

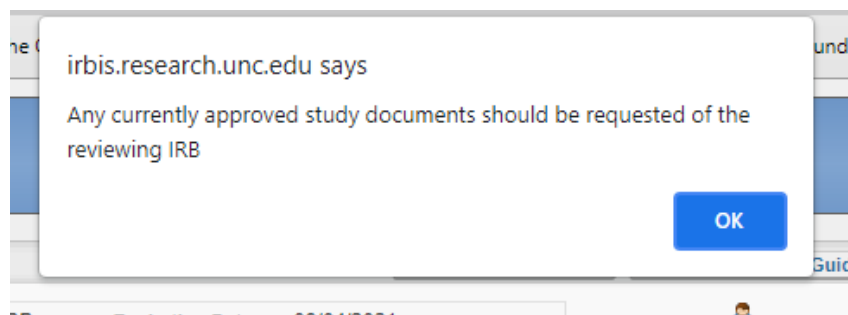
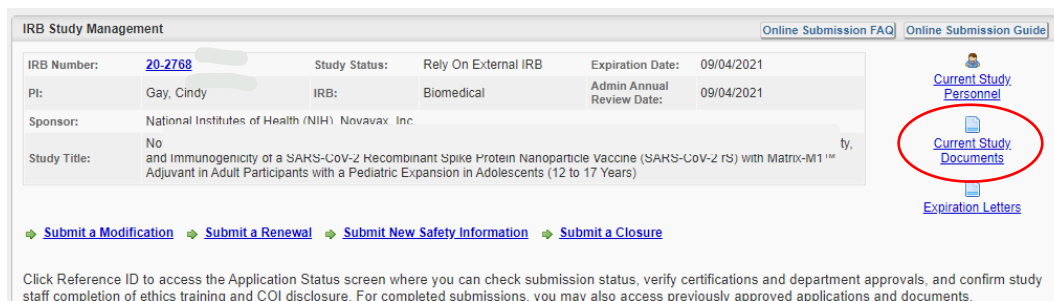
# IRBIS changes, effective 12:00 PM, August 24, 2021

## IRBIS System Update:

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## Investigator 'Current Study Documents' for Rely-On Studies

The Current Study Documents on the IRB Study Management screen will no longer display any submitted documents for studies where UNC is relying on another IRB. This change was made to reflect the fact that UNC IRB is not approving these documents. Any current documents should be obtained from the reviewing IRB.



If the study team needs to access the most recent HIPAA or MyChart advertisement, they can open the most recent submission and go to the Submitted Documents tab. These are the only documents that will be reviewed by UNC IRB.

>> Application Status Reference ID: 334349

Submission Status: Revised/Resubmitted to IRB Created By: [Redacted]  
Principal Investigator: [Redacted] Being Routed By: [Redacted]  
Submission Type: Renewal (w/ Modification) Submission IRB: Biomedical  
Study Title: [Redacted]

Routing Routing Comments Status History **Submitted Documents** Addenda Personnel sIRB

Investigator(s) who must certify this Submission

Investigator	Role
[Redacted]	Principal Investigator

Department(s) that must approve this Submission

>> Consent Forms:

This application requires the following consent forms

Template Name
HIPAA Authorization

This application includes the following consent forms

File Name	Document Type
<a href="#">[Redacted]</a> Uploaded by: Cheryl Hendrickson On: 04/30/2021 At: 10:39 AM	Assent Form Ages 15-17
<a href="#">[Redacted]</a> Uploaded by: Cheryl Hendrickson On: 06/21/2020 At: 12:00 AM	HIPAA Authorization
<a href="#">[Redacted]</a> Uploaded by: Cheryl Hendrickson On: 04/30/2021 At: 10:39 AM	Parental Permission Form
<a href="#">[Redacted]</a> Uploaded by: Cheryl Hendrickson On: 12/29/2020 At: 12:00 AM	Foreign Language Consent Form
<a href="#">[Redacted]</a> Uploaded by: Cheryl Hendrickson On: 04/30/2021 At: 10:38 AM	Sponsor's Model Consent Form

>> Attachments:

This application requires the following attachments

Document Type
External IRB Approval Letter
Master Protocol
IDS Approval <b>This attachment not provided because:</b> Not Yet Available / Not Applicable
Recruitment Listing PDF – Research for Me @UNC
Other Materials for Recruitment <b>This attachment not provided because:</b> Not Yet Available / Not Applicable

This application includes the following attachments

File Name	Document Type
<a href="#">[Redacted]</a> Uploaded by: Cheryl Hendrickson On: 04/30/2021 At: 10:42 AM	Master Protocol
<a href="#">[Redacted]</a> Uploaded by: Cheryl Hendrickson On: 12/27/2020 At: 12:00 AM	Recruitment Ad for Participant Pool
<a href="#">[Redacted]</a> Uploaded by: Cheryl Hendrickson On: 10/30/2020 At: 12:00 AM	Recruitment Listing PDF – Research for Me @UNC

## Scheduled Administrative Closures for Expired Studies

For any study that has been expired for over 90 days and does not currently have an active submission (in draft, routing, under review, etc.), an administrative closure will be created automatically. These will be reviewed by IRB Staff who may contact the study team or close the study administratively. If you have questions about an Administrative Closure, contact the assigned analyst or [IRB\\_questions@unc.edu](mailto:IRB_questions@unc.edu). If the study has been administratively closed, you will need to submit a new application to resume IRB oversight.

## Update to Administrative Review Stipulations

The Administrative Review Stipulations will look a bit different. Each stipulation will appear separately and require a response to each, similar to other submission types.

To view the stipulations, click on the highlighted 'Stipulations' option on the left-hand dashboard.

To respond to the stipulations, click on the 'Respond' link in each stipulation box.

**Submission Routing**

- ➔ **Stipulations**
- ➔ Resubmit
- ➔ PI Certified On 08/25/2021

**Submission Management**

- ➔ View Submission
- ➔ View Revisions
- ➔ View History
- ➔ View PDF

IRB  
University of North Carolina -  
Chapel Hill  
720 Martin Luther King, Jr. Blvd.  
Bldg. 385, 2nd Floor  
CB #7097  
Chapel Hill, NC 27599-7097  
(919) 966-3113

Reference Id: [336784](#)      Submission Status: Reopened  
Date Submitted: 08/19/2021      Date PI Certified: 08/25/2021 at 12:00 AM

» **Administrative Annual Review Submission Stipulations**

**INSTRUCTIONS:** Please review and respond to the stipulations as follows.

1. Respond to each stipulation in the response field and click save. If the stipulations are not prepopulated, please copy and paste the stipulations into the response field.
2. Make any requested changes to the Administrative Review application
3. When all changes AND responses are complete, please click the yellow Resubmit button, on the left navigation bar.

» **Current Study Status**

**1. Choose only one: \***

**Stipulation by IRB Admin 8/25/21 11:37 AM**  
Last edited by IRB Admin 8/25/21 11:41 AM

This submission cannot be approved until all study personnel have up to date required training. Please have the following personnel complete the Human Subjects Protections (HSP) Core Refresher, [\[redacted\]](#)

Additionally, please note that [\[redacted\]](#)'s HSP training expires August 28th. To avoid delay in processing this AR, please have him complete the refresher as well.

- The CITI course may be accessed at: <https://www.citiprogram.org/>
- Do not resubmit to the IRB until CITI training has been completed for all personnel.
- See [here](#) for instructions on how to access the HSP Core Refresher.

Respond

**Stipulation by IRB Admin 8/25/21 11:40 AM**

It appears several study team members may no longer be UNC employee or student. Please review your list carefully to ensure that all remain employed or enrolled.

If any personnel have left and are no longer involved in the research, please submit a personnel modification to remove them.

If any personnel are still involved with the research but have left UNC, please submit a study modification to remove them and re-enter them as external personnel.

Respond

## External Personnel Management Policy Display

In order to assist investigators in discerning the requirements for external sites and their investigators, a legend that describes the Personnel Management policy is displayed at the top of the external personnel table in several places.

**Personnel Management - External Site policies**

**Policy Undetermined** - Default setting, policy will be set by IRB upon submission.  
**Policy TBD** - Site policy has not been set by the IRB. May be set in a later submission.  
**UNC Policy** - Site does not have an FWA, please list ALL engaged personnel from the site. The site's personnel will be required to complete UNC ethics training in CITI, a COI disclosure when applicable, upload their current CV and any medical licensures to Section 5 - Multi-Site.  
**Site Policy** - Site has an FWA, please list ONLY the site PI and study liaison. The site will manage their own personnel requirements. No UNC trainings or COI disclosure required and no CVs or licensures collected.

The Personnel section of a Multi-Site application at the top of the external personnel section and as a pop-up when clicking on the '?' icon in the Policy cell.

External Institutions

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Boston Children's Hospital				Site Policy
Liaison	Last Name	First Name	Department Name	Role
★	Rollins	Caitlin	Neurology	Co-investigator <a href="#">view</a>
	Haile	Hannah		Study Coordinator <a href="#">view</a>
	Herrera Pujols	Kaysi		Study Coordinator <a href="#">view</a>
	Rohde	Julia		Study Coordinator <a href="#">view</a>
Boston Medical Center				Site Policy
Liaison	Last Name	First Name	Department Name	Role
★	Cronin			External Site PI <a href="#">view</a>
	Douglass			Co-investigator <a href="#">view</a>
	Jara			Co-investigator <a href="#">view</a>
	Rana			Co-investigator <a href="#">view</a>
	Sakai			Co-investigator <a href="#">view</a>
	Setty			Co-investigator <a href="#">view</a>
	Hua			Other <a href="#">view</a>
	Jahromi			Other <a href="#">view</a>
	Kaliaev	Artem	Radiology Research Enterprise	Other <a href="#">view</a>
	Mian	Asim	Neuroradiology	Other <a href="#">view</a>
	Pieper	Chris		Other <a href="#">view</a>
	Qureshi	Muhammad	Radiation Oncology	Other <a href="#">view</a>

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[close](#)

On the 'Personnel' tab of the Submission:



Routing   Routing Comments   Status History   Submitted Documents   Addenda   Personnel   sIRB

Trainings and Conflict of Interest entered for this Submission (Modified Personnel)

- University of North Carolina at Chapel Hill (UNC-CH)

Full Name	Role	Department	CITI HSP Training	CITI GCP Training	COI Training	COI Number	Initial COI Disclosure	Potential Conflict	COI Review
Ashley Rumble	Research Assistant	Frank Porter Graham Child Development Institute	✓	n/a	✓	n/a	n/a		

**External Institutions**

**Personnel Management - External Site policies**

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- Boston University

Full Name	Role	Department	CITI HSP Training	CITI GCP Training	COI Training	COI Number	Initial COI Disclosure	Potential Conflict	COI Review
Nicholas Warner	Co-investigator		--	n/a	--	n/a	n/a		
Nina Shabkha	Research Assistant		--	n/a	--	n/a	n/a		

- Michigan State University (MSU)

Full Name	Role	Department	CITI HSP Training	CITI GCP Training	COI Training	COI Number	Initial COI Disclosure	Potential Conflict	COI Review
Rebecca Koickney	Co-investigator		--	n/a	--	n/a	n/a		
Ann Alex	Research Assistant		--	n/a	--	n/a	n/a		

And in the 'Current Study Personnel' window on the Study Management page:

Study Status: Approved   Expiration Date: 07/21/2022

IRB: Non-Biomedical

[Current Study Personnel](#)

**Current Personnel for IRB Number 17-1914**

Full Name	Role	Department	CITI HSP Training	CITI GCP Training	COI Training	COI Number	Initial COI Disclosure	Potential Conflict	COI Review
Quan Wang	Research Assistant	School of Education Deans Office	✓	✗	✓	n/a	n/a		n/a
Camille Williams	Research Assistant	Frank Porter Graham Child Development Institute	✓	✗	✗	n/a	n/a		n/a
Amanda Wylie	Research Assistant		✓	✓	✓	n/a	n/a		n/a
Nichole Zhang	Research Assistant	Frank Porter Graham Child Development Institute	✓	✗	✗	n/a	n/a		n/a

**External Institutions**

**Personnel Management - External Site policies**

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External Institution: Research Triangle Institute (RTI International)

External Institution	COI Policy	Assurance Letter	Management Plan
Research Triangle Institute (RTI International)	Site Policy		

## My Letter History Feature for Investigators

Study teams will now have a mechanism to see the list of letters that have been emailed from IRBIS. On the left-hand dashboard of the IRIBS Home page, they can select 'View Letter History' at the bottom of the screen to obtain a list of the letters which is sortable by column.



**Dashboard**

Create New Submission

- [New Study](#)
- [Modification](#)
- [Renewal](#)
- [New Safety Information](#)
- [Closure](#)

Submissions In Progress

- [In Draft \(9\)](#)
- [Being Routed \(1\)](#)
- [Dept Waiting PI Response](#)
- [Submitted to IRB \(3\)](#)
- [IRB Waiting PI Response \(1\)](#)

All My Studies

- [My Studies](#)
- [Studies in My Dept](#)

Routing Inbox

- [PI/Advisor Certification](#)
- [Dept Approval](#)
- [Dept Reviewer](#)

My Letter History

- [View Letter History](#)

IRB  
University  
720 Marti  
Bldg. 385  
CB #7097  
Chapel HI  
(919) 966

**All My Emails**

Show  entries

Search:

IRB ID	Date Sent	Time Sent	Letter Header	Letter Type	Open
<a href="#">21-0034</a>	05/11/2021	04:53:23 PM	Submission Notification sent to Marcus Hannah	Routing Email	
<a href="#">19-2497</a>	05/11/2021	10:20:38 AM	Submission Notification sent to Jeff Hartman	Routing Email	
<a href="#">21-0034</a>	05/05/2021	02:43:24 PM	Submission Notification sent to Marcus Hannah	Routing Email	
<a href="#">21-0034</a>	05/05/2021	02:17:34 PM	Submission Notification sent to Marcus Hannah	Routing Email	
<a href="#">16-1070</a>	11/15/2016	07:03:57 PM	Submission Notification sent to Hans Herfarth	Routing Email	

Showing 1 to 5 of 5 entries

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