













# IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

## QUARTERLY CALL FOR STUDY MANAGERS

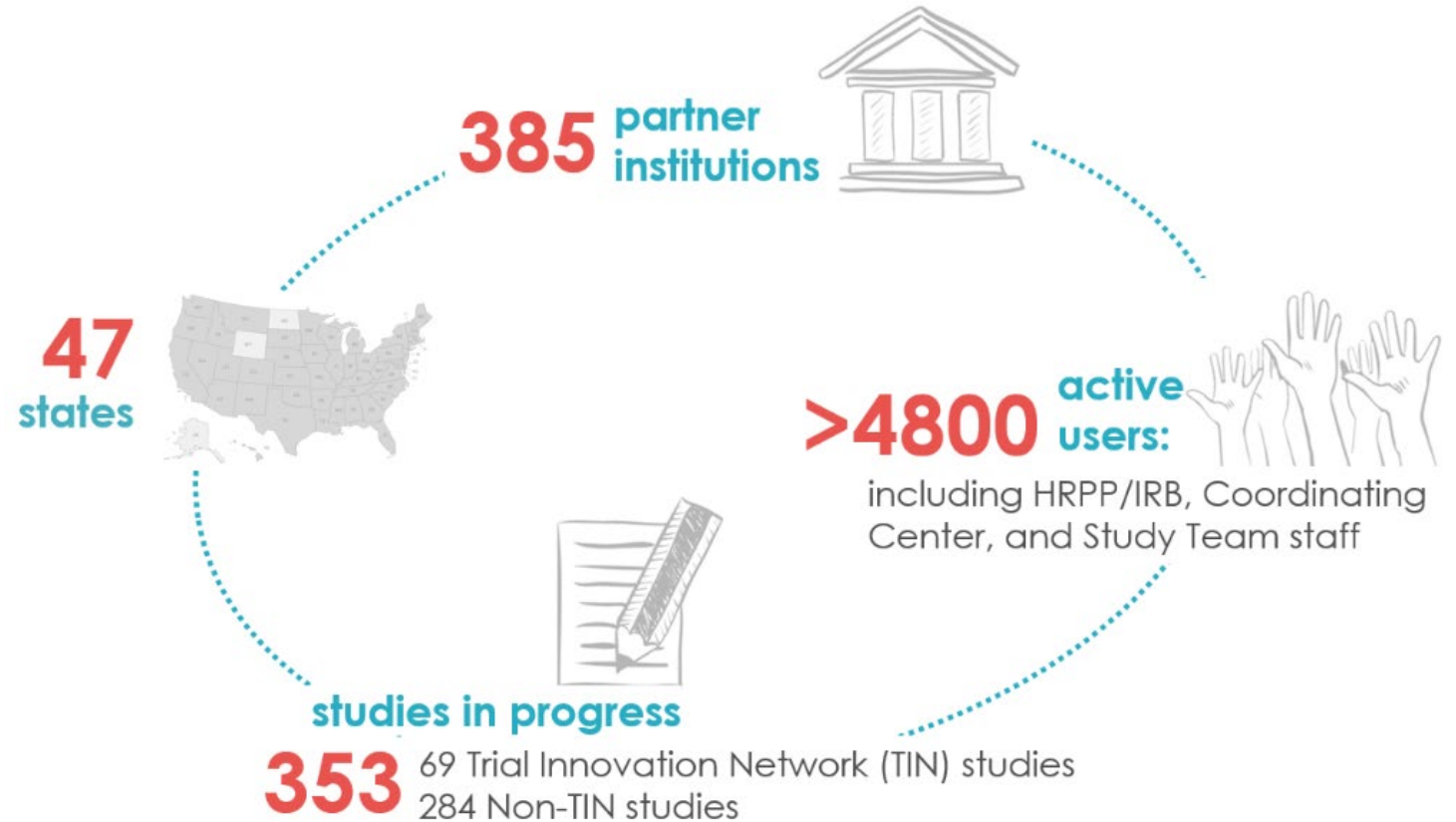
July 16, 2021

<ul style="list-style-type: none"><li>• User Materials Development</li><li>• User Support</li></ul> <p><b>Katelyn Benhoff</b> </p>	<ul style="list-style-type: none"><li>• Onboarding</li><li>• Study Support</li></ul> <p><b>David Crenshaw</b> </p>	<ul style="list-style-type: none"><li>• Training</li><li>• Study Support</li></ul> <p><b>Natalie Dilts</b> </p>	<ul style="list-style-type: none"><li>• Lead Application Developer</li></ul> <p><b>Bryce Embry</b> </p>	<ul style="list-style-type: none"><li>• System Development</li></ul> <p><b>Asri Mumpuni</b> </p>
<ul style="list-style-type: none"><li>• Project Director</li></ul> <p><b>Emily Serdoz</b> </p>	<ul style="list-style-type: none"><li>• Onboarding</li><li>• Study Support</li></ul> <p><b>Bridget Swindell</b> </p>	<ul style="list-style-type: none"><li>• Application Developer</li></ul> <p><b>Jason Tan</b> </p>	<ul style="list-style-type: none"><li>• Website &amp; System Dev</li><li>• Study &amp; User Support</li></ul> <p><b>Linda Tan</b> </p>	<ul style="list-style-type: none"><li>• Application Developer</li></ul> <p><b>Evan Wimberly</b> </p>

# QUARTERLY CALL AGENDA



- **Welcome!**
- **Recent System Updates**
- **Upcoming System Updates**



# Recent System Updates

Since April 2021

# “Date Added” included for Approval Documents

Continuing Review: Full Board (exp. 2/18/2022) Current

Edit review Site approvals

## Study Info

**Role:** Reviewing IRB  
**IRB Number:** 200533  
**Status:** approved  
**Submission Type:** Continuing Review: Full Board  
**Review Cycle:** 12 mo

## Key Dates

**Submitted:** 2/16/2021  
**Pre-Reviewed:**  
**Reviewed:** 2/19/2021  
**Approved:** 2/19/2021  
**Expires:** 2/18/2022

## Documents

Type	Name	Date Added	Size
Protocol [Protocol V5 Dated 10/2/2020]	ORCHID_PRO_V5_02OCT2020.pdf	10/26/2020	655 KB
Determination Letter	IRB_FAL_2021CR.pdf	02/22/2021	139 KB
Continuing Review Application	IRB-Submission_2021CR.pdf	02/22/2021	157 KB
Consents & Assents - Consents & Assents	IRB_FAL_2021CR.pdf	02/22/2021	139 KB
Recruitment & Advertisements	Stamped-Internet and Social Media ads.pdf	05/29/2020	399 KB
Recruitment & Advertisements	Stamped-Informational Sheet.pdf	05/29/2020	244 KB
Other IRB Approved Documents - Study Application	Stamped-IRB-Application.pdf	10/26/2020	4 MB
Others - Discharge Drug Diary	Stamped-ORCHID_Discharge Drug Diary_Template.pdf	04/03/2020	426 KB
Others - DSMB Memo	PETAL DSMB IRB memo 19JUN2020.pdf	07/09/2020	50 KB

Use arrows to sort

Continuing Review: Full Board (exp. 2/18/2022) Current

Edit review Site approvals

## Study Info

**Role:** Relying Site  
**IRB Number:** 200533  
**Reviewing IRB Decision:** approved  
**Review Cycle:** 12 mo

## Key Dates

**Submitted for Local Review:**  
**Local Review Conducted:**  
**Local Review Completed:**  
**Reviewing IRB Submitted:** 2/16/2021  
**Reviewing IRB Reviewed:** 2/19/2021  
**Reviewing IRB Approved:** 2/19/2021

## Documents

Type	Name	Date Added	Size
Protocol [Protocol V5 Dated 10/2/2020]	ORCHID_PRO_V5_02OCT2020.pdf	10/26/2020	655 KB
Determination Letter	IRB_FAL_2021CR.pdf	02/22/2021	139 KB
Consents & Assents - Consents & Assents	IRB_FAL_2021CR.pdf	02/22/2021	139 KB

Showing 1 to 3 of 3 entries

Download All

# Add Consortia to Studies

## Participating Sites

How will you add sites to this study?  Add sites by name or FWA #  Select consortium of sites

### Provide Site Names and PI Contact Information

This information is used to notify the site HRPP and PI that the study is in IREx so they can begin documenting reliance. IREx provides the initial protocol and consent templates to site PIs. The **lead study team / coordinating center** should provide these materials with other study materials, contracts and regulatory documents outside of IREx. ?

### Indicate what sites should have access to the study in IREx

-- Choose a consortium --  
-- Choose a consortium --  
Midwest Research Network  
Linda's test consortium  
Testing Consortium

### Indicate what sites should have access to the study in IREx

Midwest Research Network

+ Add Additional Site

Please let us know if you don't see your consortium.

Institution	PI (Required)	Coordinator	
Central Ohio Medical Center #123456	+ Add PI	+ Add Coordinator	✎ ✕
Columbus University	+ Add PI	+ Add Coordinator	✎ ✕
Eastman Medical Center of Ohio #45648974865	+ Add PI	+ Add Coordinator	✎ ✕
Faraday Institute of Research, Science and Technology #01569874	+ Add PI	+ Add Coordinator	✎ ✕
Hartford College of Medicine #00003216	+ Add PI	+ Add Coordinator	✎ ✕
Mellon University Medical Center #00001111	+ Add PI	+ Add Coordinator	✎ ✕
Middle-earth College of Agriculture #456431546	+ Add PI	+ Add Coordinator	✎ ✕

Close

# Document Study Closures

**SIRBs (only) can document study closures. This option is not available to Study Managers (yet?)**

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*

The screenshot displays the IREx interface for a study closure. On the left, a sidebar shows a list of 'VERSIONS' for the study '20210701 Asri Test Study 1'. The 'Study Closure' version is highlighted, showing the reviewing IRB as 'Carnegie U Med Ctr' (Closed) on 7/1/2021. Below this, 'Relying Sites' are listed: Duke Univ-Duke Childrens, Einstein, Emory, Goodall, and VUMC | Vanderbilt Univ, all marked as 'Closed' on 7/1/2021. The 'Registered / In Progress' section shows 'Baylor College Med' as 'Closed' on 7/1/2021.

The main content area is titled 'Study Closed' and shows the study title '20210701 Asri Test Study 1 High of 81 degrees today'. It includes navigation tabs for 'Study-wide IRB Approvals', 'Site-specific IRB Approvals', and 'Status Summary'. The 'Protocol Version: NA' is displayed. The 'SIRB: Carnegie University Medical Center' is listed as the 'Lead Site: Carnegie University Medical Center'. A 'Study Closure' section is expanded, showing a 'Closed' status. Below this, 'Study Info' and 'Key Dates' are provided. The 'Study Info' includes Role: Reviewing IRB, IRB Number: 443, Status: Closed, and Submission Type: Study Closure. The 'Key Dates' section shows 'Study Closed' on 7/1/2021 and 'Closure Reasons' including 'Study Completed' and 'Other: We're done with this'. A 'Documents' section is also visible, listing 'Determination Letter' (determination letter C.docx, 28 KB) and 'Others' (1.docx, 37 KB).

# New Training Offerings



Navigation: About | Resources **\*NEW\*** | FAQs | Feature Releases | IREx API | Contact Us

**SIGN UP FOR TRAINING**

Select a training below that works best for you. Don't see a training? [Contact us.](#)

### IREx Live Trainings **\*NEW\***

#### Understanding Combo Sites in IREx

Users: HRPP Liaisons | Study Managers

Wednesday at 2PM ET, July 21st

HRPPs and Study Managers join this training to learn more about:

- Defining a Combo Site
- Establishing a Combo Site on a study
- Understanding Reliance Documentation for Combo Sites
- Understanding Combo Sites for Multisite Liaisons
- Understanding Combo Sites as the Study Manager

[Register here](#)

#### IREx Resources and Navigation Tips

Users: All

Wednesday at 2PM ET, July 28th & August 25th

Attend this training to learn more about the following:

- Types of resources available in IREx
- Where to find helpful IREx resources
- IREx navigation tips

[Register here](#)

## WEDNESDAYS AT 2 ET/1 CT/12 MT/11 PT



- Understanding Combo Sites in IREx
- IREx Resources & Navigation Tips



- How to Document Study Closures in IREx
- How to Upload Continuing Reviews and Amendments
- sIRB Workflow Spotlight: Wake Forest
- IREx Resources & Navigation Tips

# Upcoming System Updates

Summer/Fall 2021



# Site Closures

- Allow sIRB to close a single site on an active study
- Bonus feature: Allow an sIRB or Study Manager to indicate a study is “closed to enrollment”, but has ongoing approval (i.e., may not have approved consents, but has CR approval)
- *ETA August 2021*

# Reorganizing Approval Documents

Provide all site's approval documents on one tab

**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 Encequidor 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

**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)


# New Resources

Spring/Summer 2021





# Recently Updated/Added SM Resources

## Bookmark for yourself

- [SM Step-by-Step Guide](#)
- [Add/Remove Participating Sites Quick Guide](#)
  - *Updated to reflect adding a consortium of sites; request your consortium be added to IREx [here](#)*
- Study Closure Quick Guide
  - July newsletter! 



## Share with your Study Teams

- [Intro to sIRB Review](#) 
  - *Great for educating those new to using a Single IRB; gives overview of local IRB responsibilities*
- [Intro to IREx](#)
- [Accessing Approvals Quick Guide](#) 
- [Add/Remove Study Team Members Quick Guide](#)

# Next Call

- October 15, 2021

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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](#)