



# IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

## QUARTERLY CALL FOR STUDY MANAGERS

October 15, 2021

- User Materials Development
- User Support

**Katelyn Benhoff**



- Onboarding
- Study Support

**David Crenshaw**



- Training
- Study Support

**Natalie Dilts**



- Lead Application Developer

**Bryce Embry**



- System Development

**Asri Mumpuni**



- Project Director

**Emily Serdoz**



- Onboarding
- Study Support

**Bridget Swindell**



- Application Developer

**Jason Tan**



- Website & System Dev
- Study & User Support

**Linda Tan**

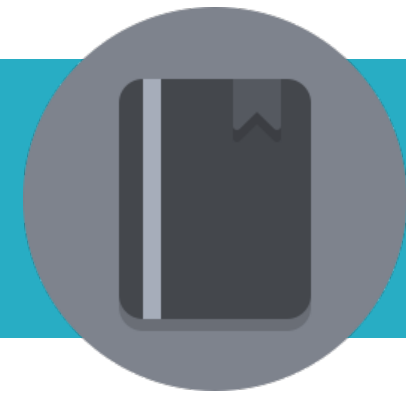


- Application Developer

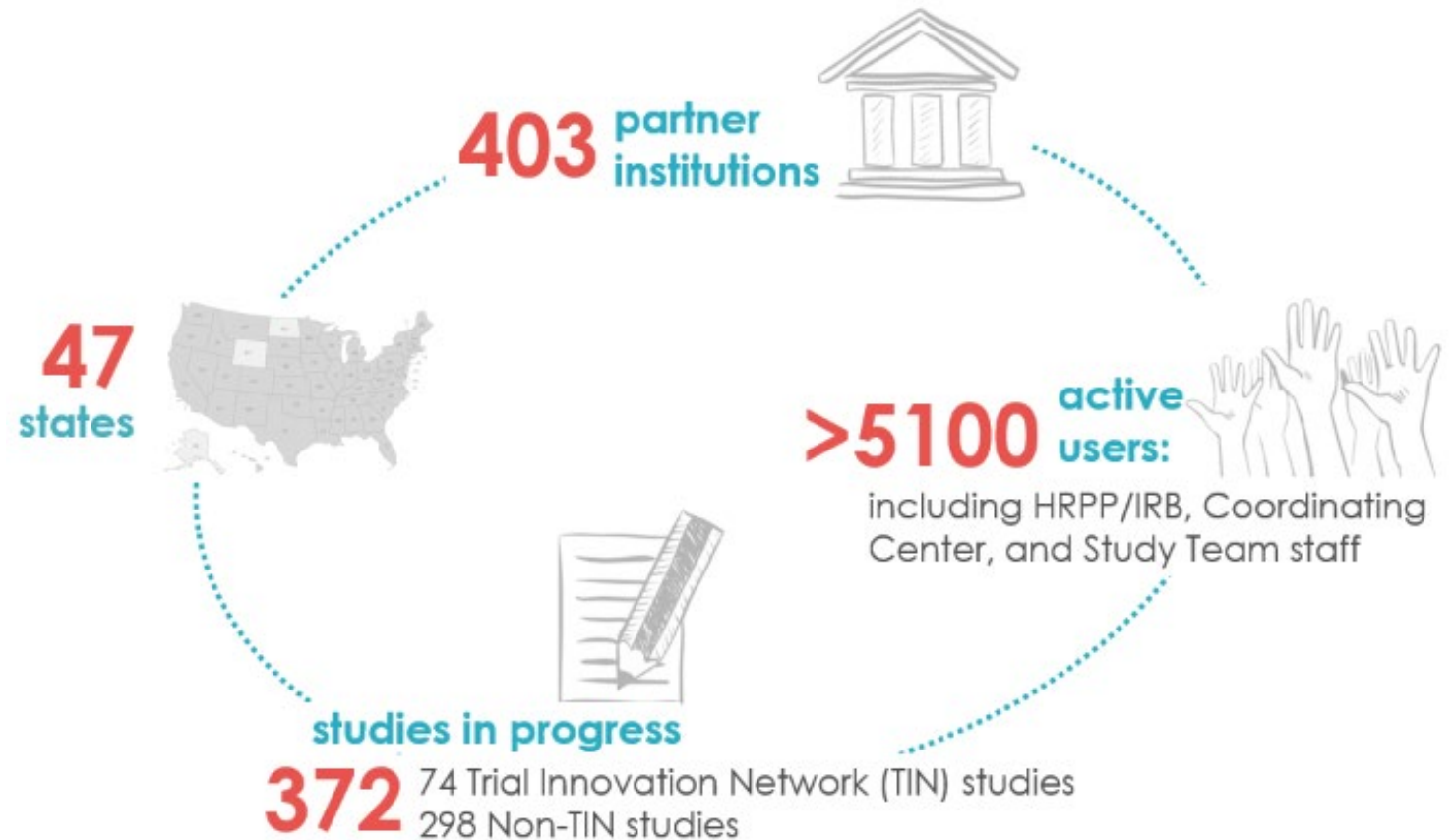
**Evan Wimberly**



# QUARTERLY CALL AGENDA



- Welcome!
- Recent System Updates
- Upcoming System Updates



# Recent System Updates

Since July 2021

# Document Study Closures (Now available to SMs as well)



Site-Specific Info

Manage Project

Study Summary

Reviewing IRB Contact

IREx Study Managers

Participating Personnel

## Influenza-associated pneumonia hospitalizations in Jupiter

Study-wide IRB Approvals

Site-specific IRB Approvals

Status Summary

Protocol Version: 1

Manage Version

SIRB: University of Black Labrador

Initial Study: Full Board (exp. 8/29/2020)

Edit Review

Site approvals

Study Info

Key Dates

Site Approvals

Add Continuing Review

Add Study-Wide Amendment

Add SITE amendment

Add Study Closure

### Study Closure

## Influenza-associated pneumonia hospitalizations in Jupiter

Reason for Study Closure  
(Select all that apply)

☒ Study Completed

☐ Study Discontinued for futility

☐ Study Discontinued for under-enrollment

☐ Study Discontinued for lack of resources or funding

☐ Study Terminated for ethical concerns or non-compliance

☐ Other

Please type any other reasons...

Date of Closure

07/01/2021

IRB Determination Letter

Choose File

determination letter.docx

Other Documents

Choose Files

No file chosen

☐ Publish study closure documents, making them visible to relying sites.

Cancel

Save

# Document Study Closures (Now available to SMs as well)



Dear Liaisons and Study Contacts,

Carnegie University Medical Center has issued a closure notification for the following study for your institution, Albert Einstein College of Medicine, in IREx:

<b>Study Title</b>	Influenza in Jupiter
<b>Type of Determination</b>	Study Closure
<b>Reason for Study Closure</b>	Study Completed
<b>Date of Closure</b>	7/1/2021
<b>Study Url</b>	<a href="https://test.irbexchange.org/feature-branch/public/study?proj=1028876">https://test.irbexchange.org/feature-branch/public/study?proj=1028876</a>

Principal Investigators & Study Contacts:

You can access the study closure information in IREx. Prior approval information will remain accessible in read-only format. Please contact your local HRPP, as needed, regarding your local submission requirements for study closure.

*Thank you for using IREx,  
The IREx Team*

VERSIONS

Study Closure

Reviewing IRB

Carnegie U Med Ctr  
Closed 7/1/2021

Relying Sites

Duke Univ-Duke Childrens  
Closed 7/1/2021

Einstein  
Closed 7/1/2021

Emory  
Closed 7/1/2021

Goodall  
Closed 7/1/2021

VUMC | Vanderbilt Univ  
Closed 7/1/2021

Registered / In Progress

Baylor College Med  
Closed 7/1/2021

20210701 Asri Test Study 1

Study Closed

Study Summary Reviewing IRB Contact IREx Study Managers Participating Personnel

20210701 Asri Test Study 1 High of 81 degrees today

Study-wide IRB Approvals Site-specific IRB Approvals Status Summary

Protocol Version: NA

SIRB: Carnegie University Medical Center

Lead Site: Carnegie University Medical Center

Study Closure Closed

Study Info

Role: Reviewing IRB  
IRB Number: 443  
Status: Closed  
Submission Type: Study Closure

Key Dates

Study Closed 7/1/2021  
Closure Reasons

- Study Completed
- Other: We're done with this

Documents

Type	Name	Date Added	Size
Determination Letter	determination letter C.docx	07/01/2021	28 KB
Others	1.docx	07/01/2021	37 KB

# Document Site Closures



Study-wide IRB Approvals | **Site-specific IRB Approvals** | Status Summary

Protocol Version: 2

Faraday Institute of Research, Science and Technology

+ Add Site Amendment + Add Site Closure

▼ Amendment: Full Board (exp. 10/31/2021) **Current**

Site Closure

## Faraday Inst: Let's Access Your Approvals (LAYA)

**Reason for Site Closure**  
(Select all that apply)

- ☐ Site Enrollment complete
- ☒ Site Discontinued for under-enrollment
- ☐ Site Discontinued for lack of resources or funding
- ☐ Site Terminated for ethical concerns or non-compliance
- ☐ Other

Please type any other reasons...

**Date of Closure** 08/31/2021

**IRB Determination Letter** Choose File Determination Letter.docx

**Other Documents** Choose Files No file chosen

Cancel Save

# Document Site Closures



## Please Confirm

Are you sure you want to issue a site closure for **Faraday Institute of Research, Science and Technology**? This will send a notification to the site liaisons and study contacts. They will have 30 days to access site closure information. After 30 days, they will no longer have access to the study in IREx.

Cancel

OK

To: [faradayhrpp@liaison.edu](mailto:faradayhrpp@liaison.edu), [liaison@faraday.xx](mailto:liaison@faraday.xx), [pi@faraday.cdu](mailto:pi@faraday.cdu), [coord@faraday.cdu](mailto:coord@faraday.cdu), [liaison@anderson.org](mailto:liaison@anderson.org), [sm@anderson.cdu](mailto:sm@anderson.cdu)

Subject: IREx: Site Closure

Dear Liaisons and Study Contacts,

Anderson Medical Center has issued a closure notification for your institution, Faraday Institute of Research, Science and Technology in IREx.

Study Title	Let's Access Your Approvals (LAYA)
Type of Determination	Site Closure
Reasons for Site Closure	<ul style="list-style-type: none"><li>Site Discontinued for under-enrollment</li></ul>
Date of Closure	Aug 31, 2021
Study Link	<a href="https://test.irbexchange.org/feature-branch/public/study?proj=668828">https://test.irbexchange.org/feature-branch/public/study?proj=668828</a>

### Principal Investigators and Study Contacts:

You will have access to the study for 30 days in order to access the closure information and prior approval information (read-only). Please contact your local HRPP, as needed, regarding your local submission requirements for site closure.

*Thank you for using IREx,  
The IREx Team*

# Document Site Closures (Viewing closed sites)



**VERSIONS**

2

**Reviewing IRB**

Anderson Med Ctr  
Amend: Full 10/31/2021

**Relying Sites**

Faraday Inst  
Site Closure 8/31/2021

Goodall | Hot Chicken Univ  
Initial: Full 10/31/2021

1, Rev. 1

1

**Let's Access Your Approvals (LAYA)**

Study-wide IRB Approvals Site-specific IRB Approvals **Status Summary**

Participant Status Summary

Q Search:

**Closed Sites** **Export Data**

**Approval Status**

Site	Reliance Agreement ?	IREx Access ?	Reliance Decision ?	Local Consideration
Goodall   Hot Chicken Univ Goodall University	Anderson IAA	✓	Completed 9/1/2021	3 / 3 Surveys Complete

Closed Sites				
Site	Reason(s) for Closure	Dates	Documented By	Version on Closure
Faraday Institute of Research, Science and Technology - FWA#01569874	Site Discontinued for under-enrollment	<i>Date of Closure</i> 8/31/2021 <i>Closure Uploaded</i> 8/31/2021 <i>Study Access Ends</i> 9/30/2021	Katelyn Benhoff	2

Close



# Upcoming System Updates

Fall/Winter 2021

# New Flexibility for Combo Sites



- “Combo Sites” occur when a single study team engages multiple FWAs.
- Each FWA must provide reliance documentation (cede decision + local considerations)
- IREx required ALL FWA in the combo to complete documentation before it could be exported for sIRB review.

Study-wide IRB Approvals

Site-specific IRB Approvals

Status Summary

Participant Status Summary

Export Data

Q Search:

Site	Reliance Agreement	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Goodall University GUMC	SMART 2	✓	Started 10/7/2021	1 / 3 Surveys Complete	Not Approved
Goodall University Medical Center Goodall	SMART 2	✓	Contacted 10/7/2021		

# New Flexibility for Combo Sites



## PROBLEMS

- Held up study initiation at some sites.
- Addition of new recruitment sites interfered with already approved sites.

## SOLUTION (coming late October)

- Local considerations can be exported individually, as they are completed
- sIRB Approvals can be posted to IREx as they are issued

Study-wide IRB Approvals

Site-specific IRB Approvals

Status Summary

Participant Status Summary

Export Data

Q Search:

Site		Reliance Agreement ?	IREx Access ?	Reliance Decision ?	Local Considerations	Approval Status (current version)
Goodall University GUMC		SMART 2	✓	Started 10/7/2021	1 / 3 Surveys Complete	Not Approved
Goodall University Medical Center Goodall		SMART 2	✓	Contacted 10/7/2021		

### IMPORTANT!

- It is the relying HRPP's responsibility to let their local study team know when they are approved to begin the study at their site.
- sIRB approval does not mean the site can begin enrolling.
- If a study team is part of a combo, and only one site has been approved, they should verify with their local HRPP that they can begin.

# New Questions on the IREx Institutional Profile (IP)



THANK YOU!

89% of IREx Institutions have completed their IP!

NAME	INSTITUTIONAL PROFILE	LOCATION	LIAISON(S)
Advanced Neurology Specialists	<a href="#">updated 4/3/2018</a>	Great Falls, MT	Laura Armstrong
Advarra, Inc.	<i>incomplete</i>	Columbia, MD	Lauri Carlile Kathleen Rankin
Adventist Health System, Sunbelt, Inc. dba AdventHealth Orlando <b>AAHRPP</b>	<a href="#">updated 7/30/2020</a>	Orlando, FL	Michelle McKinney Janice Turchin
Advocate Health Care Network (Downers Grove)	<a href="#">updated 3/5/2019</a>	Downers Grove, IL	Jasmine Taylor Sherri Velez
Akron General Med Ctr	<a href="#">updated 1/4/2021</a>	Akron, OH	Kalisha Washington
Albany Medical Center	<a href="#">updated 10/22/2019</a>	Albany, NY	Katy Regan
Albert Einstein College of Medicine <b>CTSA</b>	<a href="#">updated 9/25/2019</a>	Bronx, NY	Rui Ferreira Stefanie Juell Gabriella Weston
Albert Einstein Healthcare Network	<a href="#">updated 3/15/2019</a>	Philadelphia, PA	Mary Klein
Alexian Brothers Hospital Network	<a href="#">updated 8/30/2021</a>	Lisle, IL	Shivi Stanley
Allegheny Health Network Research Institute	<a href="#">updated 12/17/2019</a>	Pittsburgh, PA	Dawnmarie DeFazio Susan Hebda Holly Wimer
Allina Health HRPP	<a href="#">updated 9/9/2020</a>	Minneapolis, MN	Gayle Kusch Christine Roering
American Natl Red Cross, Biomedical Services	<a href="#">updated 11/13/2020</a>	Washington, DC	Pampee Young
Ann & Robert H. Lurie Children's Hospital of Chicago <b>AAHRPP</b>	<a href="#">updated 10/8/2021</a>	Chicago, IL	Tricia Eifler Allison Harris Kaleigh Michalko
Arkansas Children's Research Institute	<a href="#">updated 8/9/2021</a>	Little Rock, AR	Janet Storment
Ascension Providence Hospital	<a href="#">updated 8/11/2020</a>	Southfield, MI	Nicola Bolda
Ascension St. John Hospital	<a href="#">updated 3/22/2019</a>	Detroit, MI	Lee Bowen

# New Questions on the IREx Institutional Profile (IP)



- Institutions are encouraged to update their IREx Institutional Profile annually.
- New questions will be added in November – we'll notify you by email.
- Institutions will be required to respond to the new questions in the IP before they can complete the reliance process for a study.



# Reorganizing Approval Documents



Provide all site's approval documents on one tab

Approval History | Site-specific IRB Approvals | Status Summary | Study search ... Search

View All | Amendments | Continuing Reviews

**Albany Medical Center**

- ^ Amendment: Full Board (approved 4/20/2021) **Current**
- ^ Continuing Review: Full Board (approved 1/20/2021) **Archived**
- ^ Amendment: Full Board #50 (approved 12/5/2020) **Archived**
- ^ Initial Study: Full Board (exp. ...)

**Change Summary:** Submission of ISPY2 Memo, dated 24MAR2021: -Updating the fasting instructions for the oral paclitaxel + encequidar + dostarlimab +/- carboplatin regimens as per the manufacturer, Athenex. Removing the 6hr fasting requirement prior to drug administration. -Revised Oral Paclitaxel Dosing Instructions Card v 04-Mar2021, released on March 23, 2021. - Oral Paclitaxel Encequidar Medication Diary All sites' ORAL PACLITAXEL/ENCEQUIDAR treatment ICFs have been revised to edit the fasting requirements for this drug combination. The Ohio State University: Revision to the HIPAA paragraph in the site-specific section of the Screening ICF - requested and revised by site. Redline copies of the master consent templates are available on the main study page.

Provide Document History Tab

Approval History | **Document History** | Status Summary

**Albany Medical Center**

- Consents & Assents ^ 4/1/2021
- Protocol ^ 3/11/2021
- Determination Letter ^ 4/1/2021
- Recruitment & Advertisements ^ 4/1/2021
- Device Manual ^ 7/21/2018
- Grant Application ^ **Archived**
- Measures ^ **Archived**
- Investigator's Brochure ^ 7/21/2018
- Meeting Notes ^ 3/11/2021
- Other IRB Approved Documents ^ 3/11/2021
- Others ^ **Archived**

ETA February 2022

# What's more important?

## System Development Priorities



### 1. Ability to NAME all documents; the name would replace the file name

- Could improve sorting and usability until we have the larger re-organization complete

^ Documents				
Type	Name	Date Added	Size	
Protocol 1	<a href="#">Protocol_V4_2_08JUN2021.pdf</a>	9/1/2021	1177230	
Determination Letter	<a href="#">IRB FAL Amendment 1.pdf</a>	9/1/2021	245470	
Amendment Application	<a href="#">IRB-Submission-Amendment 1.pdf</a>	9/1/2021	137619	
Consents & Assents	<a href="#">Stamped-ICD-SP_Master_V4_21JUN2021.pdf</a>	9/1/2021	2023471	
Consents & Assents	<a href="#">Stamped-ICD_P1_Master_V4_21JUN2021.pdf</a>	7/23/2021	2053161	
Consents & Assents	<a href="#">Stamped-ICD_P2_22JUN2021.pdf</a>	7/23/2021	2807000	
Investigators Brochure	<a href="#">Ascor Package Insert.pdf</a>	7/16/2021	292942	
Investigators Brochure	<a href="#">Acetaminophen_IB.pdf</a>	7/16/2021	401845	
Other IRB Approved Documents - DSMB Memo dated 7/26/2021	<a href="#">PETAL DSMB Memo_26JUL2021.pdf</a>	9/1/2021	121861	
Other IRB Approved Documents - Other	<a href="#">FDA IND Approval_ACROSS II.pdf</a>	7/16/2021	52468	
Other IRB Approved Documents - Other	<a href="#">Ascorbic Acid-Exempt Pre-IND.pdf</a>	7/16/2021	119829	
Other IRB Approved Documents - Other	<a href="#">ICD part 2 template.docx</a>	7/16/2021	1480412	
Other IRB Approved Documents - Study Materials	<a href="#">Stamped-Day90_Follow-Up_Letter.pdf</a>	7/16/2021	544611	
Other IRB Approved Documents - Study Materials	<a href="#">Stamped-Day90_Follow-Up_Questionnaire.pdf</a>	7/16/2021	815213	

### 2. Ability to given new coordinators access for a registered sites

- Ability to add Coordinator(s) at a PSite if the previous Coordinator has left the study/organization
- Could help things to run more smoothly – new Coordinator doesn't have to rely on their HRPP to provide access

# New Resources

Spring/Summer 2021



# New & Updated IREx Materials



Material	Type	Audience
<a href="#">How do sIRBs and Study Managers close a site on a study in IREx?</a>		Reviewing IRB; Study Managers
<a href="#">How do sIRBs and Study Managers close a study in IREx?</a>		Reviewing IRB; Study Managers
<a href="#">How to Document a Site Closure in IREx</a>		Reviewing IRB; Study Managers
<a href="#">How to Document a Study Closure in IREx</a>		Reviewing IRB; Study Managers
<a href="#">Using IREx as the Study Manager: A Step-by-Step Guide</a>		Study Managers
<a href="#">How to Add Participating Sites to a Study</a>		Reviewing IRB; Study Managers
<a href="#">Agreements Overview</a>		Reviewing IRB; Study Managers

# Next Call

- January 21, 2022

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# Join the IREx User Feedback Group!

- Open to HRPP Liaisons and Study Managers
- Members provide input on upcoming features and priorities.
- Current membership includes:
  - Indiana
  - Johns Hopkins
  - Ohio State
  - Oregon
  - Pennington Biomedical
  - Utah
  - Vanderbilt
  - Wake Forest
  - WashU
- Meets the 3rd Friday each month at 1 ET.
- [Sign up here](#)