



# IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

## QUARTERLY CALL FOR HRPPS

July 16, 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

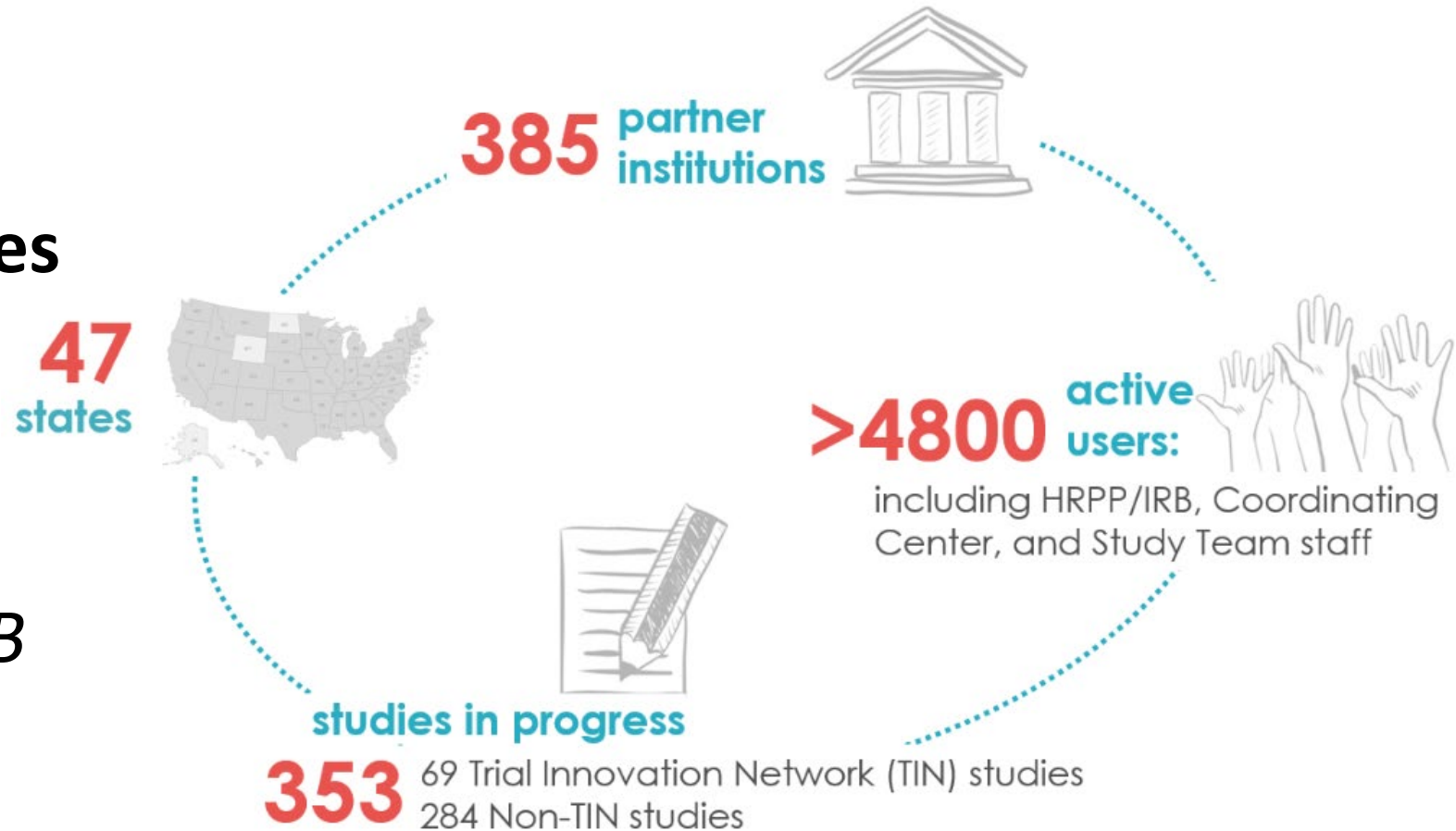
**Evan Wimberly**



# QUARTERLY CALL AGENDA



- **Welcome!**
- **Recent System Updates**
- **Upcoming System Updates**
- **Hear from the Pros –  
*University of Utah sIRB  
Team***



# Recent System Updates

Since April 2021

# New Exports Available for SIRBs



**PENNINGTON BIOMEDICAL RESEARCH CENTER**

**35** reviewer  
Your site is the reviewer for 35 studies

**14** participant  
Your site is a participant in 14 studies

**45** users  
There are 45 users at your site

## Reviewing Site's Studies

Search: crea

All Studies Export

- Overall Study Report (CSV)
- Participating Site Report (CSV)

IRB #	Study Title	Participating Sites	Approved Sites	Expiration	To Do
2019-015	Creation and maintenance of integrated biorepository databases (IBD) to support research usage of biorepository samples.	2	2	4/11/2022	No Outstanding Actions
2020-004	Pancreatic Tissue Collection	1	1	1/30/2023	No Outstanding Actions

### Overall Study Report includes the following for each sIRB study:

- Date study created in IREx
- Risk Type (GTMR, MR)
- Lead PI
- Initial review dates for lead site
- # Participating Sites
- # Registered Sites
- # Sites indicating reliance
- # Sites with initial approval

# New Exports Available for SIRBs



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Dashboard Home

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2020-004	Pancreatic Tissue Collection	1	1	1/30/2023	No Outstanding Actions

### **Participating Site Report** includes the following for each site on your sIRB studies:

- Relying site FWA and name
- Whether site signed SMART IRB, LOI, other IAA
- Site PI
- Dates of each sIRB approval (initial, CR, mods)
- Date site notified/contacted about study
- Date site registered
- Date site relied
- Local submission/review dates (if provided)
- Date HRP and PI Surveys completed, updated

# New Exports Available for Participating Site HRPPs



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Dashboard Home

## Participating Site's Studies

Search: pi

All Studies Export  
Participating Site Report (CSV)

Study Title	PI	Reviewing IRB	Expiration Date	To Do
3D Body Pilot Study		LA State Univ A & M		Register
Health Behaviors Syndrome Pilot Study	John W. Apolzan, PhD	LSUHSC at Shreveport	9/27/2021	Approved 6/23/2021
Urinalysis and STI Association in Adolescent Psychiatric Patients	Ron Horswell	LSU HSC New Orleans		Remind PI To Complete Survey

**Participating Site Report** includes the following for each study where your site is relying on an sIRB:

- Reviewing IRB name & FWA
- Local PI
- Dates of each sIRB approval for your site (initial, CR, mods)
- Date your site was notified/contacted about study
- Date your site registered
- Date your site relied
- Your Local submission/review dates (if provided)
- Date your HRP and PI Surveys completed, updated



# 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 is not the initial protocol and consent templates to site PIs. The **lead study team / coordinating center** should provide these materials to 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	<a href="#">Add PI</a>	<a href="#">Add Coordinator</a>	<a href="#">✎</a> <a href="#">✕</a>
Columbus University	<a href="#">Add PI</a>	<a href="#">Add Coordinator</a>	<a href="#">✎</a> <a href="#">✕</a>
Eastman Medical Center of Ohio #45648974865	<a href="#">Add PI</a>	<a href="#">Add Coordinator</a>	<a href="#">✎</a> <a href="#">✕</a>
Faraday Institute of Research, Science and Technology #01569874	<a href="#">Add PI</a>	<a href="#">Add Coordinator</a>	<a href="#">✎</a> <a href="#">✕</a>
Hartford College of Medicine #00003216	<a href="#">Add PI</a>	<a href="#">Add Coordinator</a>	<a href="#">✎</a> <a href="#">✕</a>
Mellon University Medical Center #00001111	<a href="#">Add PI</a>	<a href="#">Add Coordinator</a>	<a href="#">✎</a> <a href="#">✕</a>
Middle-earth College of Agriculture #456431546	<a href="#">Add PI</a>	<a href="#">Add Coordinator</a>	<a href="#">✎</a> <a href="#">✕</a>

Close

# New Training Offerings



Resources \*NEW\*

- IREx Workflow
- Sign Up for Training \*NEW\*
- Reviewing IRBs
- Participating Site HRPPs
- Coordinating Center Staff/ Lead Study Teams
- Participating Site Study Teams

**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



# Document Study Closures



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

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



# Document Study Closures



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*

## 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

#### 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

# Upcoming System Updates

Summer/Fall 2021

# Site Closures



- Allow sIRB to close a single site on an active study
- Bonus feature: Allow an sIRB 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

The screenshot shows the 'Approval History' tab for Albany Medical Center. The interface includes a search bar and navigation buttons for 'View All', 'Amendments', and 'Continuing Reviews'. A list of approval documents is displayed, with the following items highlighted:

- 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. ...)

A callout box provides a change summary for the #50 amendment:

**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.

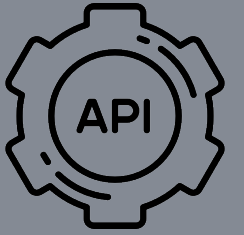
Provide Document History Tab

The screenshot shows the 'Document History' tab for Albany Medical Center. The interface includes a search bar and navigation buttons for 'Approval History', 'Document History', and 'Status Summary'. A list of document categories and their dates is displayed:

- 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)



# Enhancing IREx API

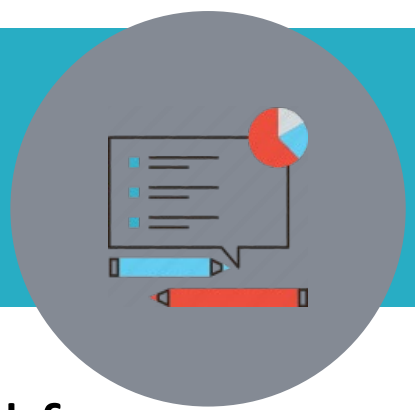


- Allow e-IRB systems to send ANY IRB approval to IREx, not just initial IRB approval
- Note: tips for connecting from API with Huron system and homegrown are available.
- *ETA December 2021*

# Public Service Announcement

For Trial Innovation Network

# TIN / University of Utah Consent Builder



- Utah Trial Innovation Center has created “Consent Builder” tool for coordinating centers/lead study teams.
- Goal is to streamline the creation of consent forms

# Next Call

- October 15, 2021

# University of Utah IRB Workflow: Using IREx

*IREx Quarterly HRPP Call – July 16, 2021*

*University of Utah Operations Managers*

Gary Henderson

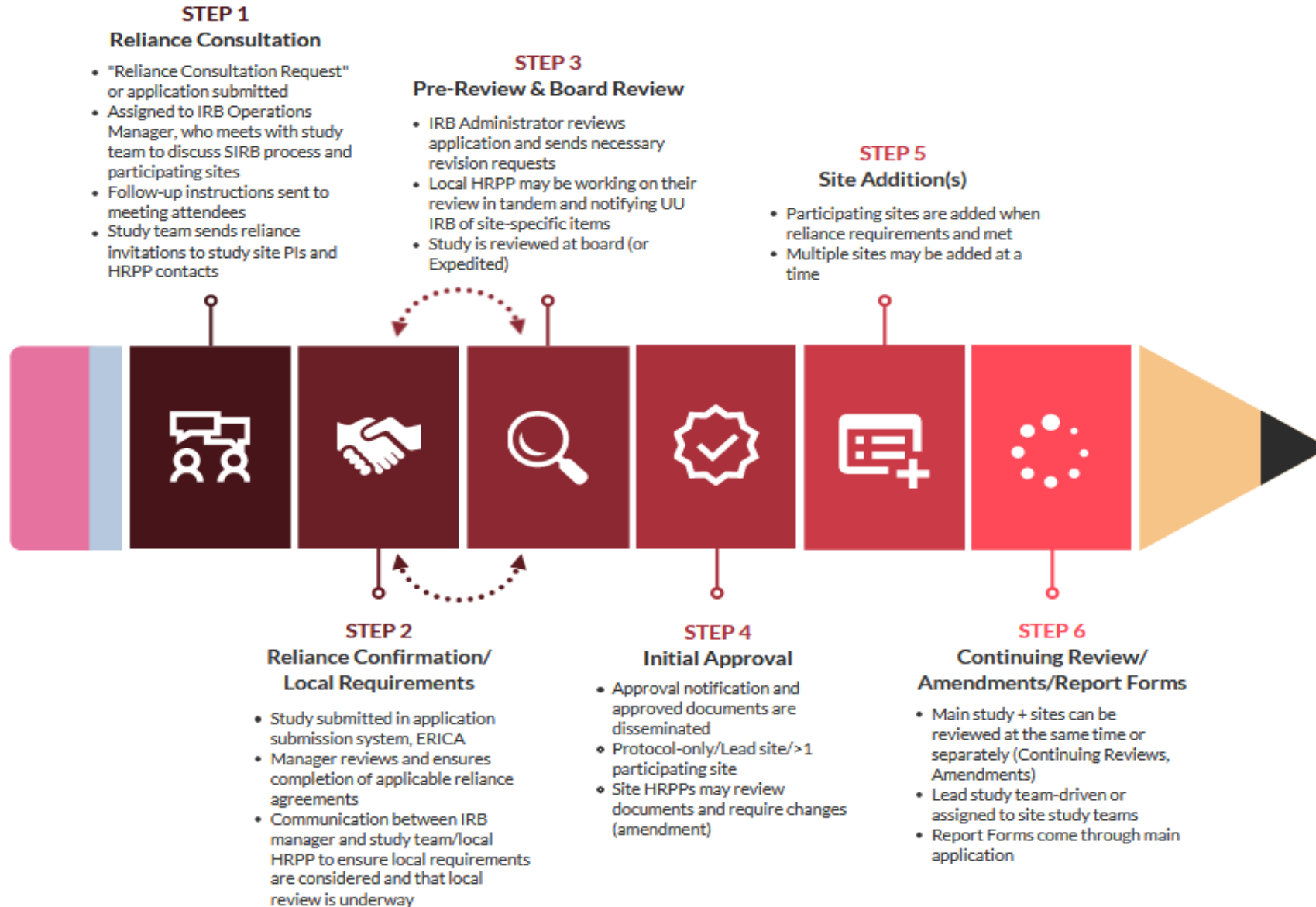
Ammon Pate

Lisa Rigtrup

Annie Risenmay



# UU SIRB Workflow



# UU SIRB Workflow – IREx Usage



## STEP 1

### Reliance Consultation

- Assess participating sites
  - IREx Registration
  - SMART IRB
  - Protocol vs. Institutional Profile



#### Resources

Find other users

Find other sites

Agreement Checker

Add HRPP Staff / Members

Request Help

Join A Training

Resources

Q Search: university of Utah

Name	SMART IRB V1	SMART IRB V2	IREx Access	Profile	Download
University of Utah <span>ctsa</span> <span>smart v1</span> <span>smart v2</span> <span>tin</span>	✓	✓	✓	<a href="#">view profile</a>	<a href="#">download profile</a>
<ul style="list-style-type: none"><li>• Huntsman Cancer Institute</li><li>• Associated Regional &amp; U Pathologists (ARUP)</li><li>• Eccles Institute of Human Genetics</li><li>• Moran Eye Center</li><li>• South Jordan Health Center</li><li>• Farmington Health Center</li></ul>					



# UU SIRB Workflow – IREx Usage



## STEP 2 Reliance Confirmation/ Local Requirements

- Create study in IREx using drafts
  - Collecting local context?
- Establish a Study Specific Reliance Plan (SSRP)
- Invite sites to rely as applicable

## STEP 3 Pre-Review & Board Review

Study-Specific Reliance Plan (SSRP)

**i** This is your initial SSRP that will be presented to Relying Sites when they join this study. You will be able to modify the SSRP for each individual IRB before reliance is finalized.

STANDARD OPERATING PROCEDURES ("SOPs") Using SMART IRB SOPs (recommended)

HIPAA DETERMINATIONS AND ACTIONS

# UU SIRB Workflow – IREx Usage



## STEP 4 Initial Approval

- Upload/publish overall study approval
  - Approved protocol/consent forms
  - IRB determinations
- Invite any remaining sites to rely
  - 'Notify HRPP'

- ✓ Complete IREx Setup
- ✓ Confirm SSRP
- ➔ Upload Overall Study Approval
- ➔ Publish Approval

VERSIONS

June 4, 2021 v1.0

Reviewing IRB

Univ of Utah  
Pending

## Endophenotypes of Persistent Post-Concussive Symptoms in Adolescents - CARE4Kids

Study-wide IRB Approvals

Site-specific IRB Approvals

Status Summary

Export Data

### Participant Status Summary

Q Search:

Site	Reliance Agreement	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Children's National Medical Center	SMART 2	✓	Notify HRPP		
Seattle Children's Hospital	SMART 1	✓	Notify HRPP		

# UU SIRB Workflow – IREx Usage



## STEP 5 Site Addition(s)

- Confirm reliance decision is established
- Collect local considerations
- SIRB review includes local considerations
- Upload site approval

Site	Reliance Agreement	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
The Ohio State University	SMART 1	✓	Completed 1/10/2019	3 / 3 Surveys Complete	Approved
University of Kentucky	SMART 2	✓	Completed 3/8/2019	3 / 3 Surveys Complete	Approved
Oregon Health & Science University	SMART 1	✓	Completed 4/25/2019	3 / 3 Surveys Complete	Approved
University of North Carolina at Chapel Hill	SMART 2	✓	Completed 6/20/2019	3 / 3 Surveys Complete	Approved

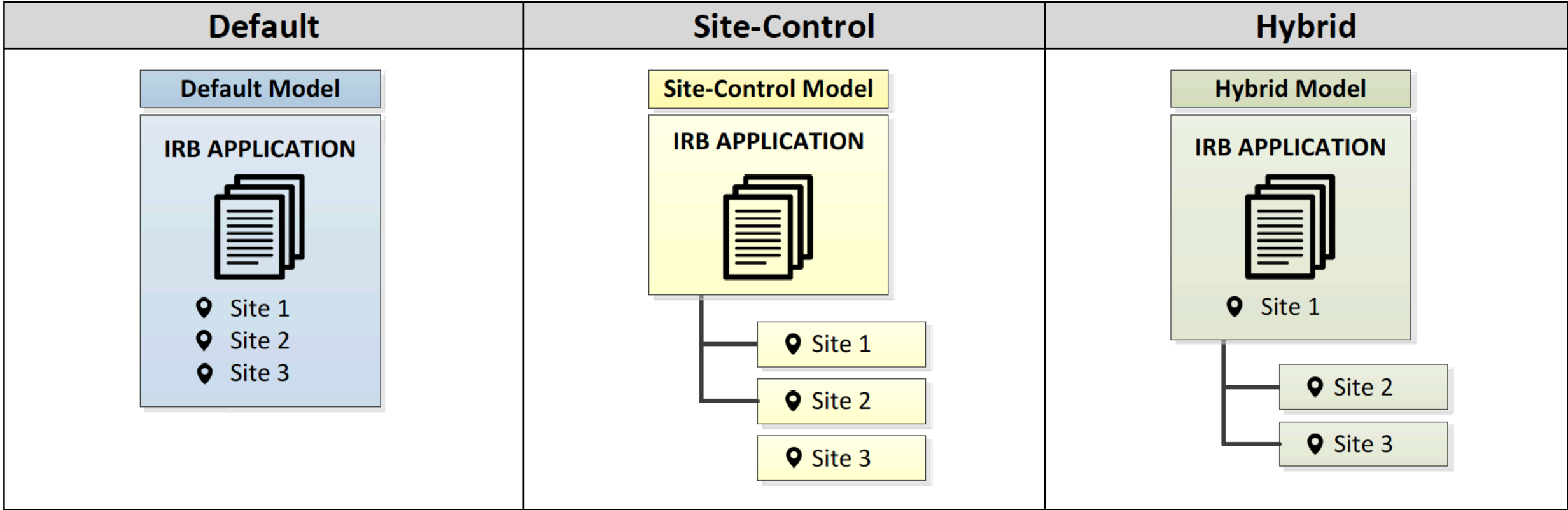
## STEP 6 Continuing Review/ Amendments/Report Forms

- Create CR and/or AM
- Publish approval

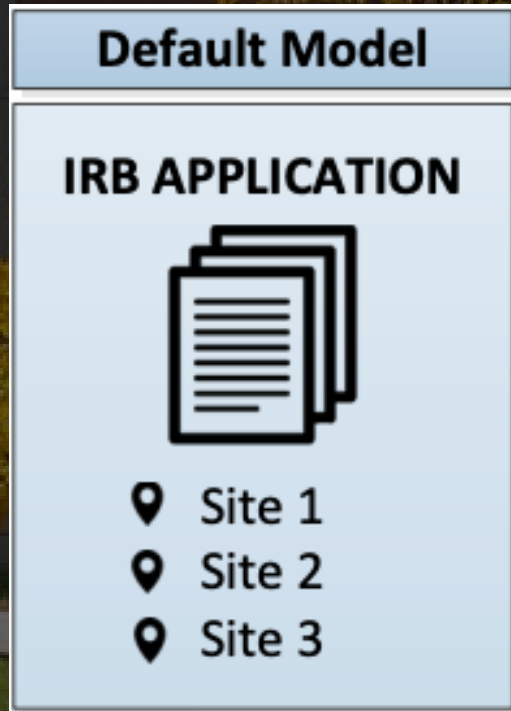




# 3 Models for Multi-Site Management



# Default Model



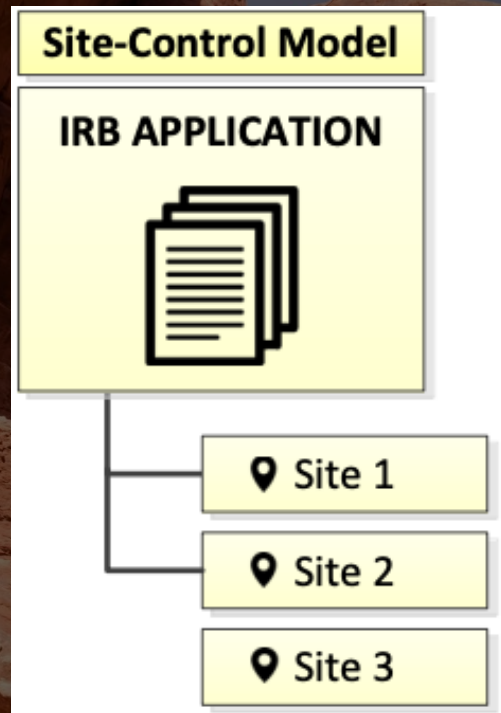
## Benefits

- Provides the benefit of having multiple sites and the protocol reviewed and approved within one process

## Challenges

- If one or more of the listed sites are not fully prepared for IRB review, the review process is halted until every site is fully prepared for IRB review
- Sites do not receive automated study notifications, unless they have an ERICA profile and are listed in the application. In this case, sites receive *all* notifications, regardless of the relevance or applicability to their site

# Site-Control Model



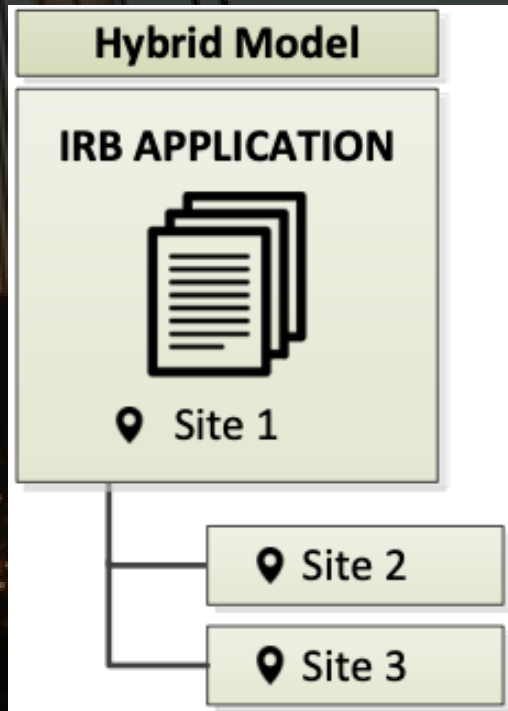
## Benefits

- Allows participating sites to be managed independently from the main IRB application
- Main application can go through IRB review process while participating sites are working on completing reliance and site-specific requirements
- Sites can be submitted for IRB review as they are ready and are not beholden to the progress/delays caused by other sites
- Sites receive automated notices relevant to their site

## Challenges

- Sites that have their own participating site application must have a Site Investigator (SI) listed. The SI must have an ERICA account and profile in order to have access to the application, enter the required information, and receive study notifications

# Hybrid Model



## Benefits

- Provides the benefits of both the Default and Site-Control Models

## Challenges

- Determining which sites to keep with the main application and which sites to “peel off” into their own participating site applications can be challenging in the early stages of the review process
- Once a site has been “peeled off” and given their own site application workspace, they cannot be re-integrated into the main application

# When Do We Choose to Use IREx?



- When the University of Utah is serving as the SIRB, we decide on a case-by-case basis when to use the IREx system.

<b>When We Use IREx</b>	<b>When We Don't Use IREx</b>
<ul style="list-style-type: none"><li>• When the study is from the TIC</li><li>• When there are lots of sites to manage</li><li>• When the majority of the sites are already signed onto SMART and have used IREx before</li><li>• When the study coordinator is from an external institution and may need an extra site management tool</li></ul>	<ul style="list-style-type: none"><li>• When it is not a TIC study (sometimes)</li><li>• When the majority of sites aren't signed onto SMART</li><li>• When the study only has a couple of sites or the other sites are inside our state (Utah)</li><li>• When we have a master agreement with sites or a SIRB and don't need to execute a study-specific reliance agreement (e.g. cooperative groups)</li></ul>



# Pros & Cons of Using IREx

*An Academic IRB's Perspective*



## Challenges to Consider

- **System saturation:** Yet *another* electronic system for study teams and HRPPs to learn; however, IREx is easier than most to use, more aesthetically user-friendly, and more useful to SIRBs
- **IREx is not a document management/distribution system**, but sites may get that impression because the system allows/requires you to upload documents – can lead to sites using versions of documents that are not the most recent version approved by the SIRB
- For the UU IRB, IREx is not as helpful after initial IRB approval because our own electronic system, ERICA has the “site-control model” available\*\*. Our electronic system allows external users to get an account and have access to their own site application.

*\*\*If your institution doesn't have this ability, you will need to come up with a way to manage each site's documents and distribute them to site PI's, who then need to keep their HRPPs informed per their local policies.*



# Pros & Cons of Using IREx

*An Academic IRB's Perspective*



## Features that Make Life Easier

- The hard part is over: Many academic HRPPs already know how to use the system
- Study teams can keep up with the status of each of their sites' reliance without sending the SIRB an email
- It can help a SIRB figure out which sites need to rely when a combo site/group relationship isn't clear
- Clean, easy to read "**Study Summary**" tab
- Collects local considerations in an easy, streamlined manner – can prevent lengthy email threads and conference calls with sites because there's a simple way for them to communicate concerns and requirements to the SIRB
- The Institutional Profile database is a game changer
- The IREx team is extremely responsive, open to feedback, and friendly – there's a real person available to help you if you need it
- Prevents HRPPs from having to use institution specific systems – one central hub for reliance and local considerations (vs. SMART IRB reliance system, which stops at indicating reliance)



Questions?

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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](#)