

IRBIS Tips & Tricks

October 2019 IRB Board Monthly Education

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THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL



Common Questions

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

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



How to enter stipulations:

The screenshot shows a software interface for entering stipulations. It features a 'Stipulation' editor window and a list of saved stipulations. Callout 1 points to the 'Add New Stipulation' icon. Callout 2 points to the 'Save Stipulation' button. Callout 3 points to the 'Double-callout' icon. Callout 4 points to the list of stipulations. The interface includes a 'Macro' dropdown, a 'Source' editor, and a list of stipulations with their creation dates and times.

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

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

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

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

Stipulation: Macro: Select Macro [Insert Macro]

Source

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%)

Stipulation: By Christina Tyler on 08/25/2014 at 01:50 PM

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

Stipulation: By Christina Tyler on 08/25/2014 at 10:18 AM

Please add estimated frequency of the IBU side effects.

Stipulation: By David Tappell on 08/27/2014 at 09:17 AM

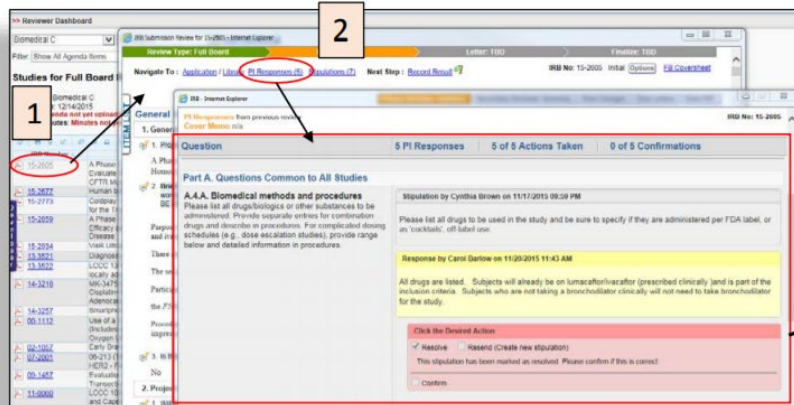
Reviewer #2 comment

Medication side effects may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, hives. 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.



How to view PI responses to stipulations:



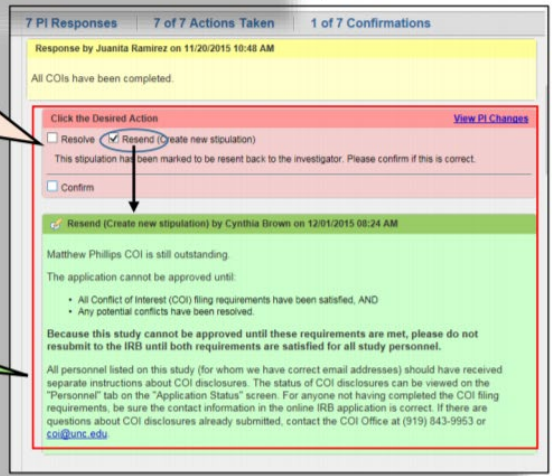
1

2

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.



7 PI Responses 7 of 7 Actions Taken 1 of 7 Confirmations

Response by Juanita Ramirez on 11/20/2015 10:48 AM

All COIs have been completed.

Click the Desired Action [View PI Changes](#)

Resolve Resend (Create new stipulation)

This stipulation has been marked to be resent back to the investigator. Please confirm if this is correct.

Confirm

Resend (Create new stipulation) by Cynthia Brown on 12/01/2015 08:24 AM

Matthew Phillips COI is still outstanding.

The application cannot be approved until:

- All Conflict of Interest (COI) filing requirements have been satisfied. AND
- Any potential conflicts have been resolved.

Because this study cannot be approved until these requirements are met, please do not resubmit to the IRB until both requirements are satisfied for all study personnel.

All personnel listed on this study (for whom we have correct email addresses) should have received separate instructions about COI disclosures. The status of COI disclosures can be viewed on the "Personnel" tab on the "Application Status" screen. For anyone not having completed the COI filing requirements, be sure the contact information in the online IRB application is correct. If there are questions about COI disclosures already submitted, contact the COI Office at (919) 843-9953 or coi@unc.edu.

Click the Desired Action



How to view revisions to the application:

(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.

The screenshot shows the IRB Submission Review interface. The 'View Changes' button is highlighted with a red circle and labeled '1'. A yellow box labeled '3' points to the 'View Findings' button. A yellow box labeled '2a' points to a hot-linked section title 'Other CPO Services' in the 'View Changes' window. A yellow box labeled '2b' points to the 'Top' button in the 'View Changes' window. The 'View Changes' window displays a list of revised sections: 'Post Approval Submissions' (Modification Information), 'General Information' (Project Personnel, Funding Sources), 'Oncology Specific Questions' (Other CPO Services), and 'Part A. Questions Common to Studies' (Background and Rationale, Biomedical methods and procedures, Risks and measures to minimize risks). A PDF icon is also visible in the 'View Changes' window.



How to view attachment updates:

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

Important

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

This submission includes the following consent forms

File Name	Document Type
13-1073 MAIN ICF 08JUL2014 Pendergraft 1-TW.docx <small>NEW</small> 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 <small>NEW</small> 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 <small>NEW</small> Uploaded by: Brenda Meier On: 08/12/2014 At: 04:02 PM	Parental Permission Form

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



How to view revisions to consent forms:

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

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 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



Ability to view past board discussions and findings

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

The screenshot displays the IRBIS (Office of Human Research Ethics) application interface. The top navigation bar includes links for HOME, COMMITTEE REVIEWS, ADMIN, HELP, DEVELOPER, and LOGOUT. The main content area is titled "IRB Submission Review for 17-0174 (irb - cfsstage.research.unc.edu) - Google Chrome". The submission status is shown as "Review Type: Full Board", "Result: Approved", and "Letter: TBD". A red box highlights the "Finalize: TBD" button, which is linked to the IRB number "17-0174 Initial". Below the status bar, there are buttons for "Primary Reviewer Summary", "Secondary Reviewer Summary", "View Changes", "View Letters", and "View PDF". The "General Information" section is visible, showing "1. Project Title" and "Marcus tank 18074 test". The bottom right corner indicates "3 of 3 Records".



Ability to view past board discussions and findings

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

IRBIS Office of Human Research Ethics
HOME | COMMITTEE REVIEWS | ADMIN | HELP | DEVELOPER | LOGOUT

Study History [Back to previous page](#)

Timestamp Log IRB Number: 00-0000 Search The Listening Project: Tuning Into Change

IRB No: 13-2304 Study Status: Approved
IRB: Biomedical Expiration Date: 10/18/2016
PI: Stephen Porges Last Approved: 10/20/2015 (FB)
Study Notes: by John Roberts on 10/20/2015 at 10:16 AM

Submissions for 13-2304

Submission Type	Reference ID	Approval State	Date Routing Complete	Action Date	Expiration Date	Review Type
>> Renewal	165942	Submitted	07/14/2017			Full Board

Submission Information Submission Status: Accepted for Review Reference ID: 165942
IRB: Biomedical Office Staff: Marcus Hannah
Accepted By IRB: 07/14/2017 IRB Analyst:
Submission Notes: None found IRB Chair:

Submission Reviews
Review Type: Full Board Result: Approved Letter: Drafted Finalize: TBD
Navigate To: Application / Library Stipulations (0) Review Result

Submission Type	Reference ID	Approval State	Date Routing Complete	Action Date	Expiration Date	Review Type
>> Renewal	160268	Approved	09/30/2015	10/20/2015	10/18/2016	Full Board
Modification	155213	Approved	08/08/2015	08/11/2015	11/06/2015	Not Full Board
Modification	150617	Approved	02/26/2015	03/19/2015	11/06/2015	Not Full Board
Modification	147670	Approved	12/23/2014	01/15/2015	11/06/2015	Not Full Board
>> Renewal	145703	Approved	10/31/2014	11/07/2014	11/06/2015	Not Full Board
Modification	144287	Approved	09/29/2014	10/28/2014	12/08/2014	Not Full Board



Ability to view past board discussions and findings

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

Submissions for 13-2304

Submission Type	Reference ID	Approval State	Date Routing Complete	Action Date	Expiration Date	Review Type
>> Renewal	165942	Submitted	07/14/2017			Full Board
>> Renewal	160268	Approved	09/30/2015	10/20/2015	10/18/2016	Full Board
Modification	155213	Approved	08/06/2015	08/11/2015	11/06/2015	Not Full Board
Modification	150617	Approved	02/26/2015	03/19/2015	11/06/2015	Not Full Board
Modification	147670	Approved	12/23/2014	01/15/2015	11/06/2015	Not Full Board
>> Renewal	145703	Approved	10/31/2014	11/07/2014	11/06/2015	Not Full Board

Submission Information Submission Status: **Completed** Reference ID: **145703**

IRB: Biomedical Office Staff: Sonya H Bateman
Accepted By IRB: 11/03/2014 IRB Analyst: Mike Matamoros

Submission Notes: by Cynthia Brown on 11/03/2014 at 11:23 AM IRB Chair: Mann, Doug

Submission Reviews

Review Type: Not Full Board > Result: Approved > Letter: Drafted > Finalize: 11/07/2014 - Jo...

Modification	144287	Approved	09/29/2014	10/28/2014	12/08/2014	Not Full Board
Modification	140134	Approved	06/30/2014	07/18/2014	12/08/2014	Not Full Board



Ability to view past board discussions and findings

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

The screenshot shows the IRBIS (Office of Human Subjects) Review Result screen for submission 13-2304. The interface is divided into several sections:

- Navigation:** A breadcrumb trail at the top shows the path: Review Type: Not Full Board > Result: Approved > Letter: Drafted > Finalize: 11/07/2014 - Jo... The current page is "Review Result".
- Study History:** A sidebar on the left shows the submission details: IRB No: 13-2304, IRB: Biomedical, PI: Stephen Porges, and Study Notes by John Roberts.
- Submission Type:** A list of actions for the submission, including Renewal (marked with a green swim lane icon), Modification, and Approval.
- SUBMISSION REVIEW: NOT FULL BOARD (EXPEDITED, EXEMPT, NHSR, OTHER):** The main content area is divided into several sections:
 - REVIEW AGENDA:** Committee Agenda: Biomedical D, Agenda Date: 11/24/2014, Primary Reviewer, and Secondary Reviewer.
 - RESULTS:** Review Result: Approved, Approval Date: 11/07/2014, Expiration Date: 11/06/2015, and Date Letter Sent: 11/07/2014.
 - RISK DETERMINATION:** Risk of Research (study level only): Minimal, Risk of Device (if any): Non-Significant Risk.
 - STUDY SPECIFIC FINDINGS:** This section contains two paragraphs of text. The first paragraph states that the research meets criteria at 45 CFR 46.404 and/or 21 CFR 50.51. The second paragraph describes a limited waiver of HIPAA authorization.
 - SUBMISSION SPECIFIC FINDINGS:** This section is currently empty.
 - INTERNAL MEETING NOTES:** This section is currently empty.
 - CATEGORIES: EXPEDITED:** A list of categories with checkboxes: 1.No IND/IDE, 2.Minimal blood draw, 3.Noninvasive bio-specimens, 4.Noninvasive clinical data, and 5.Existing or non-research data.

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



IRBIS Server Speed Issues

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

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

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



Recommendations from Boards via Survey:

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



Additional Recommendations from Boards:

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



Feature Development currently in progress:

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

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

Consent Form Tags for Adult Consent Form

[BETA]: These are the tags that are embedded into the Adult Consent Form

Triggered Tags		Non-Triggered Tags	
Tag	Resulting Text <small>(the text should be in the resulting uploaded document)</small>	Trigger Question	Trigger Answer
Funding Source	Funding Source and/or Sponsor: [FUNDINGSOURCE]	General Information 3. Funding Sources Is this project funded (or proposed to be funded) by a contract or grant from an organization EXTERNAL to UNC-Chapel Hill?	Yes
Ella A	Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.	Part A. Questions Common to All Studies A.1. Study scope, methods and procedures Will you be using any methods or procedures commonly used in biomedical or clinical research this would include but not be limited to drawing blood, performing lab tests or biological monitoring, conducting physical exams, administering drugs, or conducting a clinical trial?	Yes
Multi Site	A total of approximately number people at number institutions will take part in this study, including approximately number people from this institution.	General Information 4. Site(s) Questions Are any personnel, organizations, entities, facilities or locations in addition to UNC-Chapel Hill involved in this research (e.g., in this multi-site study or case if otherwise involve locations outside UNC-CH, including foreign locations)? You should also click "Yes" if you are requesting reliance on an external IRB, or that UNC's IRB cover another site or individual. See website.	Yes
Benefit 2	Choose or modify ONE of the following groups of sentences as appropriate to the specific study: Research is designed to benefit society by gaining new knowledge. There is a little chance you will benefit from being in the research study. Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be _____.	Part A. Questions Common to All Studies A.5. Benefits to subjects and/or society Does this study have the potential for direct benefit to individual subjects in this study?	Yes
Ella B	Pregnancy tests will be done on all females who might be able to get pregnant at the start of the study. Be sure to indicate who will pay for the pregnancy tests.	Part A. Questions Common to All Studies A.3. Inclusion/Exclusion Criteria Will pregnant women or women who become pregnant be excluded?	Yes

IGHID 11813 Sughit Phase B Assent ages 6-14 v2 0 2018-06-12.docx Foreign Language Consent Form
Uploaded File: Nazareh.Hovakimyan.PH19.0158 at 04:47 AM



Feature Development currently in progress:

- Eliminate redundancies in IRB application

Create a New Study

Use the choices below to begin the process of creating your New Study. Several time saving options have been provided to help streamline the creation of your New Study.

JIT/118	NHSR	Exempt	Full Form	Multi-Site	Rely On
Just In Time/ 118, for NIH funding opportunities only.	My study does not constitute research involving human subjects.	My study should be evaluated for a possible exemption.	My study is not JIT/118, NHSR, Exempt, Multi-site, or Rely on	My study has personnel, organizations, or locations in addition to UNC-Chapel Hill and oversight is provided by the UNC IRB.	My study will have reliance on an External IRB.
Choose ?	Choose ?	Choose ?	Choose ?	Choose ?	Choose ?

NHSR

The study does not constitute research involving human subjects, and therefore does not require IRB approval. This could be because the project does not meet the definition of research (e.g. Internal Quality Improvement Projects, Case Study) and/or because there are no human subjects (e.g. secondary data analysis of fully de-identified data). Also use this application for Expanded Access Drug or Device applications, as well as Humanitarian Use Device applications.



Who to contact for questions:

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

IRBIS@unc.edu

- Please visit IRBMember.web.unc.edu
[Member Orientation, 4. IRBIS System Orientation](#)