' is indicated. Below this, the 'Navigate To' section shows links for 'Application', 'Library', and 'Stipulations (0)'. The 'View Findings', 'View Changes', 'View Letters', and 'View PDF' buttons are visible. The 'View Changes' button is highlighted with a yellow box labeled '1'. The 'View Findings' button is highlighted with a yellow box labeled '3'. The 'Modification Submission Cover Sheet' is displayed, showing a list of sections: 'Post Approval Submissions', 'General Information', 'Oncology Specific Questions', and 'Part A. Questions Common to Studies'. The 'Other CPO Services' link under 'Oncology Specific Questions' is circled in red and labeled with a yellow box '2'. A 'Top' button is also circled in red. A blue arrow points from the 'View Changes' button to the 'Modification Submission Cover Sheet'.

ITEM LIST

Application Cover Memo

Prepared by Nicole Spruell on 08/06/2014 at 04:06 PM

Modified by Nicole Spruell on 08/06/2014 at 04:14 PM

Modification Submission Cover Sheet

Top

This online submission has been revised within the following screens:

- Modification Information

General Information

- 2. Project Personnel
- 3. Funding Sources

Oncology Specific Questions

- Other CPO Services

Part A. Questions Common to Studies

- A.1. Background and Rationale
- A.4.A. Biomedical methods and procedures
- A.6. Risks and measures to minimize risks

Global Stipulations

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.”




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 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 Pendergraft11.docx Uploaded by: Brenda Meier On: 03/12/2014 At: 11:11 AM	HIPAA Authorization
13-1073 PGX HIPAA 04APR2014 Pendergraft11.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

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.

All Study Attachments (OHRE Admin Only)

File Name	File Size	Attachment Type	
marked_13-1073_Adult_Consent_Form.docx Uploaded by: Flora Davidson On: 08/13/2014 At: 01:32 PM Submission Type: Modification On 08/13/2014	81 k	a consent form-MARKED	
13-1073 REVIEWER CHECKLIST.pdf Uploaded by: Arielle Wright On: 03/21/2013 At: 11:32 AM Submission Type: Initial On 02/27/2013	9421 k	Reviewer Checklist	
13-1073 Rad Safety 02-18-13.pdf	5.4 k	Other	

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).

marked_13-1073_Adult_Consent_Form (Protected View) - Microsoft Word

File Home Insert Page Layout References Mailings Review View Acrobat

Protected View This file originated from an Internet location and might be unsafe. Click for more details. [Enable Editing](#)

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 08 JUL 14 ~~FEB~~ 2014

IRB Study # 13-1073

Title of Study: A Phase 3 Randomized, Double-Blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of BMS-188667 (Abatacept) or Placebo on a Background of Mycophenolate Mofetil (MMF) and Corticosteroids in Subjects with Active Class III or IV Lupus Nephritis IM101-291

Principal Investigator: William F. Pendergraft, MD, PhD

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.

This submission includes the following consent forms

File Name	Document Type
13-1073 MAIN ICF 08JUL2014 P Draft 1-TW.docx NEW	Adult Consent Form
Uploaded by: Brenda Meier On: 03/12/2014 At: 11:10 AM Modified by: Brenda Meier On: 07/21/2014 At: 02:33 PM	
13-1073 Assent Form Ages 16-17 07AUG20141.docx NEW	Assent Form Ages 15-17
Uploaded by: Brenda Meier On: 08/12/2014 At: 04:02 PM	

- (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.

The screenshot shows the Microsoft Word interface with the **Review** tab selected. A blue arrow points from the 'New Comment' button in the ribbon to a comment box in the document. The document content includes:

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: _08 JUL 2014_

IRB Study # 13-1073

3 Randomized, Double-Blind, Placebo-controlled Study to Evaluate the
 BMS-188667 (Abatacept) or Placebo on a Background of Mycophenolate
 corticosteroids in Subjects with Active Class III or IV **Lupus Nephritis**

William F. Pendergraft, MD, PhD
 Department: Medicine


Two comment boxes are visible on the right side of the document:

- Comment [DT1]:** Comment 1
- Comment [DT2]:** Comment 2

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.

This submission includes the following attachments


File Name	Document Type
im101291-revprot01.pdf  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




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.

>> Review Document Library 

CONSENT FORMS


 This submission requires the following:



-  Adult Consent Form
-  Text for Online Consent Form
-  Text for Consent Embedded in

This submission includes the following:

File Name
There are no consent forms attached to this submission.

ATTACHMENT FILES

 This submission requires the following:

-  Electronic Questionnaire Survey
-  Other Materials for Recruitment

This submission includes the following:

File Name
CFSI SDC UNC Test and Le Uploaded By: Jessica Dorrance on Modified By: Jessica Dorrance on

IF YOU HAVE QUESTIONS

Contact—during business hours:

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