



IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR HRPPPS

April 16, 2021

- User Materials & Support

Katelyn Benhoff



- User Training
- Study Support

Natalie Dilts



- Lead Application Developer

Bryce Embry



- System Development

Asri Mumpuni



- Project Director

Emily Serdoz



- Application Developer

Jason Tan



- Site & User Onboarding
- Study Support

Bridget Swindell



- Website & System Development
- Study & User Support

Linda Tan

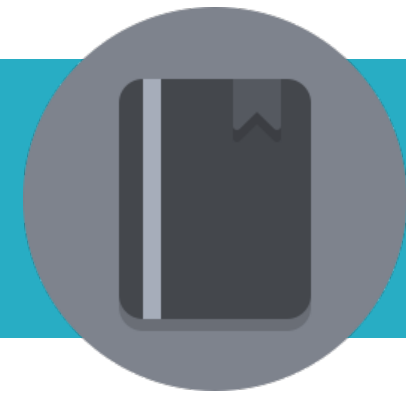


- Application Developer

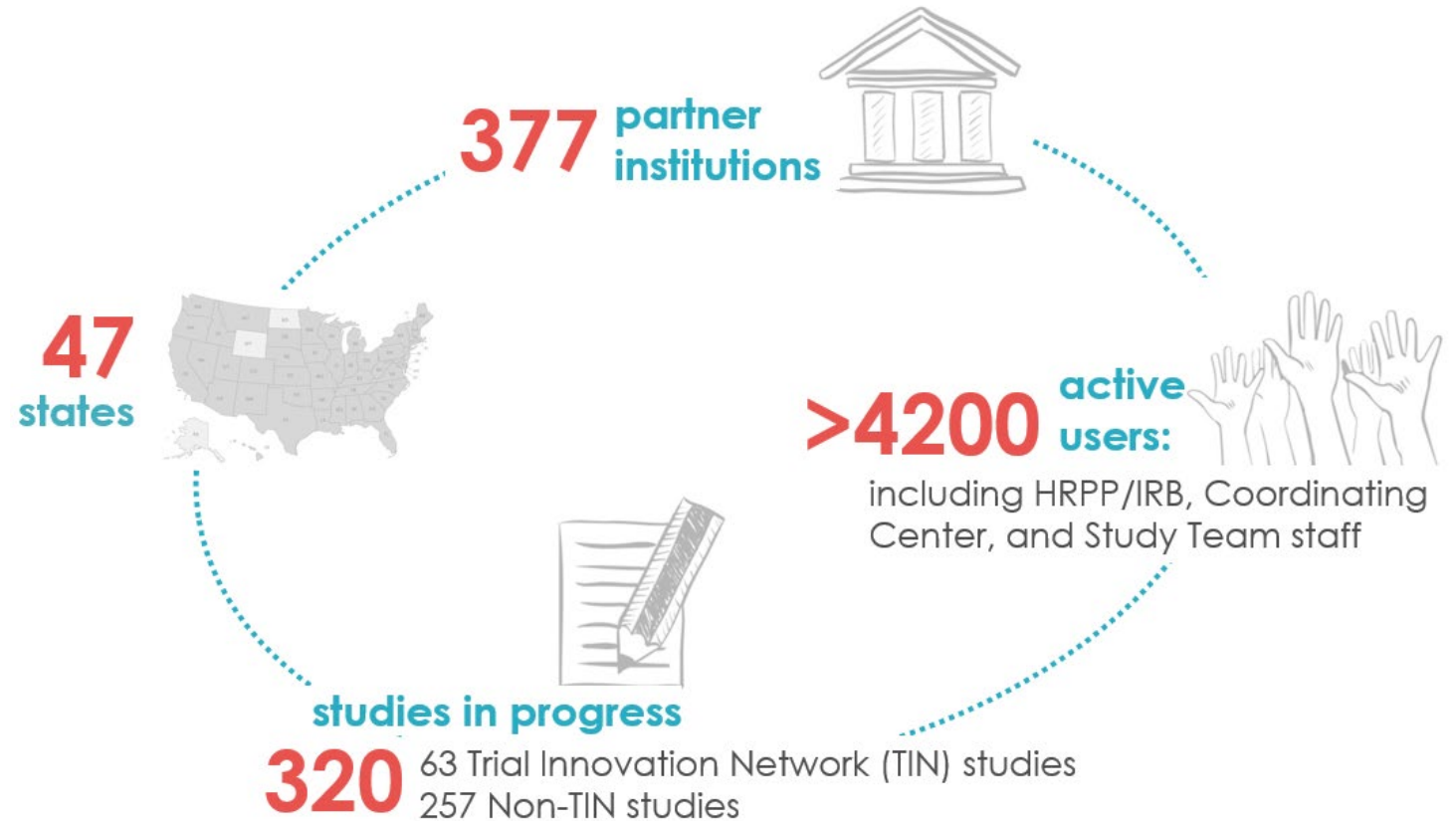
Evan Wimberly



QUARTERLY CALL AGENDA



- **Welcome!**
- **Looking Back -**
Reminders from 2020
- **Looking Bright in 2021 -**
New System Features
- **Looking Forward –**
What's on Deck for IREx!
- **Next Call**



Looking Back – *Reminders from 2020*

IREx API for sIRBS



1. Push study to IREx

Replaces “Create Study”

Streamlines sIRB processes

2. Publish Lead Site Initial Approval

Replaces manual upload

Streamlines sIRB processes

3. Import site’s reliance and local review information

Replaces manual download and submission to eIRB system

Streamlines Study Manager processes

4. Publish relying site initial approvals

Replaces manual upload

Streamlines Study Manager processes

Fully Integrated
VUMC

API Piloted
Utah, CCHMC

Expressed Interest
Emory, JHU, Ochsner,
PBRC,

IREx API for sIRBS



1. Push study to IREx

Replaces "Create S

Lessons Learned:

1. sIRBs see value of using API.
2. sIRBs are challenged to allocate developer time given other e-IRB system needs.
3. sIRBs will see **greater value** when **all approvals** can be pushed via API (not just initial approval).

2. Publish

Replaces manual u

3. Import site's r

Replaces manual dow
submission to eIRB

4. Publish relying site initial

Replaces manual upload


Streamlines Study Manage
processes

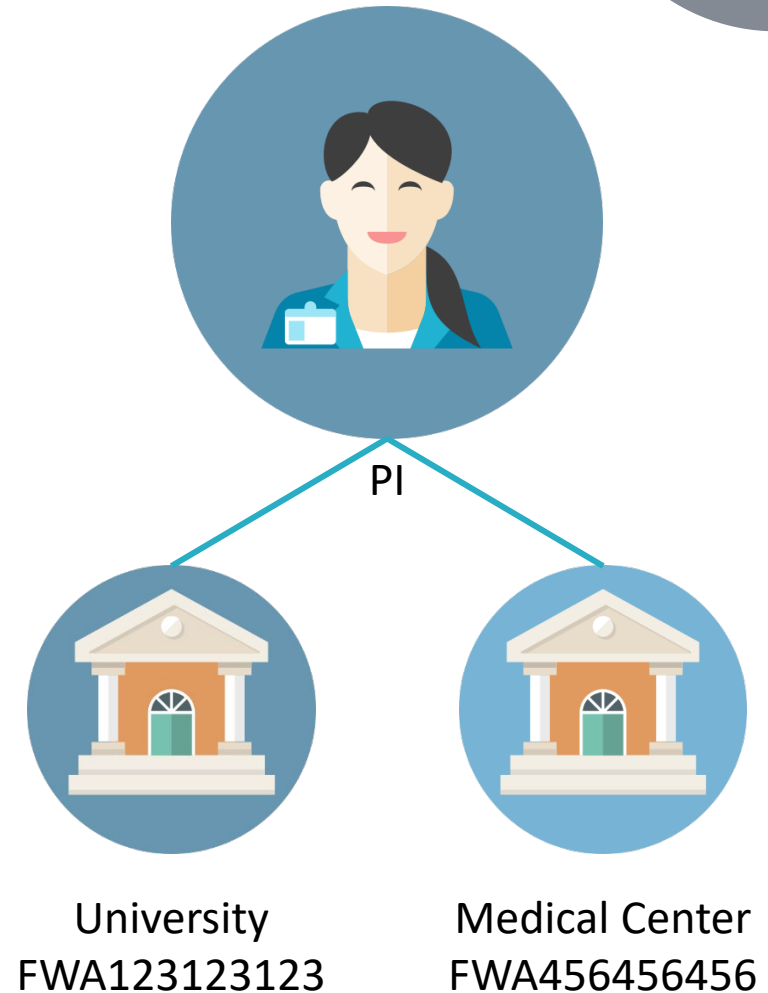
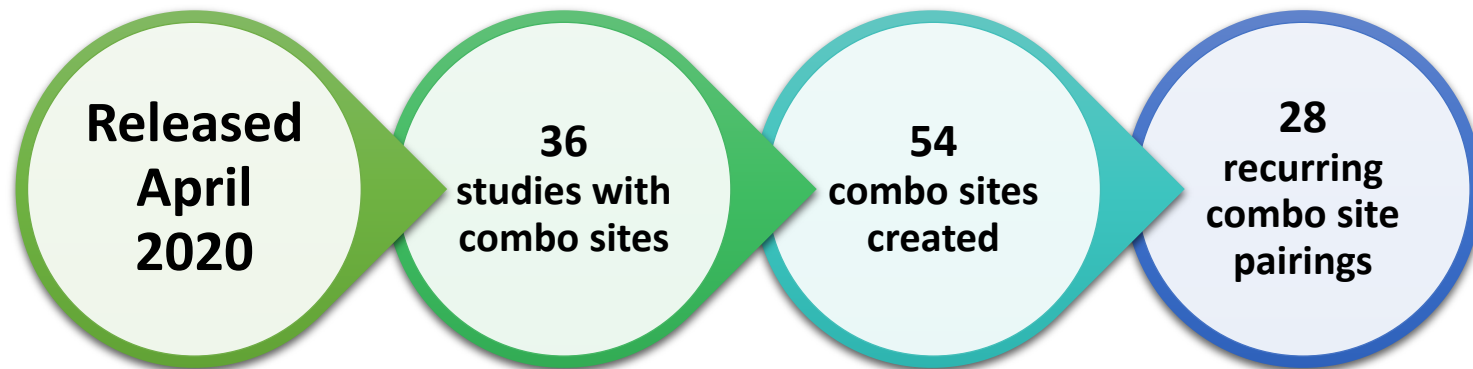
Contact us to learn more!

ssed Interest
JHU, Ochsner,
PBRC,

Combo Sites



A **Combo Site**  occurs when **one investigator or study team** engages **multiple FWAs** for a study



Combo Sites



Lessons Learned:

1. Reliance on an external IRB creates challenging workflows for AMC IRBs and local hospitals/research centers with long standing relationships between.
2. Who should create the combo?
 1. sIRB/Study Manager during study setup
 2. Participating sites when they register (**recommended**)

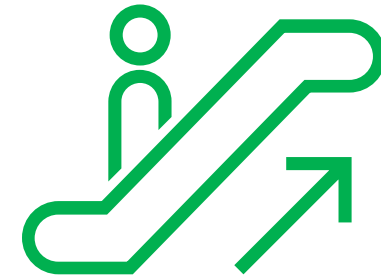
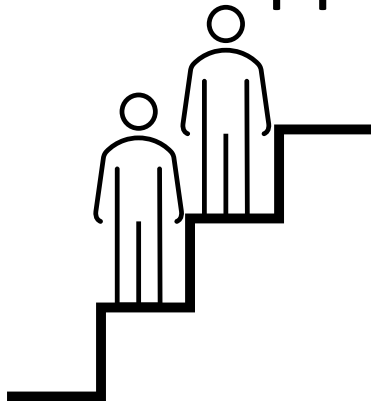
FWA123123123

Medical Center
FWA456456456

Study Managers can Upload Continuing Reviews / Amendments



Originally: sIRB had to upload **overall approval for continuing review and study-wide amendments.** Then, Study Managers could upload site-specific approvals.



To save the sIRB time, **Study Managers can now upload the overall and site-specific approvals for continuing reviews and study-wide amendments.**

Agreement Checker



- **Use case:** Identify whether sIRB has agreements in place with potential study sites
- **Available to all users**
- **Data can be exported**

Agreement Checking Tool

Report Parameters							
SIRB	Mammoth University						
Add Participating Site	Select a site						
							Download CSV
Site Name	FWA	SMART 1	SMART 2	Other Reliance	IREx	Indemnification	
Faraday Institute of Research, Science and Technology	01569874	✗	✓	✗	✓	Mammoth LOI	Remove
Relying Site 3 (NS)	31341424234	✗	✗	Mammoth IAA	✓	✗	Remove
University of Arkansas for Medical Sciences	00001119	✓	✗	✗	✓	✗	Remove
Vanderbilt University Medical Center	00005756	✓	✓	✗	✓	✗	Remove

sIRB can Reset SSRP for Relying Site



Site	SMART IRB	LOI	IREx Access	Reliance Decision ?	Local Considerations	Approval Status (current version)
Me Re				Started 9/15/2020	1 / 3 Surveys Complete	Not Approved
Our Lady of Hospital, In				Completed 9/4/2020		

Edit prior to acceptance →

Edit after acceptance →

Study-Specific Reliance Plan (SSRP)

Reviewing IRB
Faraday Institute of Research, Science and Technology
✓ created SSRP
contact liaisons

Relying Sites
The Square
✓ accepted SSRP on Sep 15, 2020
contact liaisons
Reset SSRP

Documents
Letter of Reliance
SSRP Response

STANDARD OPERATING PROCEDURES ("SOPs")	Using other SOPs as mandated by an external group with authority for the study.
NAME OR DESCRIPTION OF MANDATORY SOPs	harvard component
WHERE CAN PARTICIPATING INSTITUTIONS ACCESS THE SOPs	I will provide a hyperlink to the SOPs
ENTER THE URL FOR ACCESS THE SOPS	square

HIPAA DETERMINATIONS AND ACTIONS

sIRB can Reset SSRP for Relying Site



[TEST] 123 -- IREx Update: Reviewing IRB revised your SSRP



admin@irbexchange.org

To ✓ Serdoz, Emily Sheffer



3:22 PM

Dear Liaison,

Faraday Institute of Research, Science and Technology has edited the Study-Specific Reliance Plan (SSRP) for your site for the study below. Please login to [IREx](#) to view the revised SSRP and indicate reliance on the Reviewing IRB.

Study Title: Turning off Lead Site Approval Notification to Notified Sites

Field	Previous Value	Updated Value
INDEMNIFICATION	Indemnification agreements not required: Indemnification agreements or other contractual arrangements for allocation of liability are not required with respect to the identified study(ies).	One or more Participating Institutions require agreement: The Reviewing IRB and Relying site must enter into a separate indemnification agreement or agree to other contractual arrangements for allocation of liability with respect to the identified study(ies). The Reviewing IRB will be the primary indemnification agreement(s) will be maintained by the Reviewing IRB.
Indemnification Terms	-	Changed for Central OH-IO

[View the Study](#)

Thank you,
IREx Administrator

Study-wide IRB Approvals

Site-specific IRB Approvals

Status Summary

Export Data ▼

Participant Status Summary

Search: cen

Site	SMART IRB	IREx Access	Reliance Decision ?	Local Considerations	Approval Status (current version)
Carnegie U Med Ctr Carnegie Univ Carnegie University Medical Center	✓	✓	Updated 9/15/2020	3 / 3 Surveys Complete ▼	Not Approved
Central Ohio Medical Center	✓	✓	Reset 9/15/2020	3 / 3 Surveys Complete ▼	Approved

Looking Bright in 2021 – *New System Features*

More Agreement Options in IREx



1

**SMART IRB
Versions 1 & 2**

2

**Other Reliance
Agreements
(IAAs, MOUs)**

3

**Indemnification
Agreements
(Broad & Study
Specific)**

- 1. SIRBs can offer SMART IRB + an IAA on the same study.**
(Sites in SMART IRB will default to that agreement.)
- 2. SIRBs can add an IAA to an existing IREx study.**
- 3. Reliance and indemnification agreements can be study-specific or broad in scope.**

Agreement Resources



VANDERBILT UNIVERSITY MEDICAL CENTER

92 reviewer
Your site is the reviewer for 92 studies

19 participant
Your site is a participant in 19 studies

238 users
There are 238 users at your site

[Dashboard](#) [Home](#)

🌟 New February 2021
IREx can be used with ANY reliance or indemnification agreement. [Read more](#) or [Watch a video](#)

Find a Study

by Name:

by Sponsor:

[Create a Study](#) [Admin Dashboard](#)

[Find](#)

IREx Project Settings

Agreements [Help](#)

What reliance agreement(s) can be used by relying sites?
(Check all that apply)

☒ SMART IRB Agreement
☐ Other Reliance Agreement

Is Indemnification required of any relying site? ☒ Yes ☐ No

Is Indemnification executed *separately* from the reliance agreement? (e.g., a Letter of Indemnification (LOI)) ☒ Yes ☐ No

Name (ShortName)	Template Name
Smart IRB Clarification of Terms (Intermountain SMART Terms)	2020031-Shelby-All Sitres-SMART IRB COT-ASV1.docx

IREx Project Settings

Agreements [Help](#)

IREx can be used with the SMART IRB Agreement and/or any other reliance agreement. You can offer SMART IRB and another reliance agreement on the same study.

How Reviewing IRBs Set Up Agreements **Add Another Agreement to an Existing Study**

How Reviewing IRBs set up Reliance and Indemnification...
Watch later Share

IREx IRB Reliance Exchange
YOUR SYSTEM FOR SINGLE IRB REVIEW
How Reviewing IRBs set up Reliance and Indemnification Agreements for a Study

What reliance agreement(s) can be used by relying sites?
(Check all that apply)

☒ SMART IRB Agreement
☐ Other Reliance Agreement

sIRBs List Agreement Options in IREx Setup



IREx Project Settings



Agreements

Help

What reliance agreement(s) can be used by relying sites?

(Check all that apply)

☒ SMART IRB Agreement

☒ Other Reliance Agreement

☐ Use Existing Broad Reliance Agreement ☒ Add New Reliance Agreement

Type: ☐ Broad
☐ Study Specific
Required

Name:
Required

Short Name:
Required


Template: **X**

Is Indemnification required of any relying site?

☒ Yes ☐ No

Is Indemnification executed separately from the reliance agreement? (e.g., a Letter of Indemnification (LOI))

☒ Yes ☐ No

Name (ShortName)	Template Name
Faraday_Indemnification_Broad	 Faraday_INDEM_12122019

Be sure the Study-Specific Reliance Plan (SSRP) also reflects that indemnification is required for this study. This is the last question on the SSRP.

Do sites using "Custom Reliance Agreement" also complete a separate indemnification agreement?

☐ Yes ☒ No

Note: Answer NO if indemnification is included in "Custom Reliance Agreement"

****sIRBs****

Track Agreement Completion



Participant Status Summary

Manage Agreements Export Data

Search:

Site	Reliance Agreement	Indemnification	IREx Access	Reliance Decision	Local Considerations
Relying Site 1 S1	SMART 1	SIRB MC - Indem.	✓	Add PI Info	
Relying Site 3 (NS)	IAA v20200821	N/A	✓	Add PI Info	
Relying Site 6 NS	+ Agreement	SIRB MC - Indem. Update	✓	Add PI Info	

Study Reliance Agreements

Use this tab to indicate what sites have signed or plan to sign your institution's reliance agreement offered on this study.

IRB Authorization Agreement v20200821

Site: Relying Site 6 NS

Signed Copy: Choose File No file chosen

Date Sent: mm/dd/yyyy Date Executed: mm/dd/yyyy

Notes:

☐ This site is restricting the broad Reliance Agreement to this study only.

Cancel Save

Search:

Site	Agreement Name	Sent	Executed	Signed Copy	Notes
Relying Site 3 (NS)	IAA v20200821	2/2/2021	2/12/2021		
Relying Site 6 NS	+ Agreement	-	-	-	

1. Study Managers **cannot** enter completed agreements
2. Relying Site HRPPs do not upload executed agreements

Using the Agreement Dashboard



Your Institution

Profile

Components

Agreements

Agreement & Indemnification Management:

Your Reliance Agreements

Your Indemnification

External Agreements

All Reliance Agreements

Download CSV

Search:

Site	Agreement Name	Type	Related Studies	Sent	Executed	Document	Notes
Anderson Medical Center	Stanford IAA	BROAD RELIANCE Restricted	Related Studies ▼	3/5/2021			
Faraday Institute of Research, Science and Technology	Stanford SS IAA	STUDY SPECIFIC	-	7/1/2020	7/4/2020		
Relying Site 3 (NS)	Stanford IAA	BROAD RELIANCE	Related Studies ▼	7/1/2020	3/11/2021		
University of Arkansas for Medical Sciences	Stanford SS IAA	STUDY SPECIFIC	Related Studies ▼		3/8/2021		

Previous

1

Next

Using the Agreement Dashboard



Your Institution

Profile

Components

Agreements

Agreement & Indemnification Management:

Your Reliance Agreements

Your Indemnification

External Agreements

All Indemnification Agreements

Download CSV

Search:

Site	Agreement Name	Type	Related Studies	Sent	Executed	Document	Notes
Duke University Health Systems, Inc.	Stanford SS LOI	STUDY SPECIFIC INDEMNIFICATION	Related Studies ▼		7/4/2020		
Faraday Institute of Research, Science and Technology	Stanford Broad LOI	BROAD INDEMNIFICATION	Related Studies ▼		7/4/2020		
University of Arkansas for Medical Sciences	Stanford Broad LOI	BROAD INDEMNIFICATION Restricted	Related Studies ▼		3/3/2021		
Vanderbilt University	Stanford Broad LOI	BROAD INDEMNIFICATION	Related Studies ▼	3/9/2021			

Previous

1

Next

Using the Agreement Dashboard



Your Institution

Profile

Components

Agreements

Agreement & Indemnification Management:

Your Reliance Agreements

Your Indemnification

External Agreements

SIRB	Type	Agreement Name	Related Studies	Sent	Executed	Document
Loyola University Chicago	Reliance	LMC IRB Authorization Agreement	Related Studies	2/16/2021	2/19/2021	Not Uploaded
Single IRB Medical Center	Reliance	IRB Authorization Agreement v20200821	Related Studies	2/2/2021	2/12/2021	Not Uploaded
Single IRB Site - SMART 1	Reliance	SIRB1 IAA	-	2/1/2021	2/3/2021	Not Uploaded
Single IRB Site - SMART 1	Study-Specific Reliance	Study-specific IAA for Study 939203	-	1/6/2021	2/2/2021	NonTIN-NonVUMCStudies_ForQA_20210204.xlsx
Single IRB Site - SMART 2	Reliance	SIRB2 IRB Authorization Agreement	-	2/3/2021		Agreement Template
Single IRB University	Reliance	IRB Authorization Agreement v2020	Related Studies			Not Uploaded
Stanford University	Reliance	Broad IAA Stanford	Related Studies	7/1/2020	3/11/2021	Not Uploaded
University of Cincinnati	Reliance	Cincy Broad agreement	-	2/15/2021		Agreement Template

Relying HRPP Agreement Requirements



DEMO

IRB Reliance

YOUR SYSTEM STATUS

Mellon Univ. Med Ctr
GETTING STARTED

■ Using IREx as the Participating Site HRPP

■ Introducing Combo Sites

✓ Register

✓ Verify Study Team Access

➔ Complete Agreements

➔ Confirm Institutional Profile

Required Agreements

Reliance Agreements

- Your site has signed the **SMART IRB Agreement**

✓

Indemnification

- Your institution must sign University of Houston's "**Terms of Indemnification for use with SMART IRB - University of Houston**" before you can indicate reliance.
- Please send your executed indemnification and/or questions to [Liaison Houston \(liaison@houston.cdu\)](mailto:liaison@houston.cdu), unless otherwise indicated.
- Your indemnification status will be updated by the sIRB once received.

✗

Required Agreements

Reliance Agreements

- Your institution must sign the [SMART IRB Agreement](#) before you can indicate reliance.
- Please contact [Vanderbilt Liaison \(liaison@vanderbilt.edu\)](mailto:liaison@vanderbilt.edu) if you have any questions about the reliance agreement requirements.
- Your status will be updated for you when your site joins SMART IRB.

✗

Indemnification

- Your site has signed the **VUMC LOI**

✓

PSite Dialog Now Distinguishes whether Site is in IREx



If a site has not signed the IREx Terms of Use, help text explains what should happen next

Participating Sites

[How to add participating sites](#)

Add A Site

Site Name:

Union County Methodist Hospital

This site does not have an account in IREx
Please let this site know that a human research protections administrator or IRB director/manager needs to [initiate access for their site here](#).

FWA # [Look in the OHRP FWA Database here.](#)

Add site that doesn't yet exist in IREx - FWA required

[Cancel](#) [Request site be added to IREx](#)

Institution	PI (Required)	Coordinator
Anderson Medical Center #546879213	Add PI	Add Coordinator Edit Delete
Duke University Health Systems, Inc. #0009025		Add Coordinator Edit Delete
Relying Site 3 (NS) #31341424234		Add Coordinator Edit Delete
St. Jude Children's #00004985		Add Coordinator Edit Delete
University of Benhoff		
Vanderbilt University #00024139	to dd todd@pi.ccc	

This site exists in IREx, but hasn't signed the IREx Terms of Use yet

Let this site know their HRPP/IRB needs to initiate IREx access for their site here: <https://redcap.link/JoinIREx>


IREx will create account for site and will notify when you can add site contacts.

After adding a new site to IREx, they appear like this until the IREx Admins create the site


New Continuing Review Notification



EFFORT -- Time to upload Continuing Review to IREx



Serdoz, Emily Sheffer

To  Serdoz, Emily Sheffer

General

Reply

Reply All

Forward

...

Fri 3/19/2021 9:31 AM

Dear Liaison and Study Manager,

The expiration date listed in IREx for the study below is: Jun 16, 2021.

If a new approval has been issued, site liaisons and study managers can upload the new approval in IREx to keep the study up to date.

Title	The Effect of Higher Protein Dosing in Critically Ill Patients: A Multicenter Registry-based Randomized Trial The EFFORT Trial
Link	https://www.irbexchange.org/study/index/?proj=51

Need Help?

Use this [Continuing Review Quick Guide](#) to walk you through the steps to upload approval.

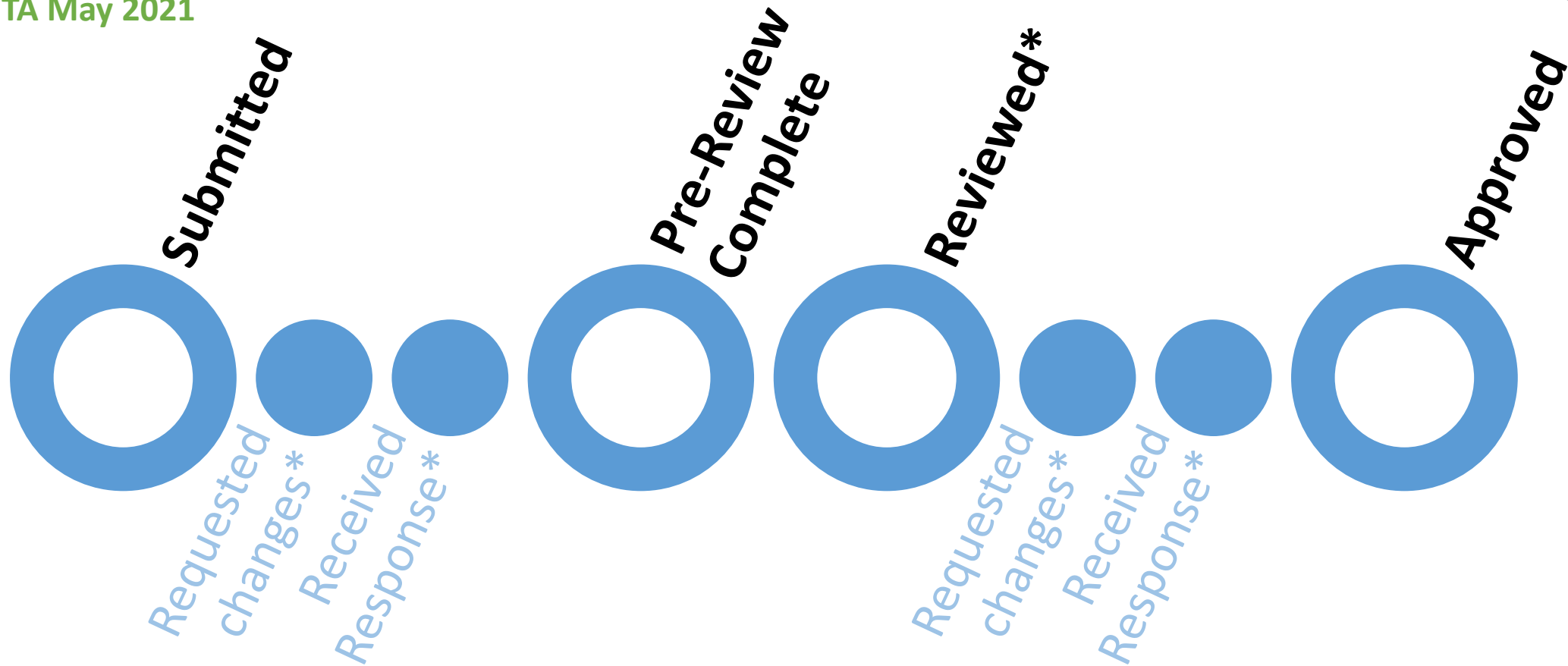
*Thank you for using IREx,
The IREx Team*

Looking Forward –
What's on Deck for IREx!

Capture & Export Additional sIRB Metrics in IREx



ETA May 2021



* = Can have multiple iterations
Bold = Required

Additional Development Priorities for 2021



Summer 2021: Allowing sIRBs to document site and study closures



Fall 2021: Reorganize how approvals are stored and accessed by study teams



Winter 2021: API Phase V – Pushing any type of approval to IREx (not just Initial approvals for lead + Psites)

Additional Priorities: (1) Capturing PSite information at Continuing Review; (2) Improving how Study Managers upload approvals; (3) Customizing Local Considerations

New Training Offerings!

Basic Trainings moving to YouTube

- Reviewing IRB Liaison
- Relying HRPP Liaison
- Study Manager

Potential Trainings (POLL!)

- Uploading Approvals in IREx
- How to use IREx Resources
- How to work IREx into your workflow
- Responsibilities of the sIRB vs. Lead Study Team in IREx
- Managing Combo Sites (one PI at multiple locations)
- Multi-site Liaison training

Spotlight Use Cases

+

•

○

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](#)

Next Call

- July 16, 2021