

# IRBIS Updates for Reviewer Worksheets and Personnel Changes



THE UNIVERSITY  
*of* NORTH CAROLINA  
*at* CHAPEL HILL

# Dr. Belmont's Rules

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- Document, document, document (If you don't say it, it did not happen!)

## Remember the BIG 5:

1. Study changes are justified (if applicable).
  2. COI is completed (if applicable-new personnel in mods, all personnel for initials & renewals)
  3. Findings are justified.
  4. Specify why minor findings are justified, i.e., the risk are greater than minimal & there is a benefit to the minor.
  5. 111 criteria is met
- Upload to IRBIS
  - Documentation for minutes, auditors & AAHRPP Site Visitors
  - Happy auditors don't go fishing
  - AAHRPP Tip Sheet #3 (Documenting Discussions & Decision on Research Studies & Activities)



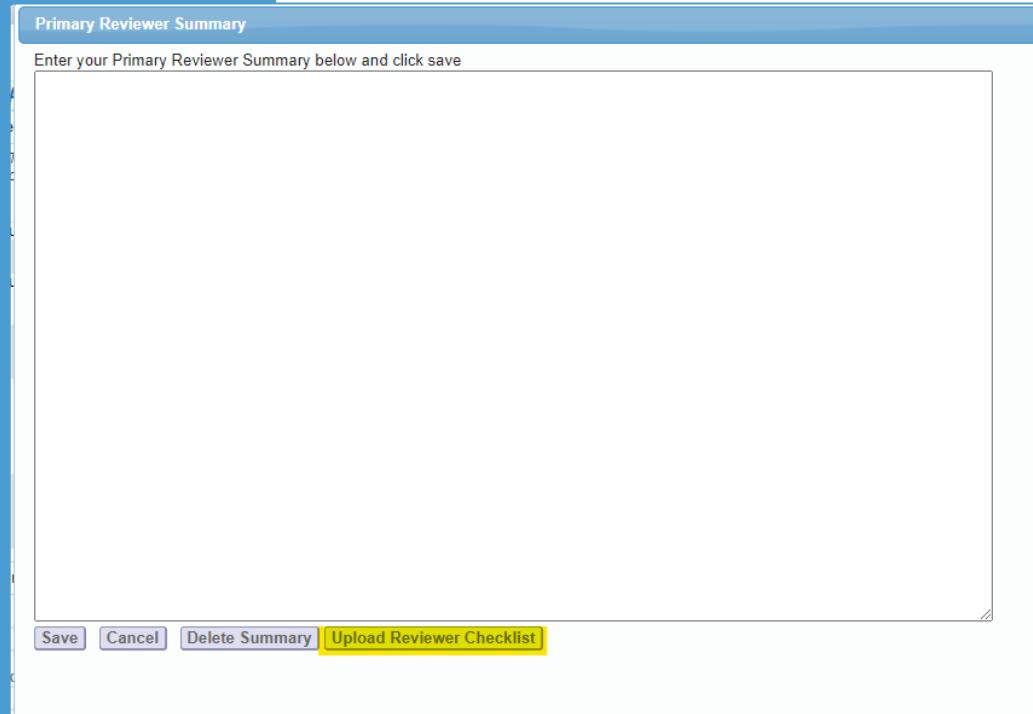
**Beginning in June 2021, IRBIS will allow for committee members to upload their reviewer worksheets directly into IRBIS.**

**This means that you do not have to remember to email your worksheet to the admin or the analyst. With the ability for direct upload, it decreases the opportunity for the worksheet to be lost.**

# Changes to Reviewer Summary Screen



When you open the Reviewer Summary screen, there is now a button to upload your worksheet.



Primary Reviewer Summary

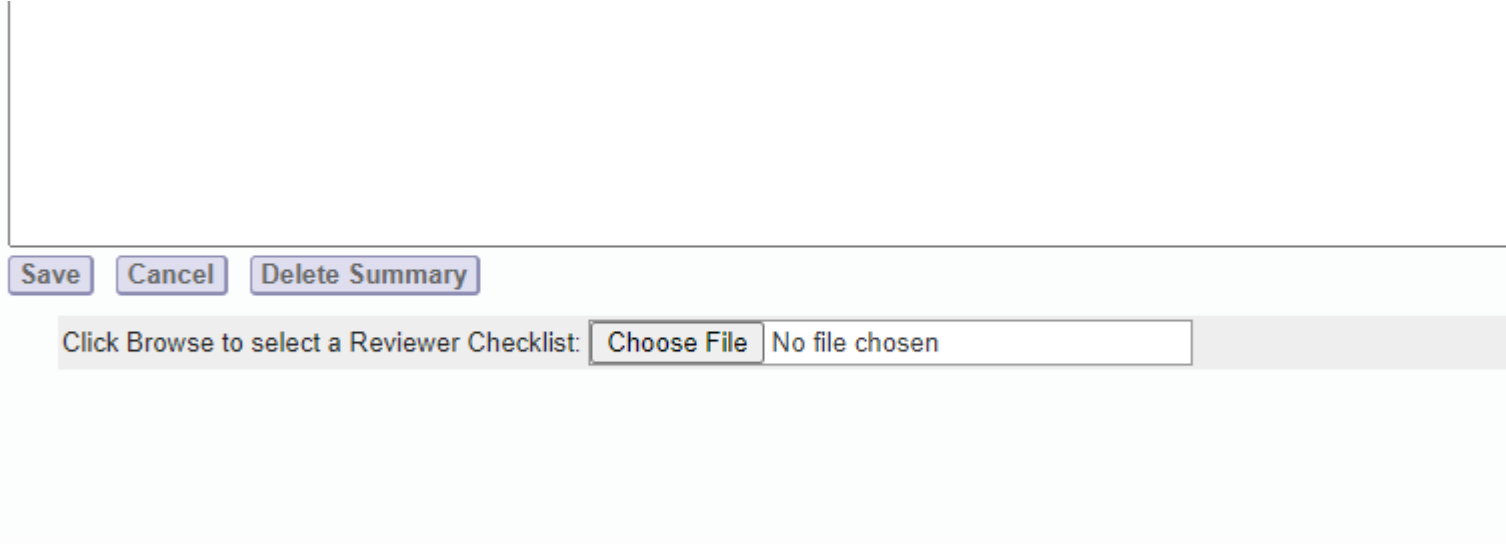
Enter your Primary Reviewer Summary below and click save

Save Cancel Delete Summary **Upload Reviewer Checklist**

The screenshot shows a software window titled "Primary Reviewer Summary". Inside the window, there is a large, empty rectangular text input area. Above this area, the text "Enter your Primary Reviewer Summary below and click save" is displayed. At the bottom of the window, there is a horizontal row of four buttons: "Save", "Cancel", "Delete Summary", and "Upload Reviewer Checklist". The "Upload Reviewer Checklist" button is highlighted in yellow, indicating it is the focus of the slide's message.

# You can navigate to the location on your computer:

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You can check to ensure that your checklist has uploaded by scrolling to OHRE Attachments. The checklist will be there and time-stamped.

All Study Attachments (OHRE Admin Only)

OHRE Attachments: These are OHRE Only Attachments

Show **10** entries Search:

File Name	Document Type	Submission	Reference Id	Date	
<a href="#">IRB-Reviewer-Checklist-Initial-Application-8.25.16.docx</a> <small>Uploaded by Celeste Cantrell on 06/04/2021 at 03:24 PM</small>	Reviewer Checklist	Renewal	328568	05/18/2021	<a href="#">Delete</a>
<a href="#">15-1775-Renewal-Application-7.29.16.pdf</a> <small>Uploaded by Sonya Bateman on 06/02/2021 at 09:15 AM</small>	Reviewer Checklist	Renewal	328568	05/18/2021	<a href="#">Delete</a>

# New Process for Personnel Changes





You may have noticed a recent update to modifications and renewals where personnel changes appear at the top of the review screen:

IRB Submission Review for 13-2710 - Google Chrome

irbis.research.unc.edu/irb/index.cfm?event=admin.review.pageReview&committeeReview=true&appid=364803&reviewId=466652&eformreviewid=240733&are...

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

Navigate To: [Application](#) / [Library](#) / [Stipulations \(1\)](#)      Next Step: [Record Result](#)      IRB No: [13-2710](#) Renewal (Full Form) (Personnel Modification Only)      Options      [FB Coversheet](#)

Awaiting PI Response      Result: TBD      Letter: TBD      Finalize: TBD

[Primary Reviewer Summary](#)    [Secondary Reviewer Summary](#)    [View Findings](#)    [View Changes](#)    [View Letters](#)    [View PDF](#)

>> Project Personnel Modifications located in Reference Id 329755      [Personnel Modification Options](#)

COI/Training for IRB NO: 13-2710 - Submission Type: Personnel Modification - ReferenceId: 329755

Full Name	Credentials	Role	Department	CITI HSP Training	CITI GCP Training	COI Training	COI WebId	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
Alif Sheikh	MD	Principal Investigator	Neurology				508466	21-24997			Completed	No Conflict
Job Dept: 411801: Neurology		Title: Clinical Assistant Professor		Pos. Type: Regular		Emp. Type: Faculty		Status: Active		FTE: 1		
Hae Won Shin	MD	Principal Investigator	Neurology	n/a	n/a		507790	n/a	n/a		Unsubmitted	n/a
Job Dept: 411801: Neurology		Title: Adjunct Professor		Pos. Type: Temporary		Emp. Type: Faculty		Status: Active		FTE: 0		

Key: Faculty | Zero Salary | Inactive Status | Hospital Employee Only | External Personnel | Liaison

[Global Stipulations](#)

### Post Approval Submissions

Renewal Action Requested

ALERT: Modifications proposed as part of this renewal must be accomplished by editing the individual answers to the questions and data elements that make up the application. The modifications cannot be processed until the actual changes have been made throughout the application.

1. Renewal action requested by Principal Investigator (choose only one):

Study has always involved only analysis of data or specimens; there has never been any direct interaction or contact with subjects:

A) Continue study as approved.

Study involves (or involved) direct interaction/intervention/contact with subjects:

B) Continue study as approved, including enrollment of new subjects.

C) Enrollment of new subjects closed; research-related intervention/interaction with previously enrolled subjects continues. *Includes any interaction with subjects*

Or you may notice the changes embedded in the personnel section:

COI/Training for IRB NO: 19-1853 - Submission Type: Modification - Referenceld: 331148

[ - ] collapse all

- University of North Carolina at Chapel Hill (UNC-CH)													
	Full Name	Credentials	Role	Department	CITI HSP Training	CITI GCP Training	COI Training	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
	<a href="#">Darren Dewalt</a>	<a href="#">MD</a>	Principal Investigator	Medicine-Internal Medicine	✓	✓	✓	513090	<a href="#">21-29684</a>	✓		Completed	No Conflict
Job Dept: 411430: Medicine-Internal Medicine				Title: Distinguished Professor		Pos. Type: Regular		Emp. Type: Faculty		Status: Active		FTE: 1	
	<a href="#">Sam Cykert</a>	<a href="#">MD</a>	Co-investigator	Medicine-Internal Medicine	✓	✓	✓	485479	<a href="#">21-01805</a>	✓		Completed	No Conflict
Job Dept: 411430: Medicine-Internal Medicine				Title: Professor		Pos. Type: Regular		Emp. Type: Faculty		Status: Active		FTE: 1	
	<a href="#">Adam Zolotor</a>	<a href="#">MD</a>	Co-investigator	Family Medicine	✓	✗	✓	511537	<a href="#">21-28122</a>	✓		Completed	No Conflict
Job Dept: 411601: Family Medicine				Title: Research Professor		Pos. Type: Regular		Emp. Type: Faculty		Status: Active		FTE: 1	
	<a href="#">Debbie Grammer</a>	--	Study Coordinator	AHEC - Administration -	✓	✗	✓	468334	<a href="#">20-55700</a>	✓		Completed	No Conflict

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We have a new Personnel Modification which allows us to process simple personnel changes outside of the regular pipeline. This alleviates the delay that accompanies review of modifications and renewals. Most personnel changes can be processed within a day or so.

If there is training or COI missing for new personnel, this will be addressed in the Personnel Modification submission.

You should continue to review the training and COI disclosures for current personnel.

# Personnel changes are no longer described on Modifications and Renewals:

1. Are you requesting any modifications to the study application, project personnel, the consent documents, or any related documents?

Yes

Changes to Project Personnel only?

Yes

Please provide the description below:

N/A

Modification Specific Questions

In the investigator view of the Renewal, there is no longer a place to describe personnel changes since those changes are outlined in the separate submission.

1. Are you requesting any modifications to the study application, project personnel, the consent documents, or any related documents?

Yes

Changes to Project Personnel only? \*

Yes

Modification Specific Questions

9a. Is this study in Data Analysis only (i.e. enrollment, intervention and follow-up are complete)? \*

Yes  No

9b. Total number of subjects actively participating (i.e., Total number of subjects involved in the intervention)



**For any questions with IRBIS changes, please  
contact us!**

**[irbis@unc.edu](mailto:irbis@unc.edu)**



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