IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR HRPPS

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

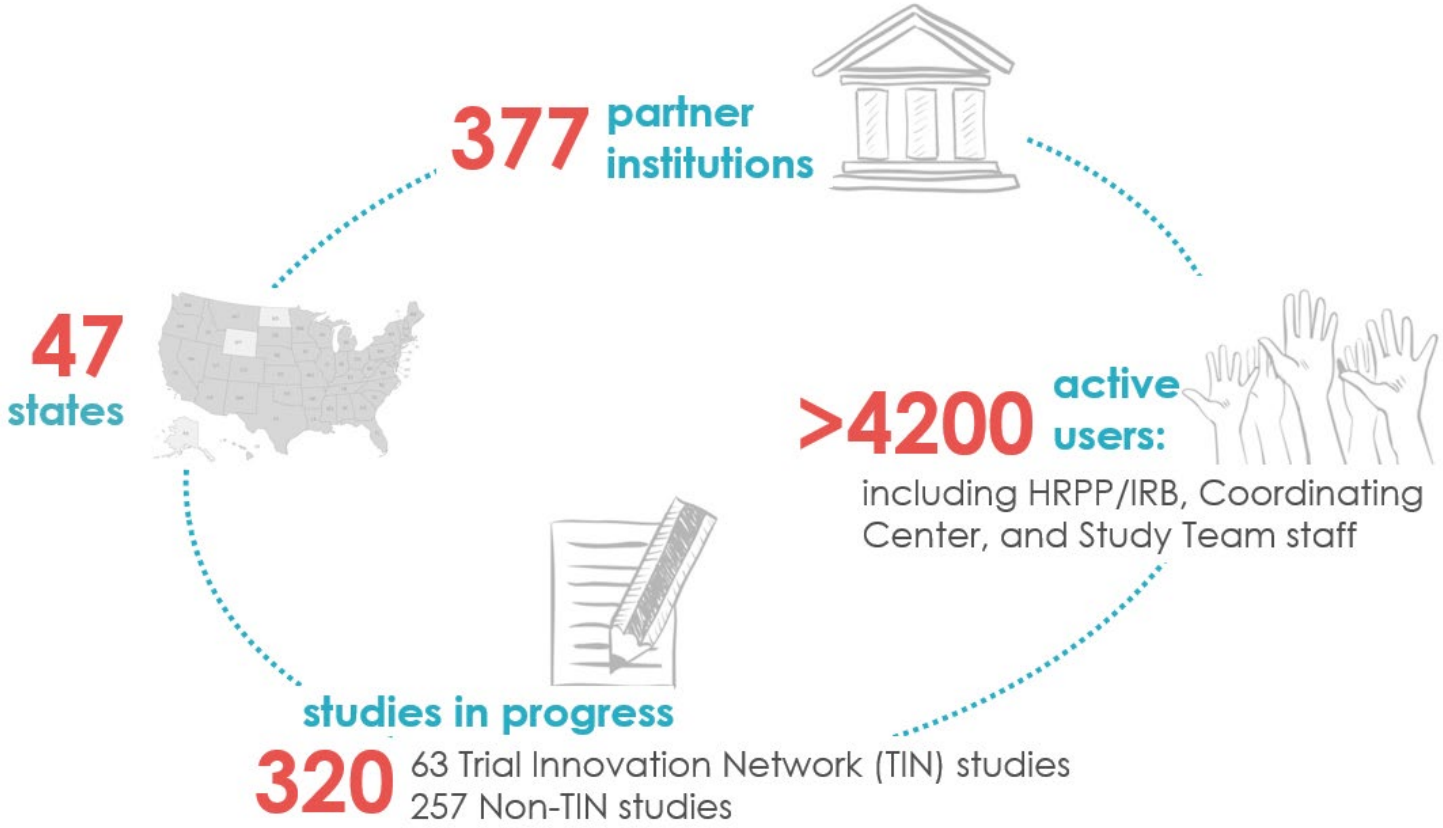
Linda Tan

- 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 uplaod	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

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processes

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).

Contact us to learn more!

Combo Sites

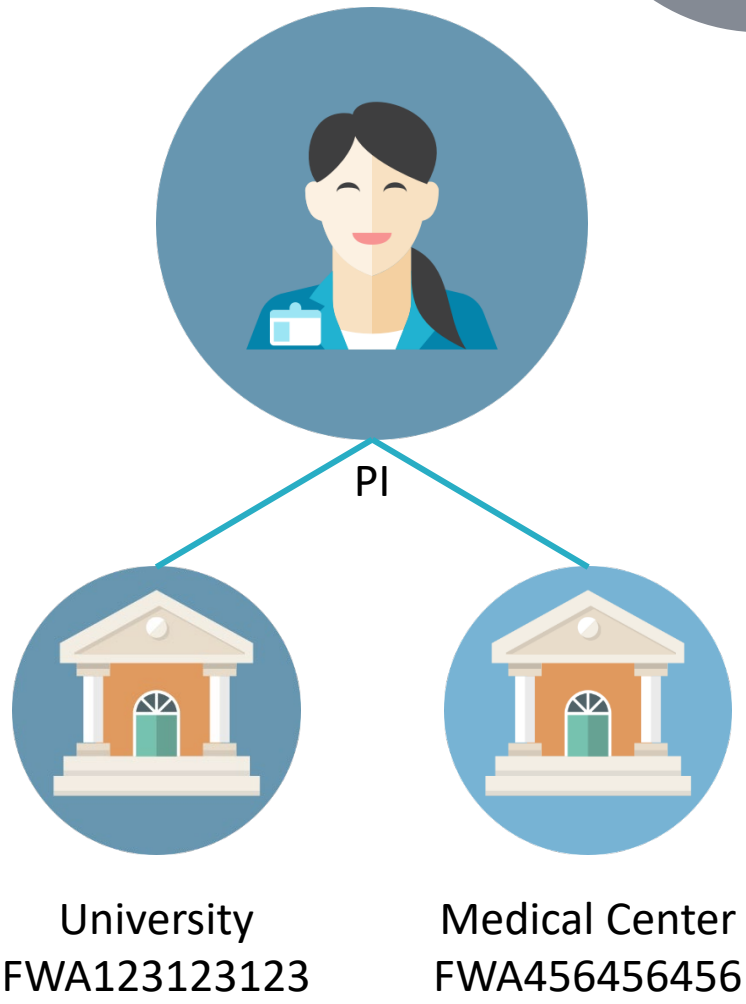
A **Combo Site** occurs when **one investigator or study team** engages **multiple FWAs** for a study

Released April 2020

36 studies with combo sites

54 combo sites created

28 recurring combo site pairings



Combo Sites

Lessons Learned:

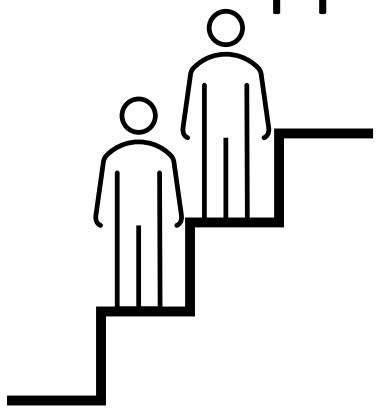
1. Reliance on an external IRB creates challenging workflows for AMC IRBs and local hospitals/research centers with long standing relationships between.
2. Who should create the combo?
    1. sIRB/Study Manager during study setup
    2. **Participating sites when they register (recommended)**

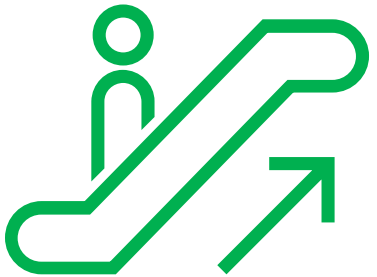
...ity
FWA123123123

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.



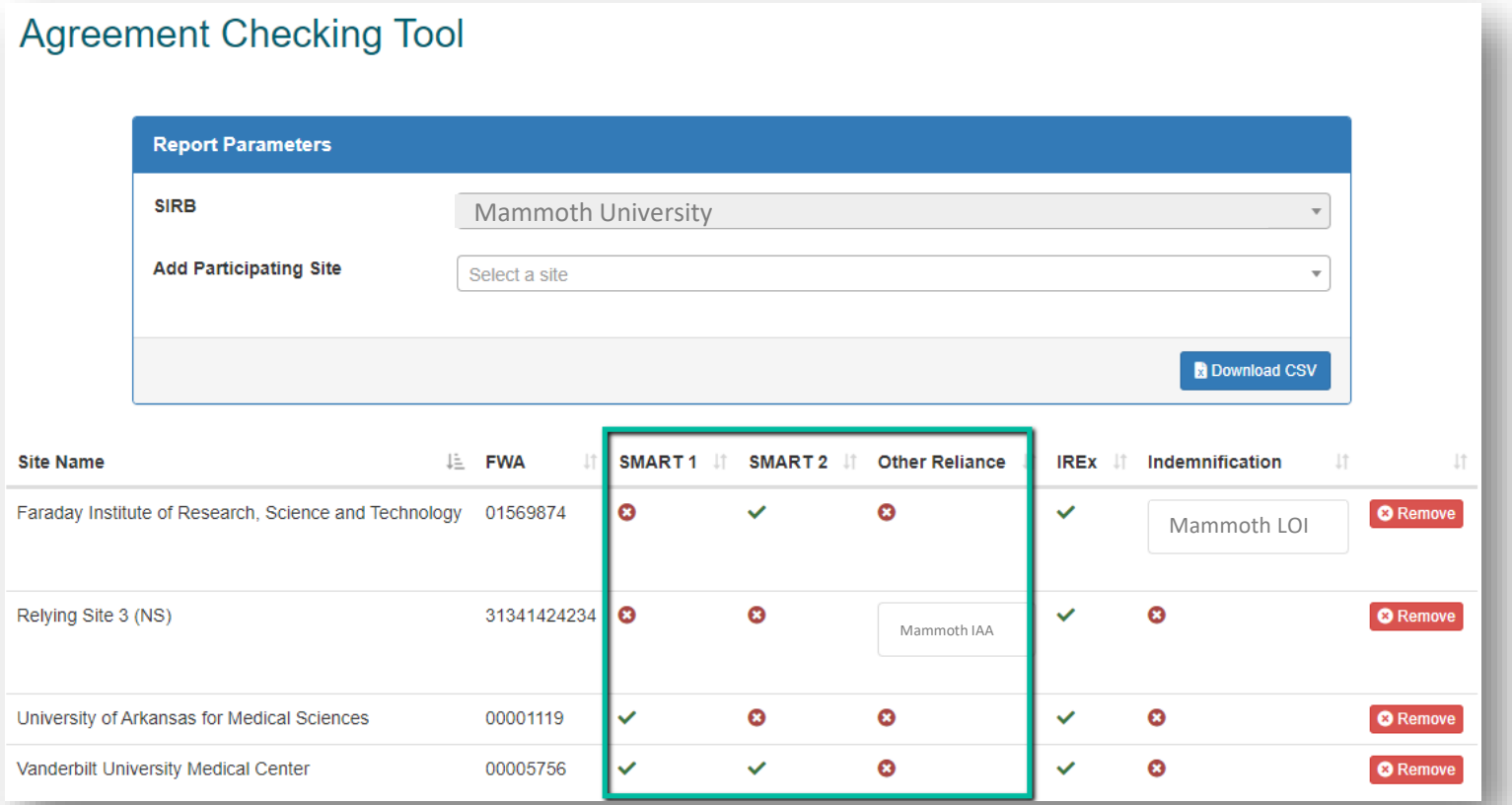


To save the sIRB time,

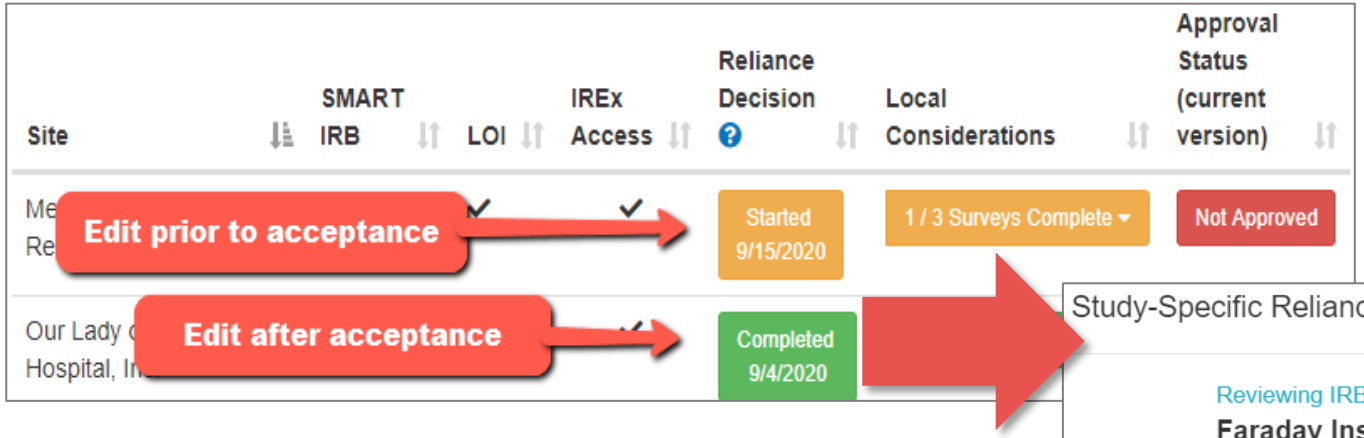
Study Managers can now upload the overall and site-specific approvals for continuing reviews and study-wide amendments.

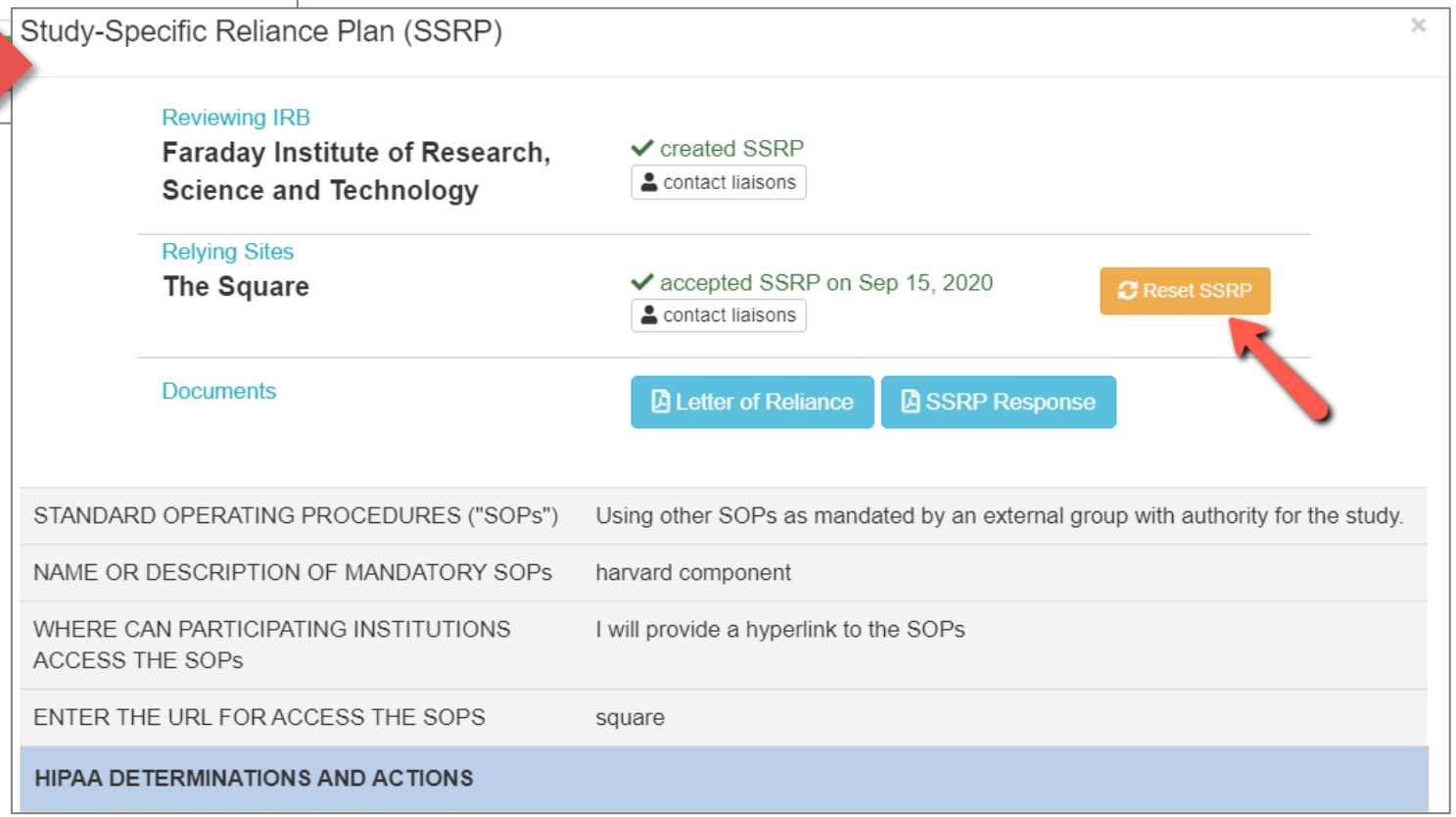
Agreement Checker

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



sIRB can Reset SSRP for Relying Site





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 req agreement: The Reviewing IRB and Relyin separate indemnification agreement or ag contractual arrangements for allocation o with respect to the identified study(ies): T indemnification agreement(s) will be mair 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

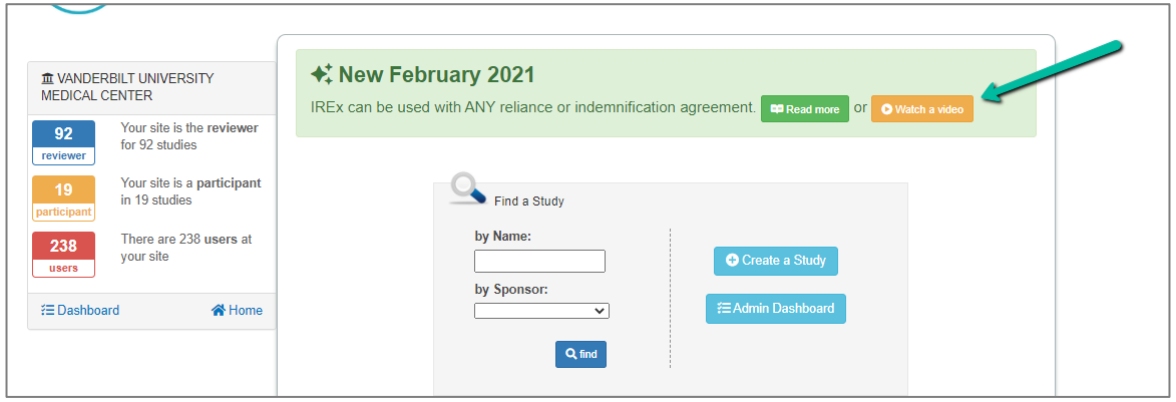
Looking Bright in 2021 –
New System Features

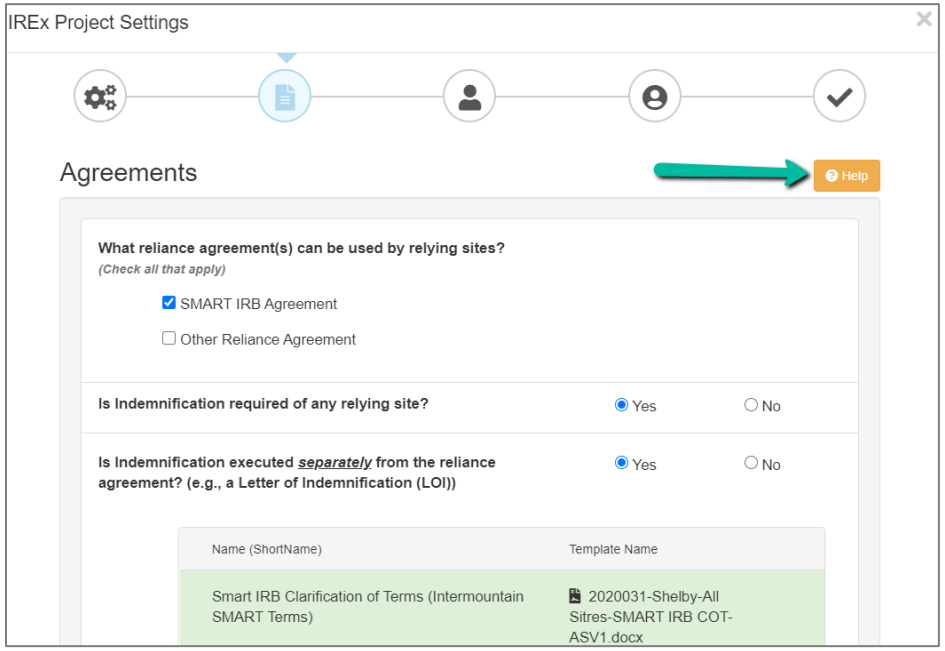
More Agreement Options in IREx

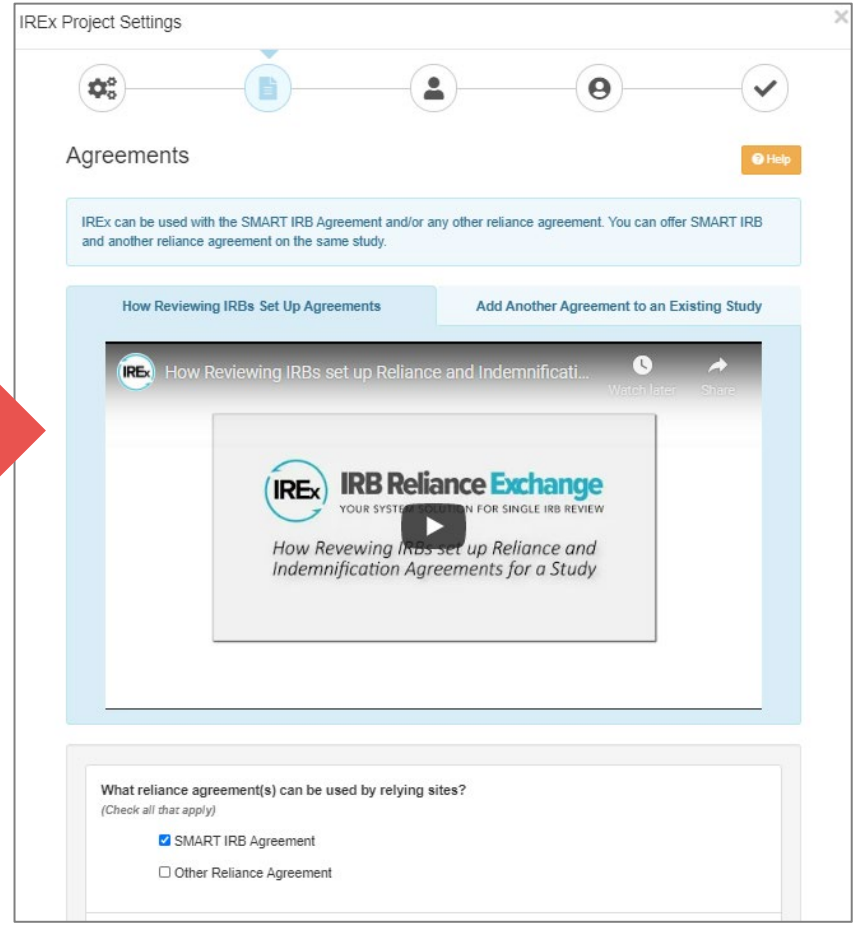
1. SMART IRB Versions 1 & 2
2. Other Reliance Agreements (IAAs, MOUs)
3. Indemnification Agreements (Broad & Study Specific)

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 <u>existing</u> IREx study.**
3. **Reliance and indemnification agreements can be study-specific or broad in scope.**

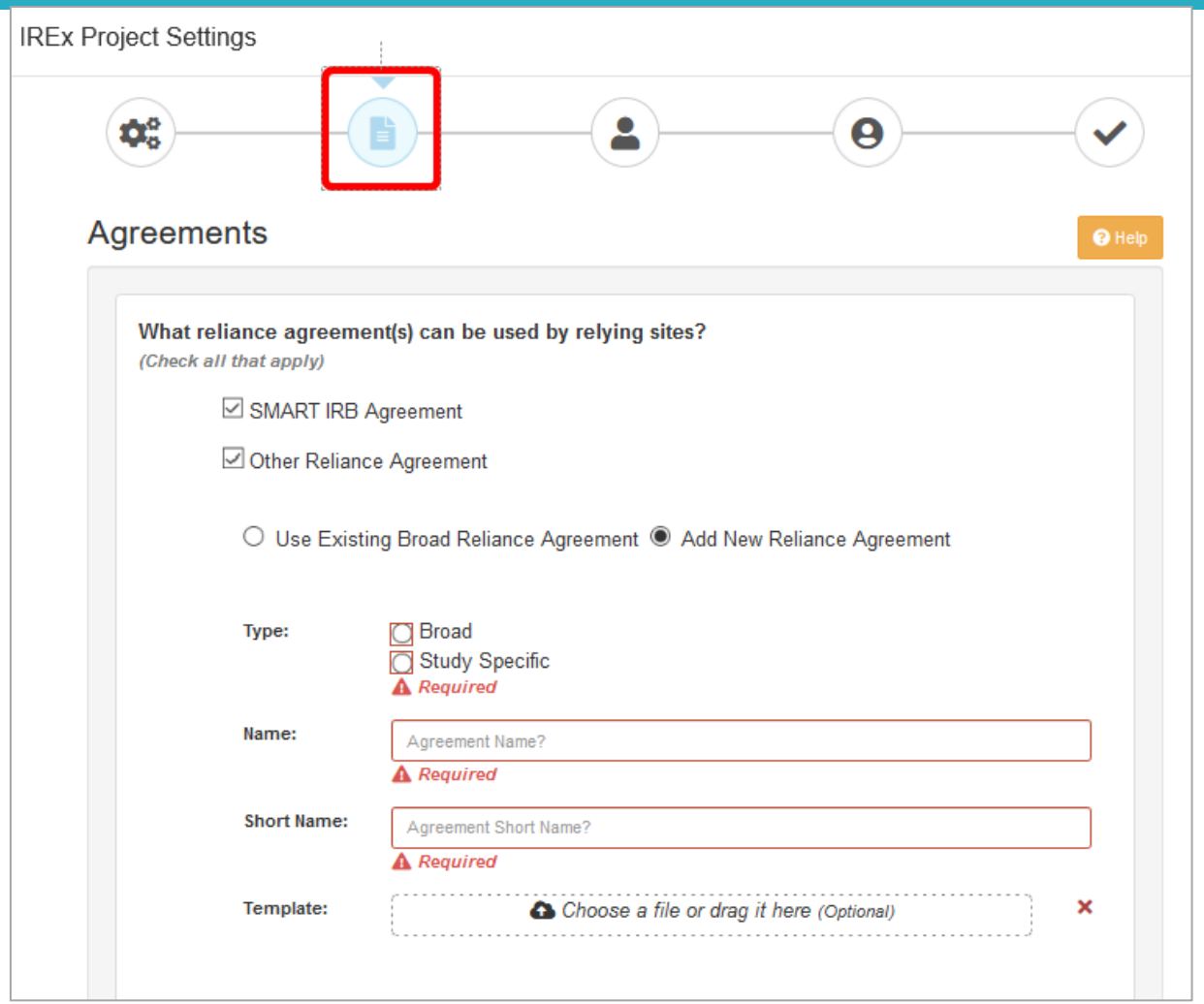
Agreement Resources

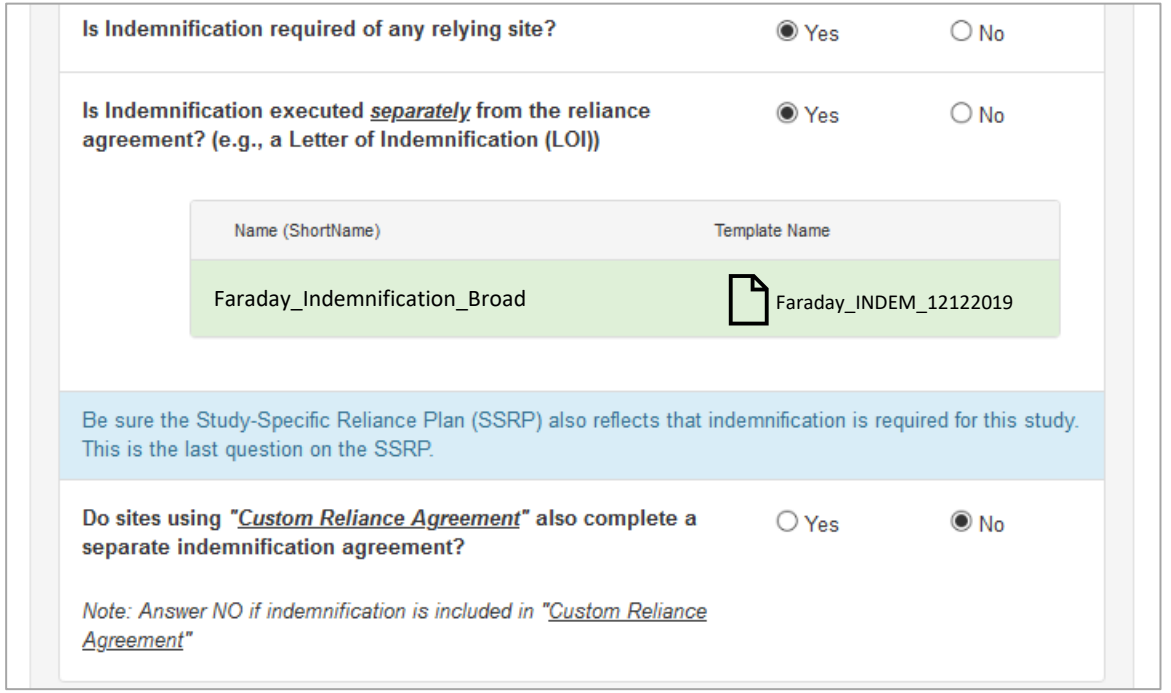




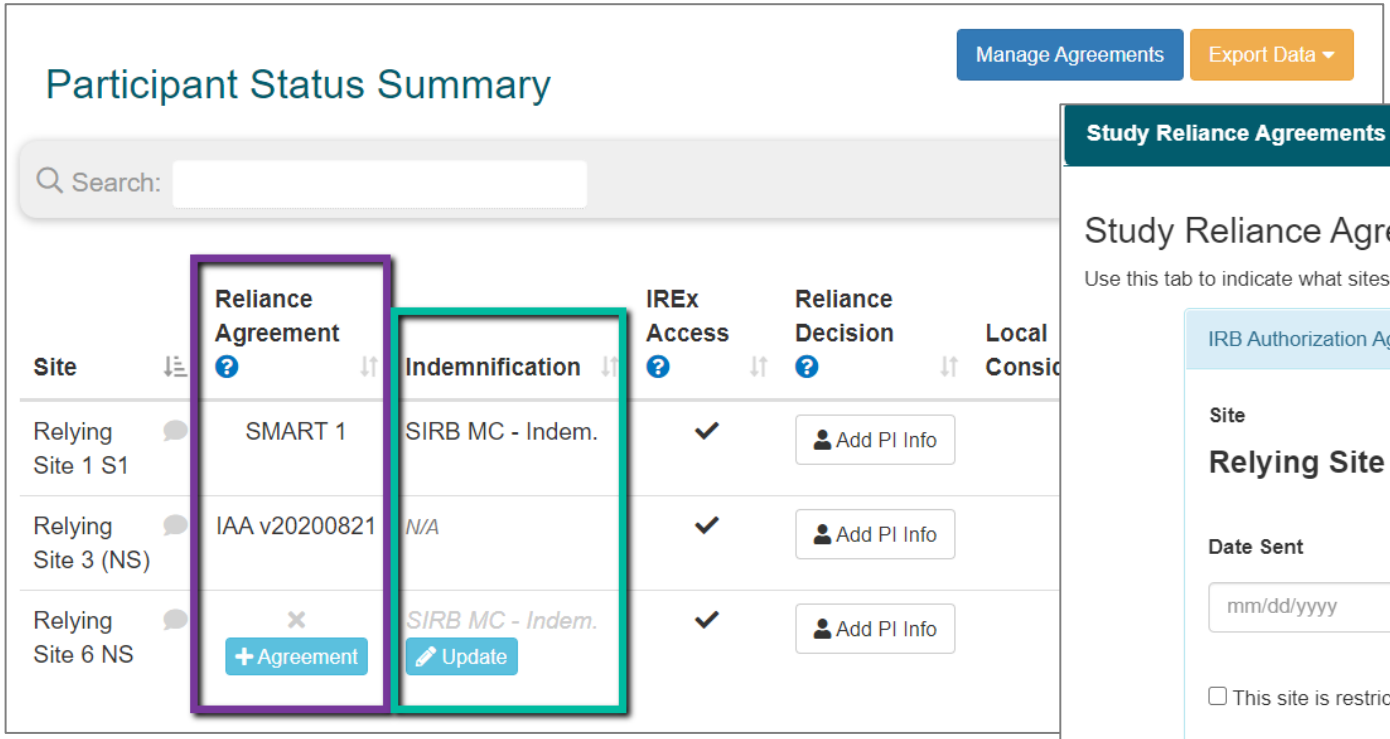


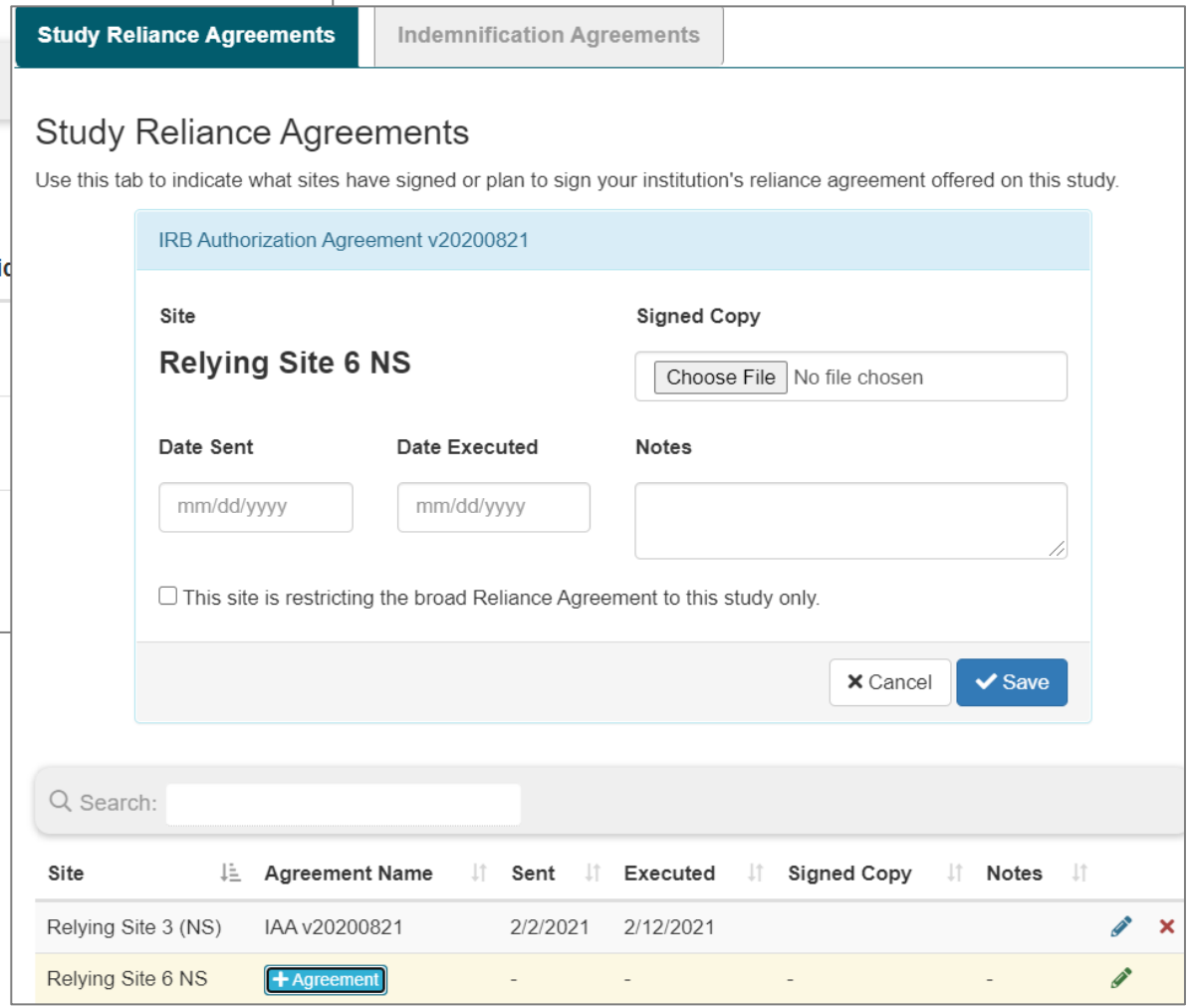
sIRBs List Agreement Options in IREx Setup





sIRBs
Track Agreement Completion





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

Using the Agreement Dashboard

Agreement & Indemnification Management:

Your Reliance Agreements | Your Indemnification | External Agreements

All Reliance Agreements

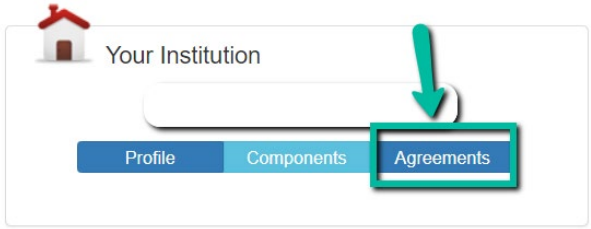
Download CSV

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



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All Indemnification Agreements

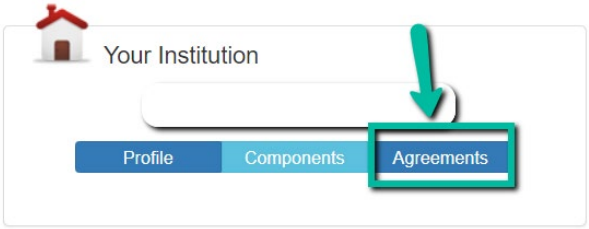
Download CSV

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

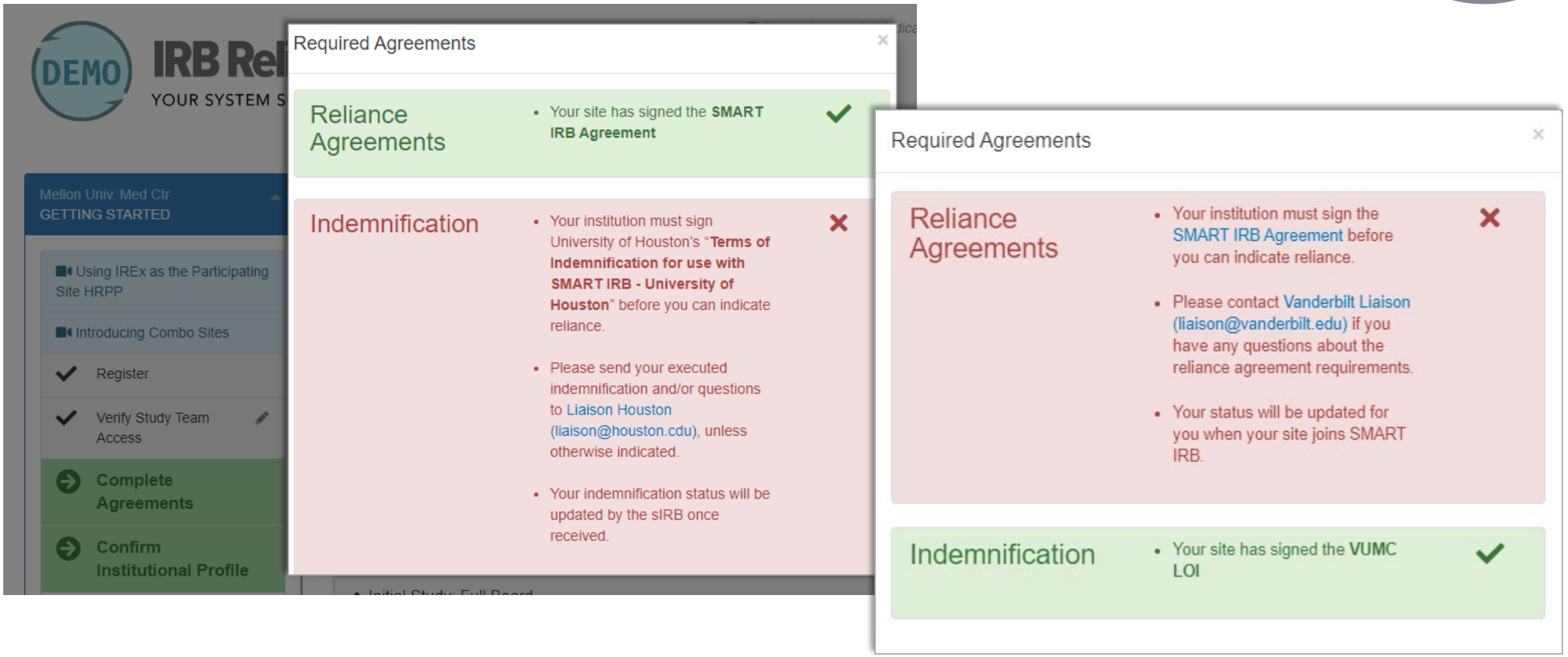


Agreement & Indemnification Management:

Your Reliance Agreements | Your Indemnification | External Agreements

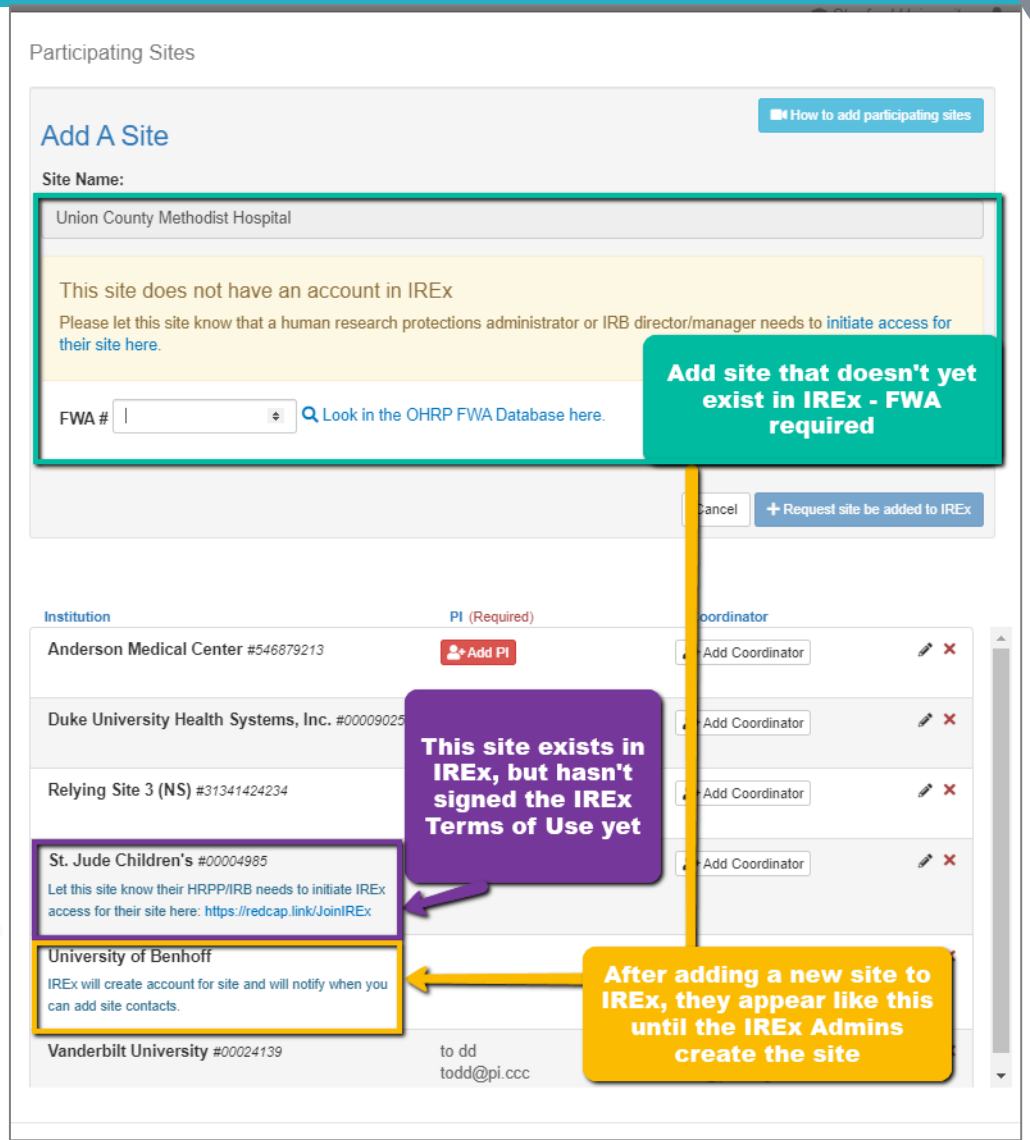
SIRB	Type	Agreement Name	Related Studies	Sent	Executed	Document
Loyola University Chicago	Reliance	LMC IRB Authorization Agreement	Related Studies	2/16/2021	2/19/2021	Not Uploaded
Single IRB Medical Center	Reliance	IRB Authorization Agreement v20200821	Related Studies	2/2/2021	2/12/2021	Not Uploaded
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



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



New Continuing Review Notification

EFFORT -- Time to upload Continuing Review to IREx

Serdoz, Emily Sheffer
To Serdoz, Emily Sheffer

Reply | Reply All | Forward | ...

Fri 3/19/2021 9:31 AM

General

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?

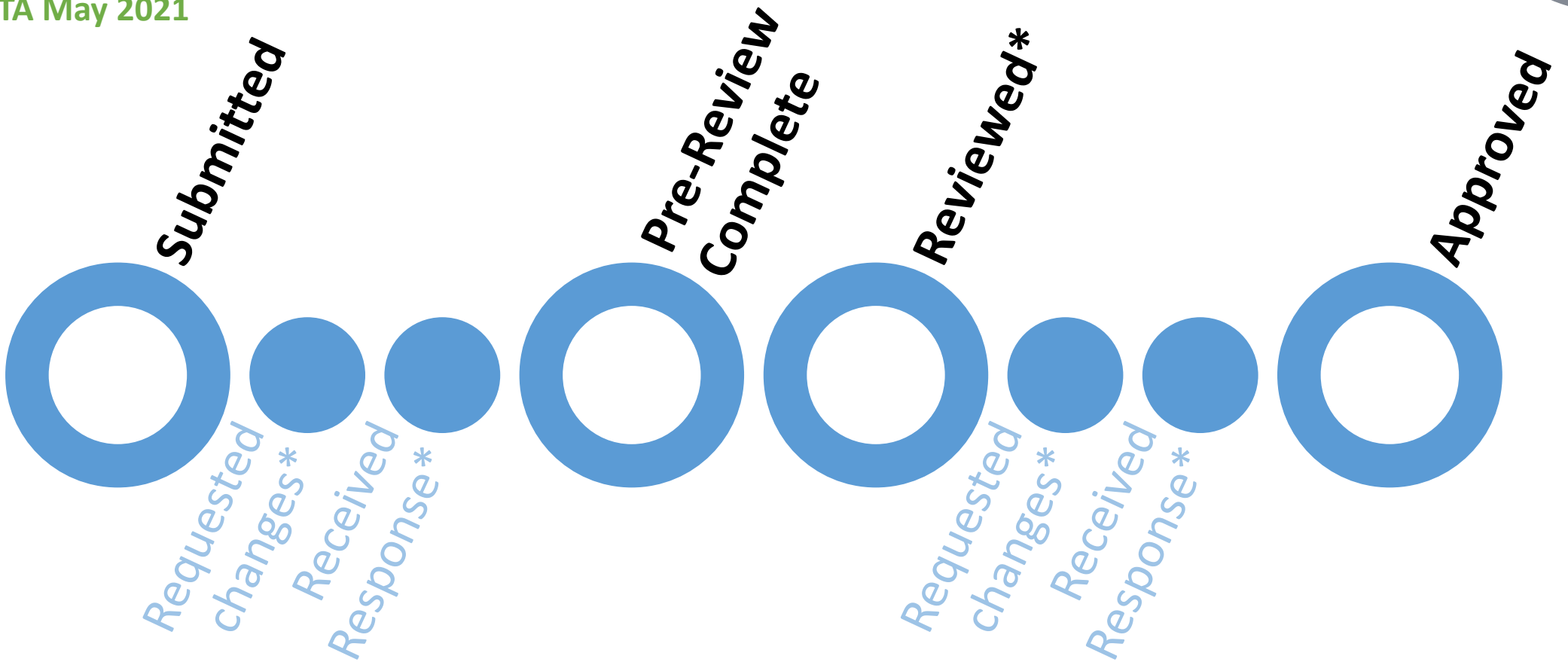
Use this Continuing Review Quick Guide to walk you through the steps to upload approval.

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