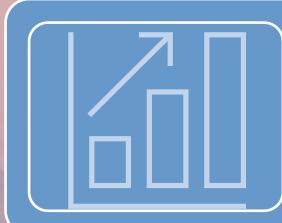
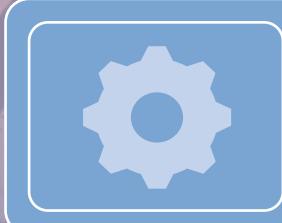
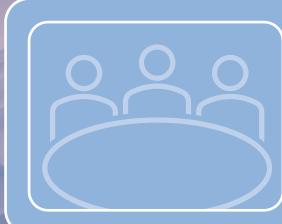
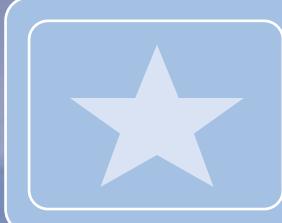


01.16.2026 QUARTERLY CALL AGENDA

-  Welcome & Announcements
-  2025 IREx Metrics
-  New IREx Features
-  Panel – IREx Relying HRPP Experts
-  Current Development

Welcome – About the IREx Quarterly Calls

hear • new • features



- You're busy.
- IREx is busy.
- Call in once a quarter to hear what's new!

learn • new • trends



- Who's using IREx?
- How are folks leveraging IREx on their sIRB studies?

share • your • voice



- Give your opinion
- Ask your questions
- Express your needs



2026 Quarterly Calls

April 17, 2026

July 17, 2026

October 16, 2026

Year-end Review: 2025 IREx Metrics



115 studies created



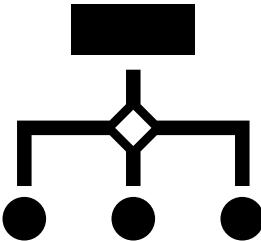
Consistent with past years!

682 new reliances



↑ 3% increase

10 average studies per relying site



*Steadily increasing:
2023 = 8 studies per site; 2021 = 5*

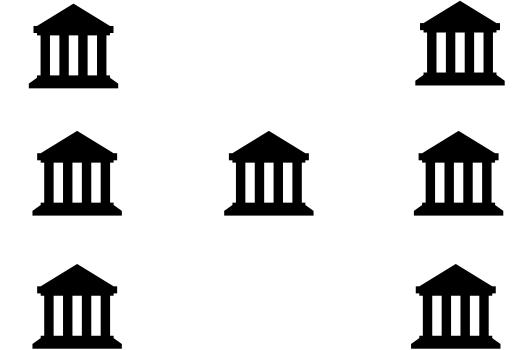
39 sites joined



↑ 22% increase



445 sites received initial approval



7 average sites per study in IREx

Consistent with past years!

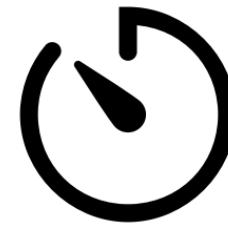
2152 users added



7 major system enhancements



13



median days from sIRB submission to approval for relying sites

Consistent with past years!

Single IRB Utilization of IREx

51 single IRBs are using IREx for over **800 studies**

- **211** Vanderbilt studies
- **148** UCSF studies
- **110** Utah studies
- **43** Wake Forest studies
- **24** Johns Hopkins studies
- **23** Nationwide Children's studies
- **17** Duke University studies
- **13** UT Southwestern studies

UCSF created the most studies in 2025

(n=44)

- **36 out of 51 sIRBs have more than one study in IREx**
- **New Institutions using IREx as the Single IRB in 2025**
 - ❖ **Cooper Health System**
 - ❖ **University of North Texas Health Sciences Center**
Forth Worth (North Texas Regional IRB)
 - ❖ **California Polytechnic State University**
 - ❖ **Loyola University New Orleans**

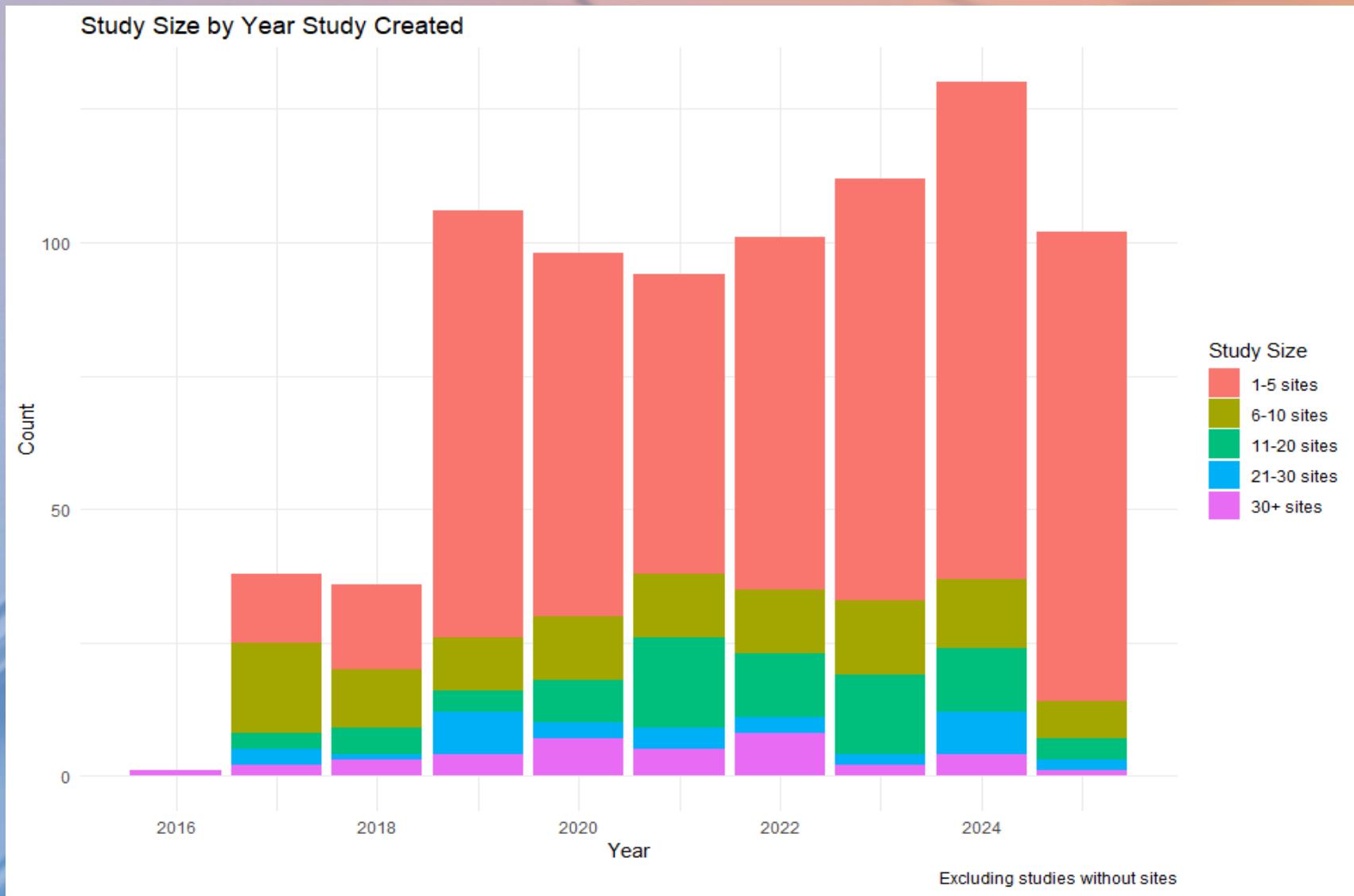
Top 10 Relying Sites in IREx



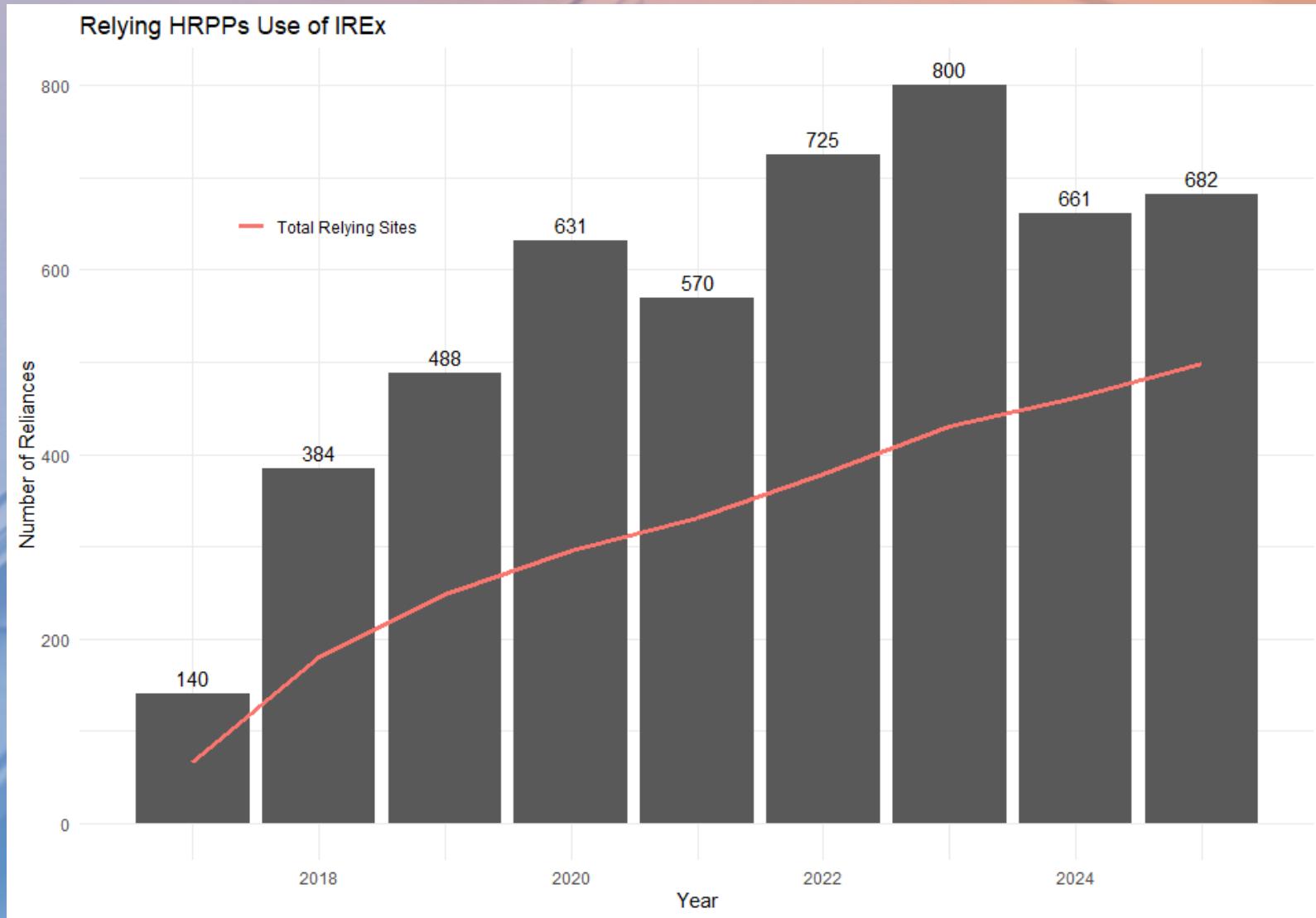
Site Name	# of Reliances
Children's Hospital of Philadelphia	93
Emory University	79
Duke University Health Systems, Inc.	78
University of Michigan	78
Washington University in St. Louis	78
Stanford University	76
University of Pittsburgh	76
University of Colorado, Denver Anschutz Medical Campus	73
Cincinnati Children's Hospital Medical Center	71
University of California, Los Angeles	68

Stay tuned to hear Tips & Tricks from CHOP, U of Michigan, and U of Pittsburgh

IREx is used for studies of all sizes



IREx continues to support hundreds of reliances per year, with new sites relying each year!



How have approval times in IREx changed?

Year Study Created	Site Contacted → Local Review Submitted	Local Submission → IREx LC Complete	IREx LC Complete → sIRB Submission	Relying site sIRB Submission → Approval	Total Days
2018	66	68	14	11	159
2024	45	36	17	15	113
	21	32	-3	-4	45

Median time to approval has decreased 45 days since 2018!



New IREx Features

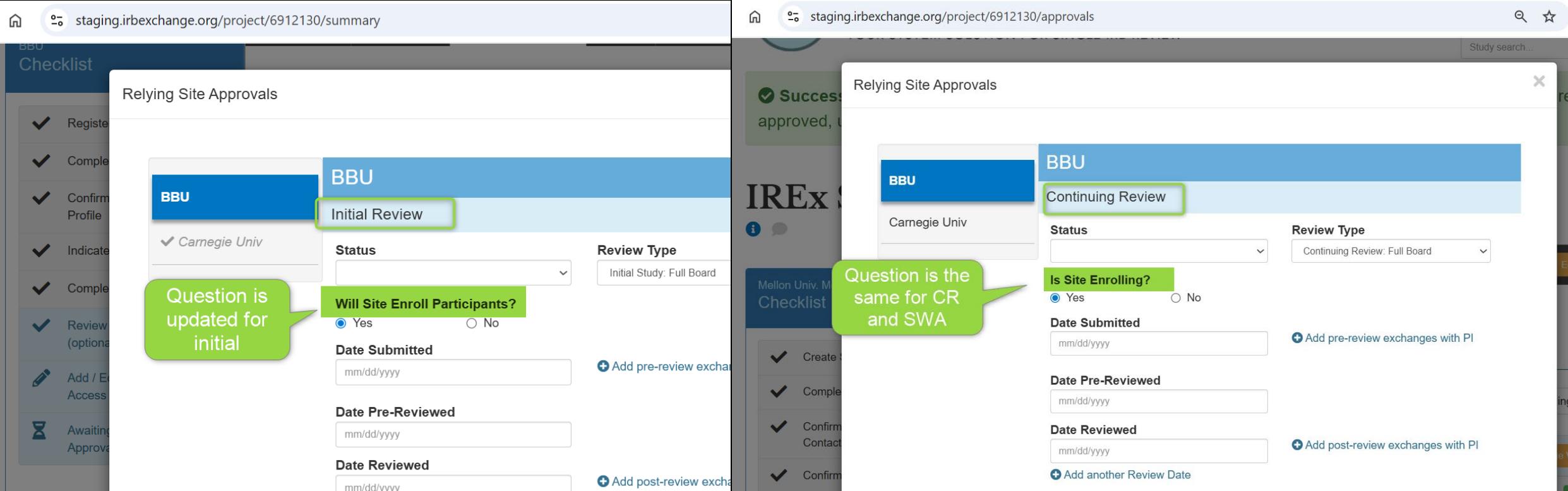
+

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◦

Clarified Field Re: Whether site is Enrolling for Initial Approval

Often Study Managers marked “No” with the initial approval because sites had not started enrollment.



staging.irbexchange.org/project/6912130/summary

BBU Checklist

Relying Site Approvals

BBU Initial Review

Carnegie Univ

Status: Initial Study: Full Board

Review Type: Initial Study: Full Board

Will Site Enroll Participants?

Yes No

Date Submitted: mm/dd/yyyy

Date Pre-Reviewed: mm/dd/yyyy

Date Reviewed: mm/dd/yyyy

Question is updated for initial

staging.irbexchange.org/project/6912130/approvals

BBU Continuing Review

Carnegie Univ

Status: Continuing Review: Full Board

Review Type: Continuing Review: Full Board

Is Site Enrolling?

Yes No

Date Submitted: mm/dd/yyyy

Add pre-review exchanges with PI

Date Pre-Reviewed: mm/dd/yyyy

Date Reviewed: mm/dd/yyyy

Add post-review exchanges with PI

Add another Review Date

Question is the same for CR and SWA

When site is not enrolling, a consent form is not required.

Study Sponsor Listed on First Emails for a Study

[TEST] SM Training - **IREx Access and Single IRB Instructions**

Lindsey Smith <donotreply@irbexchange.org>
To: Tan, Linda

Wed 11/19/2025 11:36 AM

If there are problems with how this message is displayed, click here to view it in a web browser.

Test Email

The real email would have gone to: To: [violet@blueberry.cdu](#); [hrpp@blueberry.cdu](#); [pi@blueberry.xx](#) | CC: [ka@mellon.cdu](#); [samantha@mellon.cdu](#) | BCC: [admin@irbexchange.org](#)

Dear HRPP(s) and Study Team,

This email contains instructions for completing the single IRB process for the study below.

PI Blueberry has been listed as an investigator at Blueberry University (FWA: 00043543). All study team members included on this email now have access to the study in IREx.

Study Title	IREx Study Manager Training Screenshots
Study Link	https://staging.irbexchange.org/project/6912130
Reviewing IRB	Mellon University Medical Center
Reviewing IRB Contact	Kate Austen (ka@mellon.cdu)
Study Manager	Samantha Mango
Sponsor	National Heart, Lung, and Blood Institute (NHLBI)

Action Required: Please Complete Agreement(s) for sIRB study

Dear HRPP(s) and Site Investigator,

This email contains instructions for executing the required agreements for the study below where **Patty Primary**, an investigator at **Anderson Medical Center (FWA: 54687921)**, has been listed on the following study in IREx.

Study Title	November Notifications_11/13/2025
Reviewing IRB	Mellon University Medical Center
Reviewing IRB Contact	Mellon Liaison (liaison@mellon.cdu)
Study Manager	Study Manager Mellon
Sponsor	Center for Information Technology (CIT), Clinical Center (CLC)

As a first step towards relying on Mellon University Medical Center, please execute the incomplete items below.

Agreement/Resource	Status
SMART IRB V3 Agreement: A national, master reliance agreement supporting single IRB review.	Completed
Mellon Special LOI	Incomplete — The indemnification agreement is attached. Send questions and executed agreements to Mellon Liaison (liaison@mellon.cdu).
IRB Reliance Exchange (IREx): A single IRB documentation and communication portal.	Completed

After your site has completed all the items above and the initial protocol has been approved by the Reviewing IRB, additional instructions will be sent regarding next steps.

Thank you,

Lindsey Smith
[linda.tan@vumc.org](#)

New Reviewing IRB Notification to Add Agreement

Subject: IREx: Action Required - Add Reliance Agreement

- WHAT:** A notification sent to Reviewing IRBs
- WHEN:** When a Study Manager adds a site to a study that only offered SMART V1/V2
- WHY:** So Reviewing IRB is prompted to login and offer another agreement (e.g., SMART V3) so the site can rely

[TEST] IREx: Action Required – Add Reliance Agreement

 admin@irbexchange.org
To: Tan, Linda

Wed 11/19/2025 11:54 AM

 If there are problems with how this message is displayed, click here to view it in a web browser.

Test Email

The real email would have gone to: To: liaison@mellon.cdu | CC: sm@mellon.xx; linda.tan@vumc.org | BCC: admin@irbexchange.org

Lindsey Smith has added the following sites to your study in IREx.

Action Required: The Reviewing IRB must log in to [IREx](#) and indicate another reliance agreement (e.g., SMART IRB V3.0) from the IREx Setup. This will allow the site to move forward and complete reliance since they can no longer rely using SMART IRB Agreement V1/V2 after March 17, 2025.

Study Title	Crema Coffee_20241121
Reviewing IRB	Mellon University Medical Center
Study Link	https://staging.irbexchange.org/project/9639568

Sites Added

Site Name	FWA	Reliance Agreement	IREx Access
Baystate Health, Inc	#00004355	No	Yes

*Thank you,
IREx Administrator*

This next one might need a standing ovation for our User Feedback Group...



Kevin Abner	Kelly Hitchner	Michelle Magee	Nicole Robson
Christi Banks	David Holmgren	Anna Martin	Kyle Rybczyk
Jennifer Beck	Melanie Howell	Don Mitchell	Maya Salberg
Anne Burke	Bahiyyah Jackson	Ariela Muzikansky	Molly Shiflet
Erin Coons	Veronica Jimenez	Brendan Paulman	Kiana Soriano
Lenore Crago	Erin Johnson	Jessica Phillips	Ryane Sorenson
Jennifer Ford	Aaron Jung	Kayley Pratt	Amy Trullinger
Nicole Guerrero	Patricia Kerby	Ashley Price	Shannon Watson
Kimberly Hawkins	Ariel Lewis	Lisa Rigtrup	Ashlea Wilkes
Kellie Hernandez	Lisa Lim	Michelle Robinson	Jacqueline Van Audenhove
Junie Hildenbrandt	Janelle Maddox-Regis		

Automating Local Considerations (Auto LC)

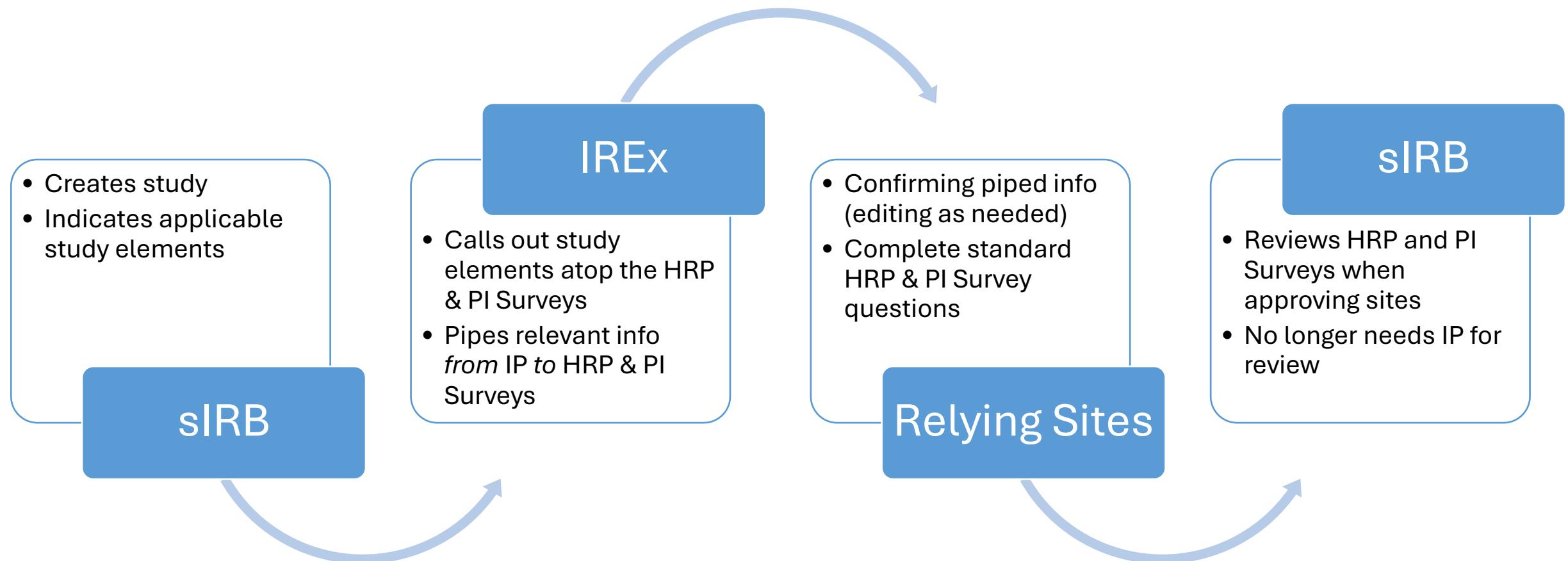


Developed with constant feedback from **September 2024 – December 2025!**

Goals:

- 1. Streamline Relying Site reporting of local considerations**
 - Leverage existing information in the Institutional Profile (IP)
 - Reduce redundant documentation/reporting of local considerations
- 2. Streamline the Reviewing IRB's review of sites**
 - Reduce documents for review
 - Minimize conflicting language in the IP and HRP Surveys

How Auto LC Works



Automating Local Considerations - Preliminary Observations & Lessons Learned

- **IREx** must support iterative documentation
 - Study Elements may change overtime, (e.g., with study-wide amendments)
 - Study Elements may not be marked when they should – so revisions must be allowed
- **sIRBs** will need to change behavior
 - Reviewing IRBs no longer need to review the IP because the relevant info is included in the HRP & PI Surveys
 - Re-training / orienting may be required for review team / committee
- **HRPP IP** accuracy will improve
 - Relying HRPPs may identify outdated information in their IP now that it is piped into the HRP Survey.
- **IREx** needs to incorporate additional flexibility
 - Not all sites enroll non-English speakers, for example, so sites need an "NA" option (*changes in progress*)
 - IREx needs to streamline the process of updating Study Elements (e.g., when they're accidentally missed and need to be updated)

Automating Local Considerations – Preliminary Results

	PRE – Automating LCs	POST – Automating LCs
Avg Time to PI Survey Complete (When Site Registered in IREx to When PI Completed / Attested to Survey)	22.5 Days	11.6 Days
Avg Time to HRP Survey Complete (When Site Registered in IREx to When HRP Completed / Attested to Survey)	28.1 Days	6.1 Days
Avg Time to Approval (When Lead Site Contacted Relying Site via IREx to Relying Site's Initial Approval)	113.8 Days	54.9 Days
Studies Included in Analysis	29	20
Total Relying Sites	111	31
Unique Relying Sites	79	25

Auto LC Usage - Relying Sites



Children's Hospital of Philadelphia (x3)	Massachusetts General Hospital	University of Utah – Moran Eye Center
Cincinnati Children's Hospital Medical Center	Medical University of South Carolina	University of California, Berkeley (x2)
Duke University Health Systems, Inc.	Northwestern University	University of California, Los Angeles
Emory University	Research Triangle Institute (x2)	University of California, San Diego
Florida International University	San Diego State University	University of Kansas Medical Center
Geisinger Clinic	Sentara Healthcare	University of Pennsylvania
Hunter College of the City University of New York	The Children's Mercy Hospital	University of Pittsburgh
Indiana University (x3)	Thomas Jefferson University	Washington University in St. Louis
KBR Government Solutions US, Space and Mission Solutions, Mission Support		

Updated Materials Related to Automating Local Considerations

PDFs Available on the IREx Website

- [How to Upload a Study-Wide Amendment](#)
- [IREx Benefits for Single IRBs](#)
- [Automating Local Consideration Overview](#)
- [Multi-Site Liaison HRPP Quick Guide](#)
- [Participating Site HRPP Quick Guide](#)
- [Reviewing IRB Quick Guide](#)

Videos Available on the IREx YouTube Channel

- [How to Create a New Study](#)
- [How to Upload a Study-Wide Amendment](#)



Panel: IREx Relying HRPP Experts

Panelists



Sarah Shade, MS, MPH, CIP
IRB Analyst III - Reliance
Specialist
Children's Hospital of
Philadelphia

*CHOP has ceded reliance >90
times in IREx.*



Nicole Robson, MHA
sIRB Team Lead and QA/QI
Specialist
University of Michigan

*UMich has ceded reliance **nearly
80 times** in IREx.*



Natalie Novak, BS, MSL
Reliance Specialist
University of Pittsburgh

*UPitt has ceded reliance **nearly 80
times** in IREx.*

University of Michigan's use of IREx

Used only when
relying upon an
external IRB.

- Our dashboard shows we have participated in 89 studies.

Why not for
Accepting
oversight?

- Our leaders wanted our teams to only worry about one system.
- Our IT group built a performance site app.

What
makes IREx
easy to
use?

Institutional profiles

Study-Specific Local Considerations

Study-Specific Reliance Plan

Combo Sites feature

This is used when one investigator engages multiple sites with unique Federal Wide Assurances for a given study.

This feature is newly useful to the University of Michigan

Why?

- University of Michigan has Network of Care sites
 - Multiple locations throughout the state where our physicians can provide care.
 - Each location has their own FWA

CHOP PROCESS

- Receive initial email from IREx
 - Forward the email to the CHOP Investigative team – the PI and the Study Coordinator
 - Include language about how to submit the study within our system, eIRB
 - Include a link to our website
 - Language differs for if the study has been started within eIRB and either has not been submitted (Pre-Submission) or if it has not yet been initiated
 - Allow for Investigative teams to come to single IRB / multicenter Office Hours or schedule calls with a member of the Reliance Team
 - Include an IRB Note to complete reliance in IREx once local context review is complete

PITFALLS

- Not providing a consent form with required site-specific language included
 - TIP: Provide our PDF of required language to our Investigators via email and available on our website and try to emphasize this within our initial email
- Not providing the determinations made by the Reviewing IRB if not included in the initial study approval letter
 - TIP: Revising our policies to include language about what we require for local submission; Instructing our Investigators to refer to the information within IREx since all documents and determinations should be included by the main site; start-up calls/Office Hours/trainings

HELPFUL FEATURES

- Appreciate having SMART IRB loaded in and it makes signing the agreement quicker!
- The local considerations/local context form being in one spot is great so we don't need to complete one for each individual site
 - Previously our teams did not provide this document and delayed overall site approval



+ . Current &
◦ Upcoming Feature
Development

Upcoming IREx Features



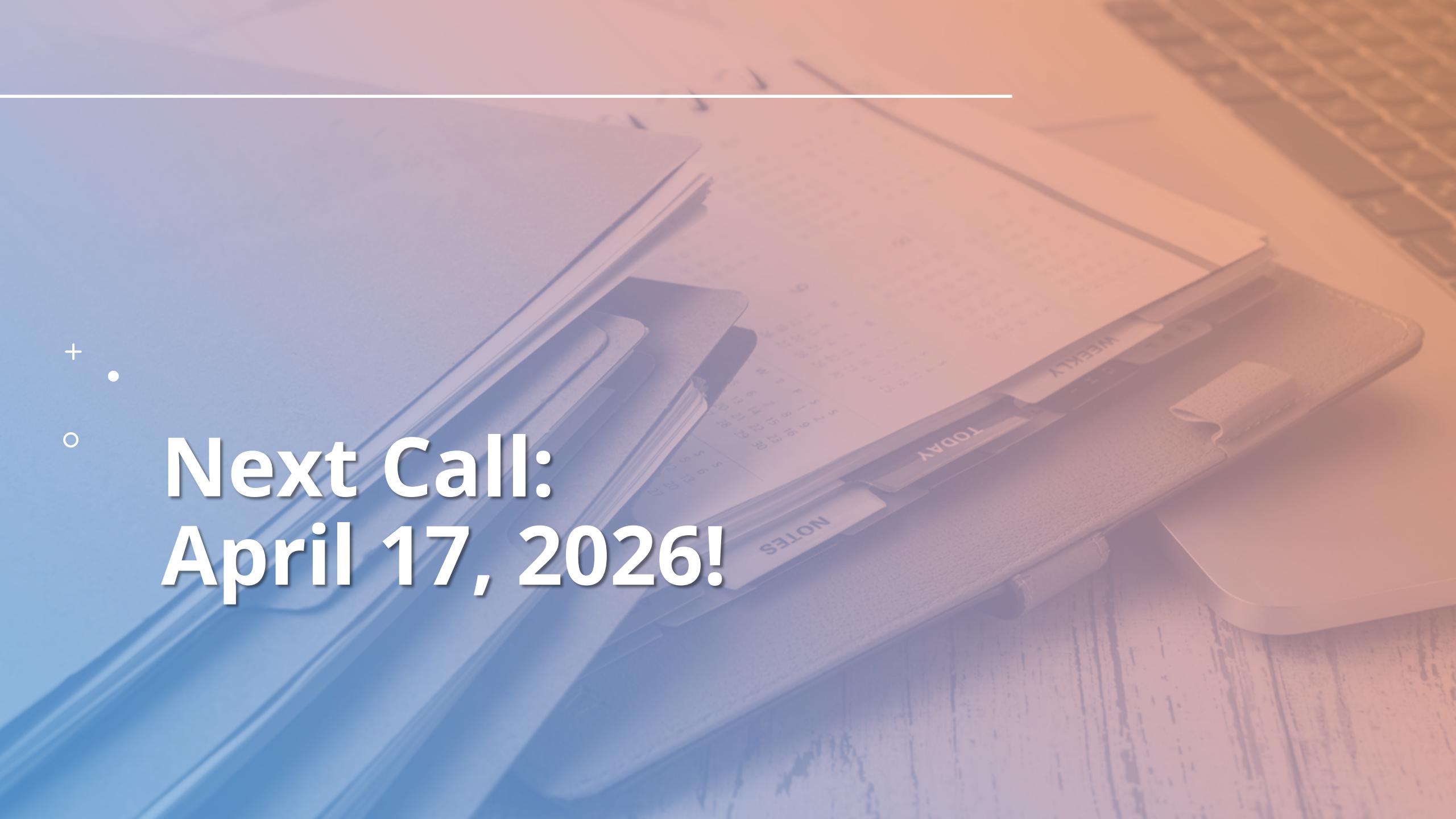
SMART IRB Indemnification Addendum tracking

Improve usability with a user specific dashboard

Improve approval document organization/history

How can IREx better support you? Chat or email us your ideas or feature suggestions!





Next Call:
April 17, 2026!