

IRBIS changes, effective 6:00 PM, March 7, 2019

Live on PRODUCTION - HOTFIXED IN 5.10.03.15:

The Chair auto-save is now repaired for all buckets.

NSIs that have been finalized should now be populating out of the buckets into the correct location.

Part C (Was this a serious adverse event?) of the NSI form is no longer populating to the admin view despite having no data entered.

Options > Change Review Type is now properly reflected in the revised buckets.

Exempt Category 3 is now properly allowing an Exempt application to be displayed.

HUD and NHSR application now show N/A for the Hospital Entities RiskManager COIs to align with UNC Policy.

Submitted NSIs (NR) ready to be accepted are now showing up correctly in the buckets

IRBIS 5.10.04 Update:

Going Live on March 7 at 6 PM:

If a letter has sent to the Chair and the Chair deletes the letter, the submission will revert to the previous Full Board or Not Full Board bucket for Analyst review.

MyChart is being added as a checkbox in the B.1. Methods of Recruiting section, just below Join the Conquest. For now, this is only available to a select pilot group of researchers --- and they must have proper approvals in place to use this option.

If MyChart is checked, the following text is displayed:

- Use of MyChart for research recruitment purposes is currently available only to studies which meet specific criteria to participate in a pilot test. Please contact stephanie.deen@unhealth.unc.edu if you would like to see if your study meets the criteria for this use.
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A new monthly report listing all researchers listed on an IRB application in the role of Principal Investigator for the first time will be delivered to: chrisnel@email.unc.edu; buchholz@unc.edu; lbcowan@unc.edu; matamoro@email.unc.edu.

Administrative Closure submissions will be added as a pilot project. To start, only the Development Team will have access to create this submission type by clicking a new Admin Study Closure button, but we expect a full launch in late Spring.

IRBIS Office of Human Research Ethics

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Admin Study Closure | Timestamp Log | IRB Number: 00-0000 | Search | Marcus task: 24610 test - Prevent Withdrawn Renewals from rolling up to the study level

IRB No: 18-0249 | Study Status: Approved

IRB: Non-Biomedical | Expiration Date: 08/05/2019

PI: Marcus Hannah | Last Approved: 09/05/2018 (FB)

Study Notes: None found

Study Tags:

Submissions for 18-0249

Submissions for 15-2587

Submission Type	Reference ID	Approval State	Date Routing Complete	Action Date	Expiration Date	Review Type
Administrative Study Closure	198735	Submitted	02/26/2019			

Submission Information: Submission Status: Accepted for Review | Reference ID: 198735

IRB: Non-Biomedical | Office Staff: Marcus Hannah

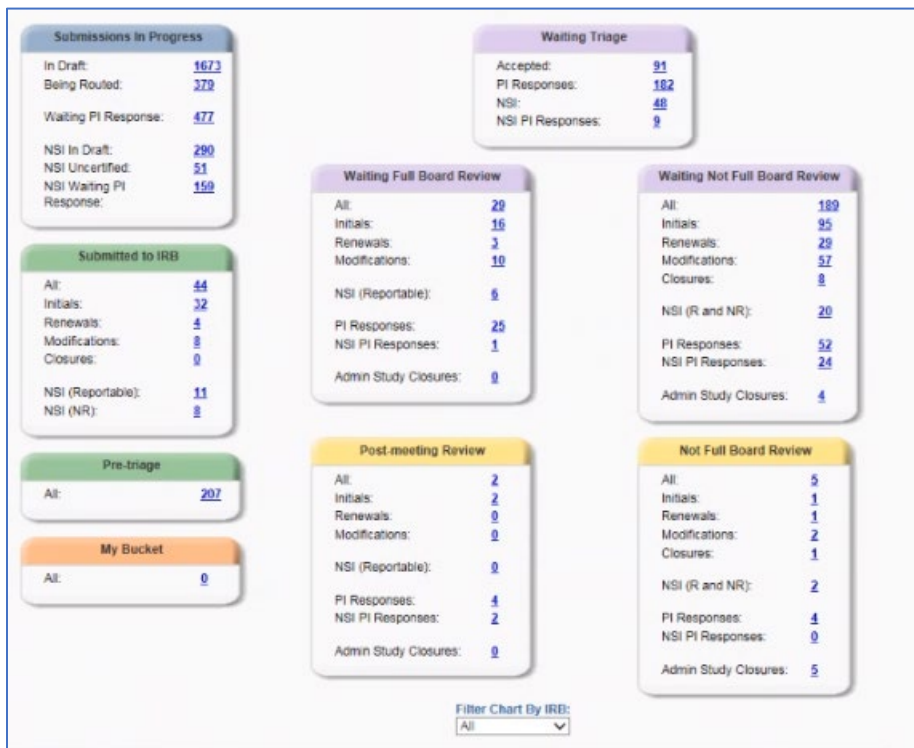
Accepted By IRB: 02/26/2019 | IRB Analyst:

Submission Notes: None found | IRB Chair: Hannah, Marcus

Submission Reviews: Review Type: TBD | Result: TBD | Letter: TBD | Finalize: TBD

Navigate To: Application / Library / Stipulations (0) | Next Step: Add Review Type

Once the Administrative Closure submission has been created, they will be visible in Waiting Triage > Accepted. Once the review type has been added, they will move to the next bucket, as appropriate.



The Development Closure Team will need to review any submissions in routing, in draft, waiting PI responses, or awaiting review prior to the Administrative Closure being finalized. In the next IRBIS update, additional improvements are planned for this process.

Institutional COI display has been added in the Principal Investigator COI review result column.

Display of the Institutional Review Results in the COI Review Result column have a few options:

1. If both PI and Institutional are No Conflict - only a single No Conflict result will be displayed
2. If one is No Conflict and the other is a "conflict" - The "conflict" determination will be displayed.
3. If both PI and Institutional have differing conflict results, both conflicts will be displayed (if both the same, only once)

Investigator Review Results:

No Conflict	Acknowledged	Admin Considerations	Deferral	FCOI Management	No Evaluation – Declined/Withdrawn
Not Funded	Not Manageable	Rely Ext Policy (Manage)	Rely On Ext Policy	Transparency	<i>Unsubmitted</i>

Institutional Review Results:

No Conflict	ICOI management	ICOI transparency	UNC Transparency	<i>Blank</i> (in which case the hardstop will request you contact COI@unc.edu)
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If no Institutional Conflict selection has been finalized in AIR, *Blank*, you will encounter a hardstop screen at the time of letter creation which says:

The Principal Investigator has not had their Institutional COI Disclosure reviewed at this time.

In this circumstance, the COI office would need to indicate the appropriate Institutional Review Result or OHRE may choose to override the requirement with proper approval.

The NSI Form, Question E1 has been updated:

Prior:

Have you established a corrective action plan to prevent future occurrence of the event? Yes/no
Describe the corrective action plan:

Revised:

Please indicate the root cause of the event and provide a Corrective and Preventative Action (CAPA) Plan that addresses the root cause.

When an existing research personnel team member has been promoted to new Principal Investigator of a project, the new icon will now be displayed next to their name.

The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.
 If a change to the Principal Investigator is requested during the course of the study, a [PI Change Form](#) must be submitted.

University of North Carolina at Chapel Hill (UNC-CH)												
	Full Name	Role	Department Name	IRB Training	GCP	COI Training	COI WebID	COI Number	Initial COI Disclosure	Potential Conflict	COI Review Process	COI Review Result
★	Council Mintz	Principal Investigator	Obstetrics and Gynecology-Advanced Laparoscopy and Pelvic Pain	✓	✓	✓	196821 Add COI	17-08573	⚠	--	--	--
	Dennis Zohoun	Co-investigator	Obstetrics and Gynecology	✓	✗	✓	196820	17-08572	✓		Completed	No Conflict
	Greg Eastick	Other	Prosthodontics	✓	✓	✓	244756	19-00421	✗		Unsubmitted	
	Rick Orsely	Other	Endodontics	✓	✗	✓	244755	19-00420	✗		Unsubmitted	
	John Mann	Other	Neurology	✓	✓	✓	244757	19-00422	✗		Unsubmitted	
	Gary Stoltz	Other	Dental Ecology	✓	✓	✓	244754	19-00419	✗		Unsubmitted	
	William Whitehead	Other	Medicine-Gastroenterology	✓	✓	✓	244758	19-00423	✗		Unsubmitted	

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

Additionally, a yellow triangle will indicate they have not yet had the special PI COI disclosure generated. You will still need to contact IRBIS@unc.edu to have the new COI generated, but we are working to get that function opened to all staff in the next few months.

In the Multisite section, the Local Consent Forms document type has been revised to read Local Consent forms and Ads:

Yes No
 2. Is UNC-CH the Lead Site or Coordinating Center or Sponsor of a multicenter project?
 Yes No
 3. Is UNC-CH taking or being asked to take responsibility for the oversight of research by individuals, groups or organizations?
 Yes No
 When a collaborator(s) outside of UNC-CH is (a) exercising authority or responsibility on behalf of a group or organization or a group or organization, complete the following information:

External Institution	Has or will the external institution agree to rely on the UNC-Chapel Hill IRB?	Local Consent Forms and Ads	Local Context Worksheet	Agreement
⚠ Duke University	No	📄	📄	📄
Personnel	Role	Ethics	CV	MD License
Carlos Boozer	External Site PI	📄	📄	📄

View Local Consent Forms and Ads for Duke University

>> View the "Local Consent Forms and Ads" document for Duke University

- 📄 [Adult Consent Form_11102013_revised.docx](#)
Uploaded by: Marcus Hannah On: 02/28/2019 At: 06:17 AM
- 📄 [746470.txt](#)
Uploaded by: Marcus Hannah On: 02/28/2019 At: 06:18 AM