



IRBIS

Office of Human Research Ethics

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.

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

[Continue to Login](#)

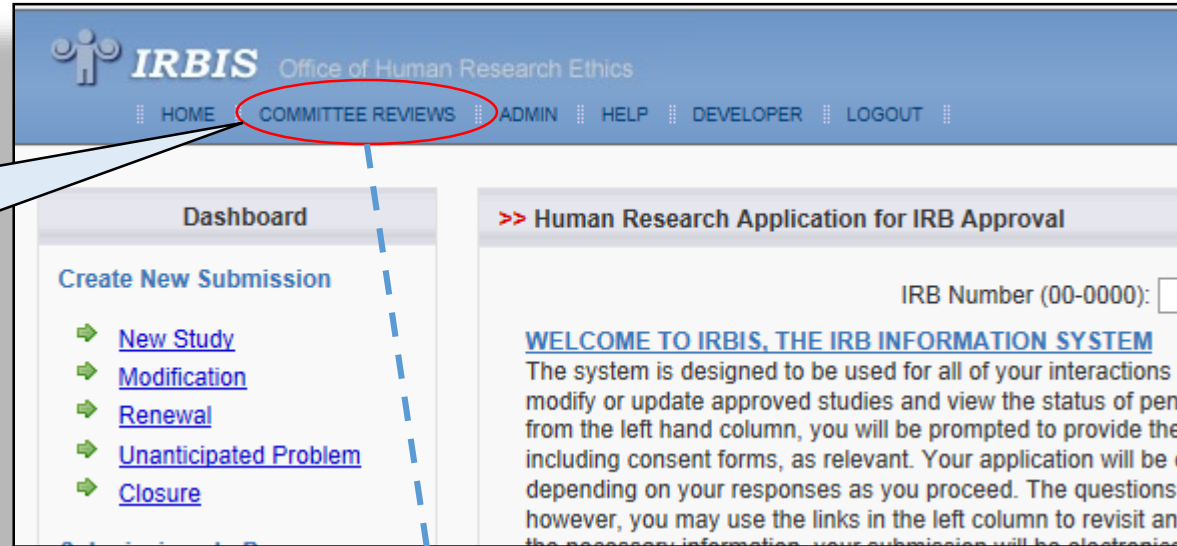
Onyen -or- UNC Guest ID: [Forgot Username: Onyen | UNC Guest ID](#)

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

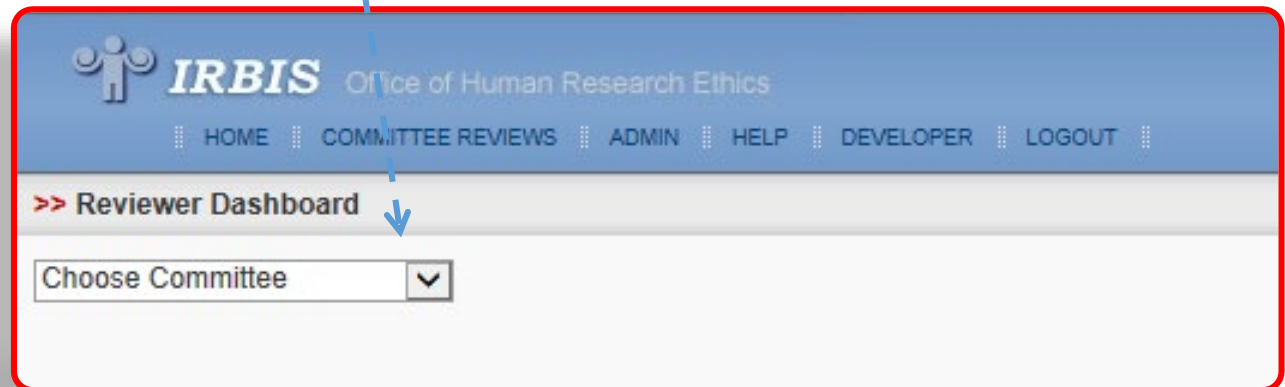
[Sign in](#) [Learn more about: Onyen | UNC Guest ID](#)

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

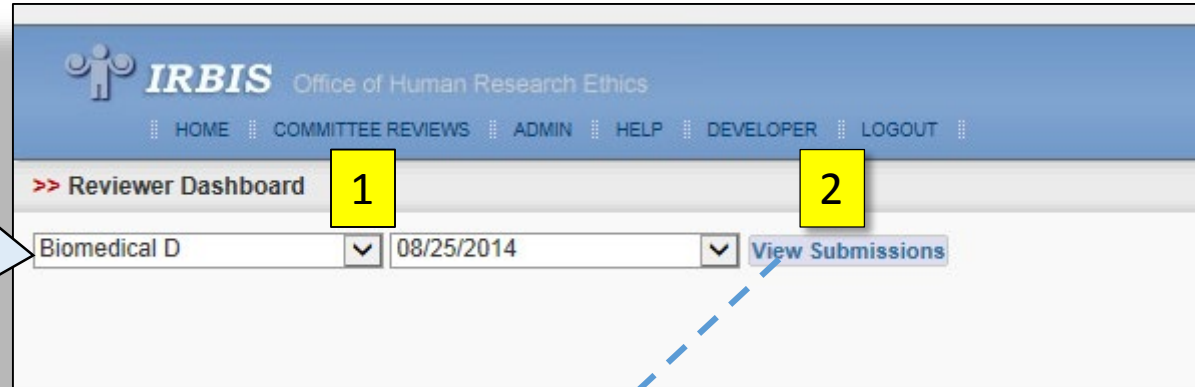


At IRBIS Home (your landing screen), click COMMITTEE REVIEWS to access Reviewer Dashboard.



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**).



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

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	A Phase IV, Open-Label Study to Compare Virologic and	Kashuba, Angela	Initial	08/14/2014	Full Board		

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

Navigate To: [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 [Global Stipulations](#)

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

The screenshot shows the IRB application interface. At the top, there is a navigation bar with "Review Type: Full Board", "Result: TBD", "Letter: TBD", and "Finalize: TBD". Below this is a "Navigate To:" section with links for "Application", "Library", "Stipulations (6)", and "Step: Record Result". A yellow box with the number "1" is placed over the "Application" link. To the right of the navigation bar is a vertical "ITEM LIST" sidebar. A red circle highlights the "ITEM LIST" text. Below the sidebar, there are several sections: "Part C. Existing Data, Records, Specimens", "Part D. The Consent Process", "Data Security Requirements", "CTRC Addendum", and "Consent Forms". A yellow box with the number "2" is placed over the "Consent Forms" link in the sidebar. Below the sidebar, there is a main content area with text, including "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.", and "lab in patients eligible for Part 1 (OLE) safety monitoring (Part 2)".

- (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.

2

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.*

The screenshot shows a window titled "Online Submission - Windows Internet Explorer". The main content area is titled ">> Consent Forms:". Below this, there is a section titled "This submission requires the following consent forms" with a "Stipulation: by Christina Tyler on 08/12/2014 at 02:04 PM". Below this, there is a section titled "Consent form (pg. 2), please indicate whom will pay for pregnancy tests." with a "Stipulation: by Christina Tyler on 08/12/2014 at 02:04 PM". Below this, there is a section titled "Consent form (pg. 3), under 'Will it cost you anything to be in this study?' please remove 'N". Below this, there is a section titled "Template Name" with a "✓ Adult Consent Form". Below this, there is a section titled "This submission includes the following consent forms" with a "File Name" section containing a yellow box with the number "3" and a link to "Consent form.docx". Below this, there is a section titled "Uploaded by: Tanjit Taggar On: 08/03/2014 At: 07:47 PM". Below this, there is a section titled ">> Attachments:". Below this, there is a section titled "This submission requires the following attachments" with a "Document Type" section.

>> Attachments:

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 **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**.

All Study Attachments (OHRE Admin Only)

OHRE Attachments: These are OHRE Only Attachments View All Attachments

File Name	Document Type	Submission	Date	
BROAD- NCSU rely on UNC biomed engin collab: executed.pdf	Broad IAA	Initial		Delete
Uploaded by Barbara Griese on 07/14/2016				
View 1 - 1 of 1				

Email Management for IRB NO: 16-1852

Viewing 1 - 1 of 1 Records Page 1 of 1

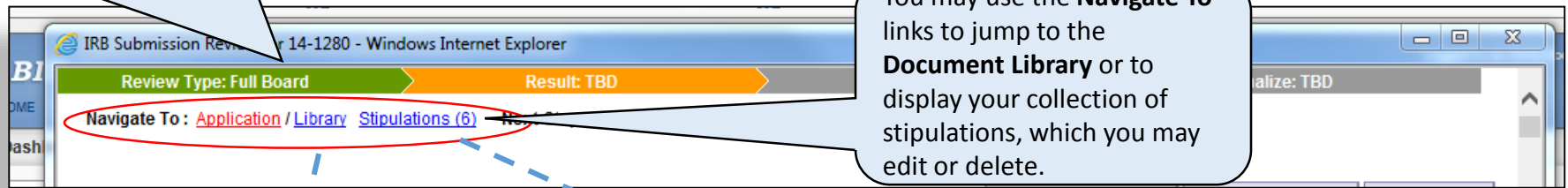
Date Sent	To	From	Subject	Uploaded By	Submission	Date
7/14/2016	IRBreliance@unc.edu	dapaxton@ncsu.edu	Re: IMPORTANT - Broad Agreement for UNC NCSU Department of BME UNC #16-1852	Barbara Griese	Initial	6/27/2016

Viewing 1 - 1 of 1 Records Page 1 of 1

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: 10:26 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

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.

The screenshot shows the top portion of an application form. At the top right, there is a yellow bar with a blue icon and the text "Global Stipulations", which is circled in red. Below this, the form is divided into sections. The first section is "1. General Information". Underneath, there are two items: "1. Project Title" and "2. Brief Summary". Both items have a small blue icon with a pencil and a plus sign next to them, indicating where to click to add a stipulation. The text for "1. Project Title" reads: "The analgesic effect of an ibuprofen sodium dihydrate formulation on odontogenic pain." The text for "2. Brief Summary" reads: "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." A blue dashed arrow points from the "Add New Stipulation" icon next to item 2 to the "Stipulation" dialog box shown in the next image.

The "Stipulation" dialog box is shown, featuring a title bar with a blue icon and a plus sign. The dialog has a "Stipulation:" label on the left, a "Macro:" dropdown menu with "Select Macro" selected, and an "Insert Macro" button. Below the title bar is a rich text editor toolbar with icons for Source, Undo, Redo, Bold, Italic, Underline, Text Color, Background Color, Bulleted List, Numbered List, Indent, Outdent, Link, Unlink, X₂, X², and ABC. The main text area contains the placeholder text "Type your comments here". At the bottom of the dialog, there are "Add Stipulation" and "Cancel" buttons. The status bar at the bottom left shows "body p".

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.

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”

- 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

The screenshot shows the IRB Reviewer Dashboard. On the left, a list of studies is displayed, with the study ID 15-2605 circled in red and labeled with a '1'. The main area shows the 'PI Responses (5)' for this study, with a '2' in a box pointing to the 'PI Responses (5)' link. The detailed view shows a stipulation by Cynthia Brown on 11/17/2015. A response by Carol Barlow on 11/20/2015 is shown in a yellow box. Below the response, there are options to 'Resolve' (checked) or 'Resend (Create new stipulation)'. A pink box indicates that the stipulation has been marked as resolved.

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.

This screenshot shows the 'Resend' action interface. The 'Resend (Create new stipulation)' option is selected and circled in blue. Below this, a green text box opens, containing the following text: 'Resend (Create new stipulation) by Cynthia Brown on 12/01/2015 08:24 AM'. The text explains that Matthew Phillips' COI is still outstanding and that the application cannot be approved until COI filing requirements are met. It also provides instructions for personnel to complete COI disclosures.

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."

13-3225

14-2016 (V600E Negative) Automated Pulse the Pediatric Intel

14-2111 LCCC 1407: Pha Nab-paclitaxel Ho Cancer (NSCLC)

13-3225

14-0993 CLEE011X2108: fulvestrant and B postmenopausal negative locally r

10-2070 NAI114373 - A P Double-Dummy 5 mg or 600 mg of 75 mg of Oral Os Hospitalized Adul EMR-63325-001: Responses to NS

NAVIGATION

Post Approval Submissions

View Findings View Changes View Letters View PDF Close

IRB Number: 13-3225

1. Pro do Ty ED

The effects of the study drug on the developing human fetus are unknown. Thus, women of childbearing potential and men must agree to use effective contraception, defined as 2 barrier methods, or 1 barrier method with a spermicide, an intrauterine device or use of oral female contraceptive. Effective contraception must be used 30 days prior to first study drug administration, for the duration of trial participation, and at least for 60 days after stopping trial participation. Should a woman become pregnant or suspect she is pregnant while she or her partner is participating in this trial, the treating physician should be informed immediately.)

ACC: Histologically or cytologically confirmed metastatic ACC. Subjects must have previously received at least 1 line of systemic therapy for metastatic disease, of which at least one must be platinum-based. Subjects receiving mitotane may continue to receive mitotane at enrollment and on study.

Mesothelioma: Histologically or cytologically confirmed mesothelioma (pleural or peritoneal) with unresectable disease. Subjects must have received and progressed after either a platinum-pemetrexed containing regimen or a platinum-containing regimen followed by pemetrexed after disease progression. Subjects must present with at least 1 measurable lesion that has not been irradiated.

Urothelial carcinoma: Histologically or cytologically confirmed metastatic urothelial carcinoma of the bladder, urethra, ureter, or renal pelvis. Subjects must have progressed on first line platinum-based chemotherapy and may have received any number of prior systemic therapies.

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IRB approval and date). N MAY BE

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Addendum

er completion

Letters

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

IRB Number: 14-07

EFORM STIPULATION

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

Kelly Giovanello

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.

General

1. Gen

1. Pro

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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.

(2a) Click hot-linked section titles to jump to revisions;

(2b) Click *Top* button to return to index.

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

Optionally, you may click pdf icon to print **View Changes** window only

The Index at the top of the **View Changes** version lists application sections that have been revised.

Note: **View Changes** is NOT interactive, i.e., you cannot write stipulations in this view. Add stipulations in the [Application](#) window.

Global Stipulations

ITEM LIST

IRB Submission Review for 14-0150 - Mozilla Firefox

https://apps.research.unc.edu/irb/index.cfm?event=...

Review Type: Full Board

Navigate To: [Application](#) / [Library](#) / [Stipulations \(0\)](#)

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

This online submission has been revised within the following screens.

- [Modification Information](#)

General Information

1. [2. Project Personnel](#)
2. [3. Funding Sources](#)

Oncology Specific Questions

- [Other CPO Services](#)

Part A. Questions Common to all Studies

- [A.1. Background and Rationale](#)
- [A.4.A. Biomedical methods and procedures](#)
- [A.6. Risks and measures to minimize risks](#)

View Findings View Changes View Letters View PDF

Top Close

PDF icon

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.

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

“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).

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 JUL14 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

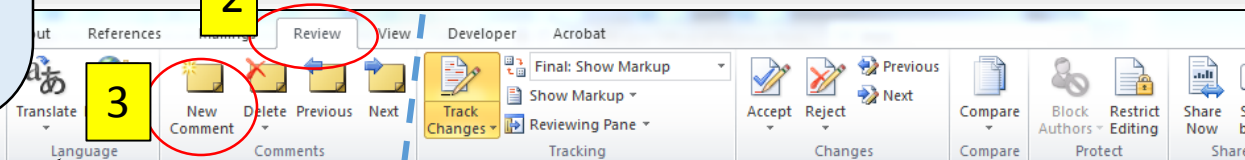
Review Modifications (and Renewals with Modifications)

Adding 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**.
Note 1: 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.

This submission includes the following consent forms

File Name	Document Type
13-1073 MAIN ICF 08JUL2014 Pendergraft 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 jump drive.
IMPORTANT: As you save, append the IRB Number and your initials to the file name.

The image shows a document with two comments. The first comment, labeled 'Comment [DT1]: Comment 1', is positioned next to the text 'University of North Carolina at Chapel Hill Consent to Participate in a Research Study Adult Participants'. The second comment, labeled 'Comment [DT2]: Comment 2', is positioned next to the text 'Lupus Nephritis'. A red dashed line connects the comment boxes to the text they are commenting on.

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.


This submission includes the following attachments

File Name	Document Type
im101291-revprot01.pdf <small>NEW</small> 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

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.

>> 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 of Modified By: Jessica Dorrance of

Add/view a primary reviewer summary

1

Primary Reviewer Summary

Enter your Primary Reviewer Summary below and click save

Summary:
For individuals implanted with FDA-approved HeartMate II LVAD, the proposed multi-center observational study will be used to estimate the incidence of pump thrombosis in the current era, and to identify risk factors for pump thrombosis.
N=300 subjects will be studied (30 at UNC).
Evaluations: baseline, implant, week 1 months 1,3, 6.
Anticipated width of 95% CI assuming thrombosis rate is 4% and N = 300 + or - 2.22.

Save Save & Close Close Delete 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.

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Primary Reviewer Summary View Changes View Letters View PDF

Primary Review Summary: David Tegnell on 09/24/2014 at 09:15 AM

3

Edit

Summary:
For individuals implanted with FDA-approved HeartMate II LVAD, the proposed multi-center observational study will be used to estimate the incidence of pump thrombosis in the current era, and to identify risk factors for pump thrombosis.
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Evaluations: baseline, implant, week 1 months 1,3, 6.
Anticipated width of 95% CI assuming thrombosis rate is 4% and N = 300 + or - 2.22.

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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