



IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

IREx Quarterly Call

- Study Support
- User Training

Amna Baig



- Resources & Materials Development

Katelyn Benhoff



- Study Support
- System Evaluation

Tiffany Chen



- Study support
- User Training

David Crenshaw



- Materials Development
- Study Support

LaShondra Deyampert



- Development Support
- Website

Kaysi Quarles



- Manager, Application Development

Joshua Milford



- System Direction & Evaluation

Emily Serdoz



- System Development

Linda Tan



- Application Developer

Jason Tan



- Application Developer

Evan Wimberly



+

○

10.18.2024 QUARTERLY CALL AGENDA



Welcome &
Announcements



System Enhancements
/ Features



IREx Metrics



Upcoming Feature

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

Next Quarterly Calls



January 17, 2025

(new Zoom information will be sent)

April 18, 2025



- +
-
-

Announcements

Stop by to see Tiffany at PRIM&R!



Single IRB Stakeholder Feedback: Evaluating the Use of the IRB Reliance Exchange

Sunday, November 17	Monday, November 18	Tuesday, November 19
4:15-6:00 PM PT PRIMR24 Workshops Networking Reception	12:30 PM-1:30 PM PT Open time on the agenda	12:30 PM-1:30 PM PT Open time on the agenda
	4:45-6:00 PM PT PRIMR24 Welcome Reception	



Single IRB Stakeholder Feedback: Evaluating the Use of the IRB Reliance Exchange

Tiffany Chen¹, MPH; Emily Serdoz¹, MPA; Natalie Dilts¹, MPH; Carrie Smith², BS; Katelyn Benhoff¹, MA

¹Vanderbilt University Medical Center, ²Wake Forest University Health Sciences

Sign up for the IREx newsletter!

BACKGROUND

In 2018, the NIH Single IRB (sIRB) Policy went into effect, requiring NIH-funded multi-site research to utilize a single IRB of record. The Institutional Review Board (IRB) Reliance Exchange (IREx) is a freely available, NIH-supported web-based platform supporting sIRBs, lead study teams (LST), and relying sites (HRPPs and study teams) through the complex sIRB process for the life of the study.

- Over 40 different sIRBs using IREx
- Over 650 studies
- 500+ sites
- 3700+ reliance decisions
- 29,000+ site approvals documented

RESULTS

- 48 total respondents:** sIRB (n=6 completed/15 sent), lead study teams (n=20/40), and relying HRPP users (n=22/55)
- All sIRB respondents would recommend using IREx to coordinate sIRB studies
- Majority of sIRB respondents said **using IREx takes less time** than studies where IREx is not used
- 85% of LST respondents were **satisfied/very satisfied** with using IREx for their studies, reported that IREx made their LST duties easier, and would recommend other LSTs use IREx
- 90% of relying site HRPP respondents found using **IREx made their steps as a relying site easier**
- 5 different feature suggestions have already been addressed and implemented in IREx, demonstrating the program's flexibility and commitment to continually improving the user experience

DISCUSSION

- IREx users are **highly satisfied** with their experience
- Utilization continues to grow** annually, both in the number of new sIRBs that use IREx for the first time and number of studies created in the platform each year
- 5/9** feature suggestions from open text fields have already been addressed and others are being worked on
- IREx team is working on incorporating user satisfaction into normal IREx workflow as well as **further quantitative evaluation**

METHODS

Users were asked to complete satisfaction surveys in Q2 of 2023

WHO to survey

- sIRB:** Primary Contact listed on the study
- Relying HRPP:** Relying HRPP contact who signed the HRP Survey
- LST/Study Manager (SM):** most active member-based a) email interactions or b) the person listed most frequently in the log

We did not contact potential respondents >2 times, even if they were eligible

WHEN to survey IREx users

- sIRBs: after lead site approval posted to IREx
- LST/SMs: after ~25% of their participating sites received initial approval
- Relying HRPPs: after receiving initial approval on a study

How easy are tasks for Lead Study Teams?

Task	Easy/very easy	Neither easy or difficult	Difficult/very difficult
Track site progress in IREx	16	2	2
Notify Sites of the study	14	2	2
Add/remove sites from the study	12	2	2
Upload site approvals	12	2	2
Know when to export sites for single IRB review	12	2	2
Use the Getting Started Checklist to complete my steps	10	2	2
Upload the initial approval for the LEAD SITE	10	2	2

"We suggest to study teams to use IREx if they have 4 or more sites for their study to alleviate the email back and forth to document reliance and provide study teams with one location to easily see all of the site information."

"We have had a few of our larger study teams and consortiums begin to use IREx within the last year. They have indicated that they can't imagine having to do the reliance process any more through email like they had in the past. One consortium has multiple studies that have a minimum of 10 sites for each study." --sIRB user

LIMITATIONS

- Small sample size for these surveys, especially for sIRB users
- Did not survey relying site study teams, as we worried they would be unable to distinguish between their frustration with the sIRB process and IREx

IREx
IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

The Trial Innovation Network is supported by the National Center for Advancing Translational Sciences, National Institutes of Health, under award numbers U24TR004437, U24TR004440, and U24TR004432.

New / Revised IREx Materials



NEW VIDEOS FOR ALL USERS:

- [IREx: Introducing Single IRB Review & Supporting Resources](#)
- [Using IREx to Support Single IRB Review Process](#)
- [IREx Support for Studies Meeting the Exception from Informed Consent \(EFIC\) Requirement](#)

FOR STUDY MANAGERS

- [IREx Study Manager Step-by-Step Guide](#)
- [Relying Site Study Team Quick Guide](#) (give to your study teams!)
- [How to Upload the Initial Approval for Relying Site\(s\) in IREx](#)

FOR REVIEWING/SINGLE IRBS

- [Using IREx as the Reviewing/Single IRB](#)

FOR ALL HRPPs: [Institutional Profile Quick Guide](#)

IRB Reliance Exchange 'IREx'
@IRBRelianceExchange · 47 subscribers · 32 videos
IRB Reliance Exchange (IREx) is a freely available, web-based portal supporting single IRB review. [more](#)
[irbexchange.org](#)
Customize channel Manage videos

Home Videos Community

IREx: Introducing Single IRB Review & Supporting Resources
127 views · 3 weeks ago

INTRODUCING SINGLE IRB REVIEW & SUPPORTING RESOURCES

0:00 / 2:27

Videos

- Using IREx to Support Single IRB Review Process (2:18)
- Introducing Single IRB Review & Supporting Resources (2:28)
- IREx Support for Studies Meeting the Exception from Informed Consent (EFIC) Requirement (6:56)
- Capturing Local Considerations in IREx for the Life of the Study (4:00)
- How to Add and Edit Relying Sites in an IREx Study (3:41)
- IREx QuickVids: How to Upload a Site Amendment... (1:51)

RESOURCES

We have resources for each role within IREx. Click the link to access each resource page:

- Reviewing IRB Resources
- Participating Site HRPP Resources
- Study Manager Resources
- Study Team Resources

+
•
○

What's New?

- *Updated Institutional Profile & PI Survey*
- *Export Institutional Profile CSV*
- *Supporting EFIC Studies*

New in IP: Include your site's instructions for relying on an sIRB!

Section 3: LOCAL INSTITUTIONAL REQUIREMENTS FOR INVESTIGATORS WHEN RELYING ON ANOTHER IRB.

This information will be communicated to your local investigator each time you are the Relying Site to facilitate compliance with your local policies and procedures.

These steps occur BEFORE the study is approved by the Reviewing IRB:

Do you have local instructions for investigators when relying on another IRB? Yes No

* must provide value

reset

Local instructions for investigators when relying on another IRB

* must provide value

 [Upload file](#)

Do you have additional files to upload? Select up to 5.

Updated PI Survey

SITE SPECIFIC PLANS FOR RECRUITMENT, CONSENTING, AND DATA AND SAFETY MONITORING

What activities does your site participate in?
** must provide value*

- Recruiting
- Consenting
- Data and Safety Monitoring
- Study procedures per the protocol including interventions, surveys, focus groups, follow-up data collection
- Review or analysis of identifiable data
- Direct recipient of funding
- None of the above

RECRUITMENT PLAN: Are there any differences to the initial contact and/or recruitment plan at your site from that described in the protocol or associated documents based on local requirements or state law?
** must provide value*

- No differences at my site
- My site will recruit differently

reset

1. Better document what activities are happening at each site
2. Continue to capture whether the site has differences from the protocol

SITE SPECIFIC PLANS FOR RECRUITMENT, CONSENTING, AND DATA AND SAFETY MONITORING

What activities does your site participate in?
** must provide value*

- Recruiting
- Consenting
- Data and Safety Monitoring
- Study procedures per the protocol including interventions, surveys, focus groups, follow-up data collection
- Review or analysis of identifiable data
- Direct recipient of funding
- None of the above

Please provide information on your site's role in the study.
** must provide value*

Expand

3. Allow sites to denote that they are engaged due to affiliations/institutional relations, but have not activities at their site.

Export Institutional Profile as CSV: From Public Website

irbexchange.org/p/participants/

541 IREx Participating Institutions

Not in IREx yet? Visit our [Join IREx page](#) to see how.
View a list of institutions using IREx as the Single IRB [here](#).

[Download the IREx Quick Guide to the Institutional Profile.](#)

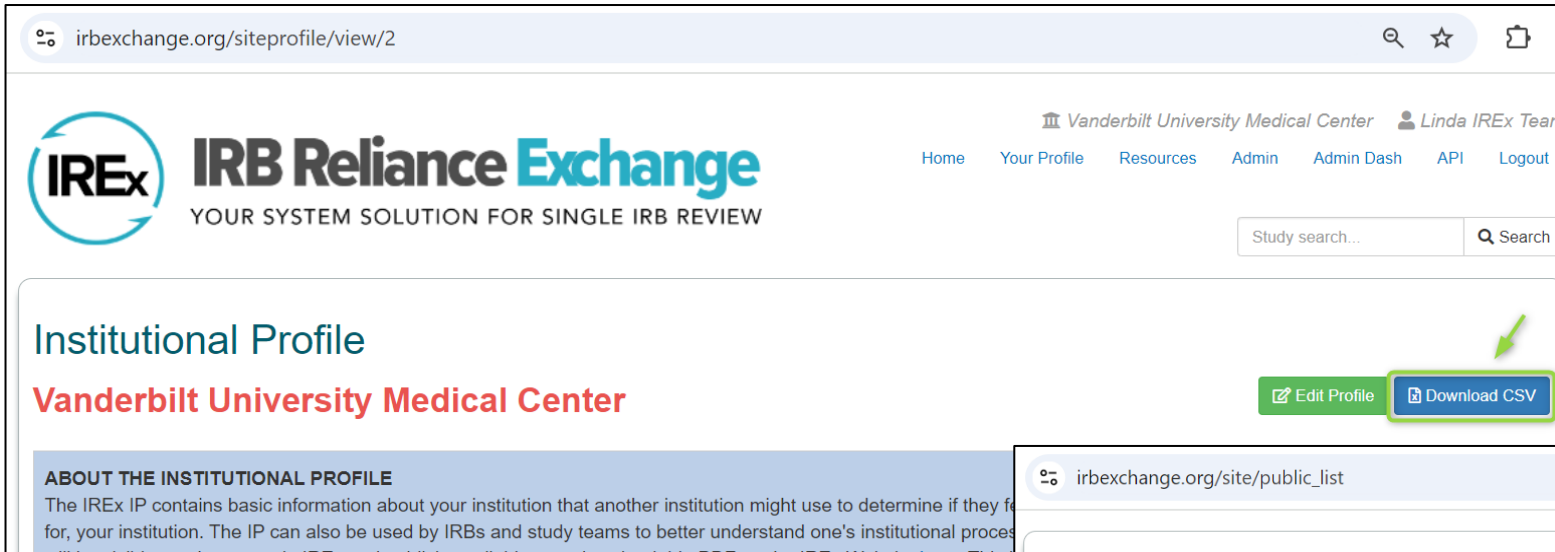
NEW

Export Institutional Profiles (IP) ▾

- Export IP Labels
- Export IP Raw

NAME	# TOTAL RELYING STUDIES	INSTITUTIONAL PROFILE	LOCATION	CONTACTS
WellSpan Health	2	PDF CSV ▾ Export IP Labels Export IP Raw	York, PA	Gabrielle Rebillard Melissa Schlenker
University of Massachusetts Medical School CTSA AAHRPP	8	PDF CSV ▾ Export IP Labels Export IP Raw	Worcester, MA	Allison Blodgett Rachel Krebs Chris Phaiah
Wooster Community Hospital	1	PDF CSV ▾ Export IP Labels Export IP Raw	Wooster, Ohio	Jeanine Fisher
Wake Forest University Health Sciences CTSA AAHRPP	42	PDF CSV ▾ Export IP Labels Export IP Raw	Winston-Salem, NC	Brian Moore Deborah Wesley

Export Institutional Profile as CSV: After logging into IREx



irbexchange.org/siteprofile/view/2

IREx IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Vanderbilt University Medical Center Linda IREx Team

Home Your Profile Resources Admin Admin Dash API Logout

Study search... Search

Institutional Profile

Vanderbilt University Medical Center

[Edit Profile](#) [Download CSV](#)

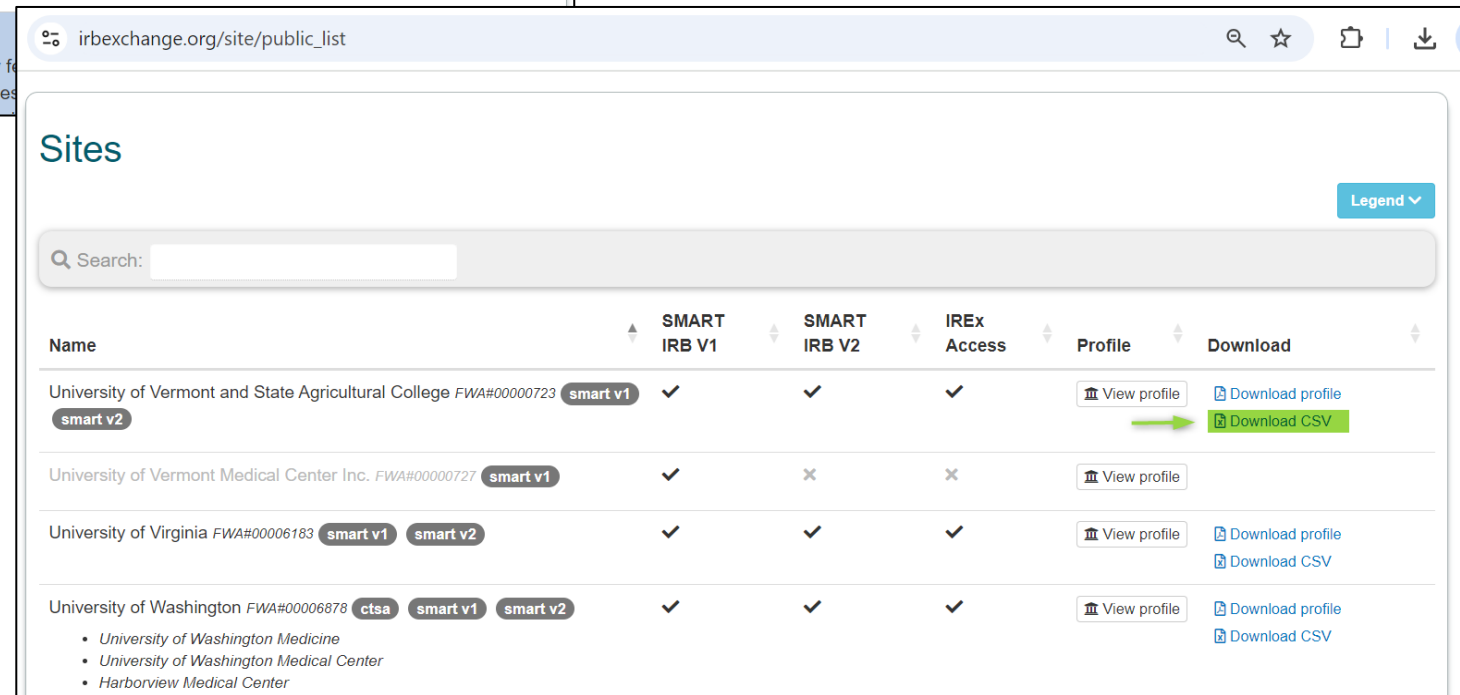
ABOUT THE INSTITUTIONAL PROFILE
The IREx IP contains basic information about your institution that another institution might use to determine if they fit for, your institution. The IP can also be used by IRBs and study teams to better understand one's institutional process.

View your IP

➤ > Download CSV for your site

From Homepage:

- Find other Sites
- Search for site
- Download



irbexchange.org/site/public_list

Sites

Legend

Search:

Name	SMART IRB V1	SMART IRB V2	IREx Access	Profile	Download
University of Vermont and State Agricultural College FWA#00000723 smart v1 smart v2	✓	✓	✓	View profile	Download profile Download CSV
University of Vermont Medical Center Inc. FWA#00000727 smart v1	✓	✗	✗	View profile	
University of Virginia FWA#00006183 smart v1 smart v2	✓	✓	✓	View profile	Download profile Download CSV
University of Washington FWA#00006878 ctsa smart v1 smart v2	✓	✓	✓	View profile	Download profile Download CSV

- University of Washington Medicine
- University of Washington Medical Center
- Harborview Medical Center

IREx Now Supports Studies with EFIC!

Goals

1. Support lead study teams as they track sites in various stages of the EFIC process
2. Standardize and centralize EFIC documentation (based on IREx User Feedback Group input)
3. Provide sites with clear EFIC processes and approval statuses

sIRBs can turn on EFIC study in IREx setup

Checklist

- ✓ Create Study
- ➔ **Complete IREx Setup**
- ➔ Confirm Primary Study Contacts
- ➔ Upload Overall Study Approval
- ➔ Publish Approval

Study Setup

Is the Lead Site also at the Reviewing IRB Institution? Yes No

Would you like to collect local considerations in IREx? Yes No

How are sites' consent forms being handled?

- Sites will provide consents for sIRB review (e.g., using a template) OR study will not have consents.
- Exception From Informed Consent (EFIC).
- A consent form generator will be used to build consents for sites

⚠ Required

Upload Community Consultation Plan (CCP) Template

With the Lead Site Approval

Upload Documents

Drag file into document type or click a document type to upload.

- IRB Approval Documentation (Required)
- IRB Application (Required)
- Consents & Assents
- Consent Plan Template**
- Grant Application
- Meeting Notes
- Investigators Brochure
- Device Manual
- Package Insert
- Measures
- Recruitment & Advertisements
- Additional IRB Approved Documents
- Others

As a document on the Onboarding Tab

Onboarding

sIRB Instructions

- sIRB Instructions





Additional Documents [+ Add Document](#)

If applicable, relying sites can use the additional documents below to facilitate their local submission process. Please contact the Reviewing IRB Contact or Study Manager with any questions.

- CCP Template 1.docx** [Archive](#)
- CCP Template 2.docx** [Archive](#)
- Site-specific consent form guidance.docx [Archive](#)
- sIRB Communication Plan.docx [Archive](#)
- Part II Consent.docx [Archive](#)

Relying HRPP must verify review of CCP in HRP Survey

Checklist

- ✓ Register
- ✓ Complete Agreements
- ✓ Confirm Institutional Profile 
- ✓ Indicate Reliance
- ➔ Complete HRP Survey**
-  Remind PI To Complete PI Survey
-  Add / Edit Study Team Access
-  Awaiting Reviewing IRB Approval

COMMUNITY CONSIDERATIONS

Please review the protocol and template consent and identify whether there are any special characteristics/concerns of your community of which the reviewing IRB should be aware for this specific study. Please also outline any steps that must be taken to address these concerns.

[Expand](#)

Have you REVIEWED and provided HRPP input into the Community Consultation Plan (CCP) outlined by the study team? Yes

If not, please return to this question after reviewing the CCP.
* must provide value

Documentation of HRPP review/recommendations for CCP (optional) [Upload file](#)

PI Uploads CCP to PI Survey

Checklist

➔ Complete/Attest to PI Survey

➔ Awaiting Community Consultation Plan (CCP) Acceptance

➔ Upload/Attest to CCP Summary of Results

✎ Add / Edit Study Team Access

⌚ Awaiting Reviewing IRB Approval

SITE-SPECIFIC CONSENT FORMS:

IF YOUR SITE HAS CONSENT FORMS, ANSWER 'YES' BELOW AND INDICATE THE # OF CONSENTS YOU WILL UPLOAD.

Consent language should be verified by your local HRPP before uploading them here. If your HRPP has not yet verified your local consent language, skip this question, submit the survey, and return later to fill in this section of the survey.

Does your site have an informed consent form(s) (ICFs), including short forms, assent forms, permission forms, etc., for this study?

- Yes
 No

* must provide value

reset

Upload your Community Consultation Plan (CCP) that has been REVIEWED by your HRPP.

 [Upload file](#)

If not, please return to this question after your HRPP has reviewed the CCP.

* must provide value

New Steps on Study Team Checklist

PI Checklist

Checklist

- ✓ Complete/Attest to PI Survey
- ➔ Awaiting Community Consultation Plan (CCP) Acceptance
- ➔ Upload/Attest to CCP Summary of Results
- ✎ Add / Edit Study Team Access
- ⌚ Awaiting Reviewing IRB Approval

Study Team Member Checklist

Checklist

- ✓ Start PI Survey for Baystate
- ✓ Awaiting PI Attestation for Baystate
- ➔ Awaiting Community Consultation Plan (CCP) Acceptance
- ➔ Upload CCP Summary of Results
- ➔ Awaiting PI Attestation of CCP Summary of Results
- ✎ Add / Edit Study Team Access
- ⌚ Awaiting Reviewing IRB Approval

Status Summary: After Site Completes Initial Documentation

Status Summary

Export Data ▾

Q Search:

Site	Agreements	Reliance Decision	Local Considerations	Approval Status
Baystate Health, Inc	Agreements Complete ▾	Completed 7/18/2024	3 / 4 Surveys Complete ▾	Awaiting CCP Acceptance

✓ Institutional Profile
Confirmed: 7/18/2024

✓ HRP Survey
Completed: 7/18/2024

✓ PI Survey
Completed: 7/15/2024
PI Attested: 7/18/2024

✗ CCP Summary of Results

✉ Email study personnel

- ✓ Relying Sites Completed Reliance Documentation and Local Considerations
- Site is ready for sIRB review of CCP

Lead Study Team Uploads CCP Acceptance from sIRB

Relying Site Approvals

Apple Health

Apple Health

Community Consultation Plan

Status

Pending

Community Consultation Plan Accepted

Date Reviewed

Date Approved

Initial Review

Status

Review Type

Initial Study: Full Board

Is Site Enrolling?

Yes No

Date Submitted

[Add pre-review exchanges with PI](#)

Date Pre-Reviewed

Date Reviewed

[Add post-review exchanges with PI](#)

[Add another Review Date](#)

Date Approved

Cancel Save

Review dates captured: CCP submissions + review + acceptance

Onboarding Approvals Status Summary

Approvals

Study-wide IRB Approvals Approval History

View As: Apple health View All Amendments Continuing Reviews

Apple Health

Protocol Version: 1.1

<p>Study Info</p> <p>IRB Number:</p> <p>Type of Study: Greater than Minimal Risk</p> <p>Reviewing IRB Decision: pending</p> <p>Review Cycle:</p>	<p>Key Dates</p> <p>Community Consultation Plan Submitted 5/20/2024</p> <p>Community Consultation Plan Reviewed 5/21/2024</p> <p>Community Consultation Plan Accepted 5/22/2024</p>	<p>Submitted for Local Review:</p> <p>Local Review Conducted:</p> <p>Local Review Completed: 5/11/2024</p> <p>Reviewing IRB Submitted:</p> <p>Reviewing IRB Reviewed:</p> <p>Reviewing IRB Approved:</p>
--	---	--

Status Summary: After CCP Accepted

Status Summary

Export Data ▾

Search:

Site	Agreements	Reliance Decision ?	Local Considerations	Approval Status ?
Apple Health	2 / 2 Agreements Complete ▾	Completed 7/18/2024	3 / 4 Surveys Complete ▾ <ul style="list-style-type: none">✓ Institutional Profile <i>Confirmed: 7/18/2024</i>✓ HRP Survey <i>Completed: 7/18/2024</i>✓ PI Survey <i>Completed: 7/15/2024</i> <i>PI Attested: 7/18/2024</i>✗ CCP Summary of Results✉ Email study personnel	CCP Accepted

Status Updated

Next Step: Upload of CCP Summary of Results

After CCP implementation, Study Team Uploads CCP Summary of Results

PI Checklist

Study Team Member Checklist

Checklist

- ✓ Complete/Attest to PI Survey
- ✓ Community Consultation Plan Accepted (CCP)
- ➔ Upload/Attest to CCP Summary of Results
- ✎ Add / Edit Study Team Access
- ⌚ Awaiting Reviewing IRB Approval

Checklist

- ✓ Start PI Survey for Revalidate
- ✓ Upload CCP Summary of Results
- ➔ Awaiting PI Attestation of CCP Summary of Results
- ✎ Add / Edit Study Team Access
- ⌚ Awaiting Reviewing IRB Approval

Coordinator can upload CCP Summary of Results, but PI must attest

Use this form to upload the Community Consultation Plan Summary of Results, along with documentation your local HRPP has reviewed and provided feedback on this document.

Has your local HRPP REVIEWED and provided feedback on your Community Consultation Plan Summary of Results? Yes

1

If not, please return to this question when ready to submit your CCP Summary of Results.

* must provide value

Please upload documentation that confirms your HRPP has reviewed the CCP Summary of Results

2

[Upload file](#)

* must provide value

Please upload the CCP Summary of Results

3

[Upload file](#)

* must provide value

Do you have any additional files to upload?

Yes
 No

4

* must provide value

reset

Submit

Status Summary: CCP Summary of Results Uploaded

Status Summary

Export Data ▾

Q Search:

Site	Agreements	Reliance Decision ⓘ	Local Considerations	Approval Status
Baystate Health, Inc	2 / 2 Agreements Complete ▾	Completed 7/18/2024	4 / 4 Surveys Complete ▾	Not Approved

✓ Institutional Profile
Confirmed: 7/18/2024

✓ HRP Survey
Completed: 7/18/2024

✓ PI Survey
Completed: 7/15/2024
PI Attested: 7/18/2024

✓ CCP Summary of Results
Completed: 7/18/2024
PI Attested: 7/18/2024

- ✓ Relying Sites Uploaded CCP Summary of Results
- Site is ready for sIRB review and initial approval

EFIC Status Summary Tab Approval Status

Status Summary Export Data ▾

Q Search:

Site	Agreements	Reliance Decision ?	Local Considerations	Approval Status ?
Anderson Medical Center	2 / 2 Agreements Complete	<div style="border: 1px solid black; padding: 5px;"><ul style="list-style-type: none">✓ Institutional Profile <small>Confirmed: 7/10/2023</small>✓ HRP Survey <small>Completed: 7/10/2023</small>✓ PI Survey <small>Completed: 7/10/2023</small> <small>PI Attested: 7/10/2023</small>✗ CCP Summary of Results</div>	3/4 Surveys Complete ▾	Awaiting CCP Acceptance
Apple Health	2 / 2 Agreements Complete		3/4 Surveys Complete ▾	CCP Pending
Bayside Research	2 / 2 Agreements Complete		3/4 Surveys Complete ▾	CCP Accepted
Carnegie University	2 / 2 Agreements Complete		4/4 Surveys Complete ▾	Not Approved
Lemon University	2 / 2 Agreements Complete ▾	Completed 1/24/2024	4/4 Surveys Complete ▾	Approval Pending
University of the Bay	2 / 2 Agreements Complete ▾	Completed 1/24/2024	4/4 Surveys Complete ▾	Approved

Approval Status Legend (EFIC Studies only)

Approval Status ?



Approval Status Legend

Awaiting CCP Acceptance	Site has completed IP, HRP and PI Surveys and is awaiting the Reviewing IRB's acceptance of the Community Consultation Plan (CCP)
CCP Pending	CCP status is being submitted to or reviewed by the Reviewing IRB
CCP Accepted	Reviewing IRB has accepted site's CCP, but site has not uploaded their CCP Summary of Results
Not Approved	Site has uploaded their CCP Summary of Results and is awaiting initial approval from the Reviewing IRB
Approval Pending	Site is being submitted to or reviewed by the Reviewing IRB for approval
Approved	Site is approved for the current protocol version



- +
-
-

IREX Metrics

October 2024

2024 Q3 Metrics Update



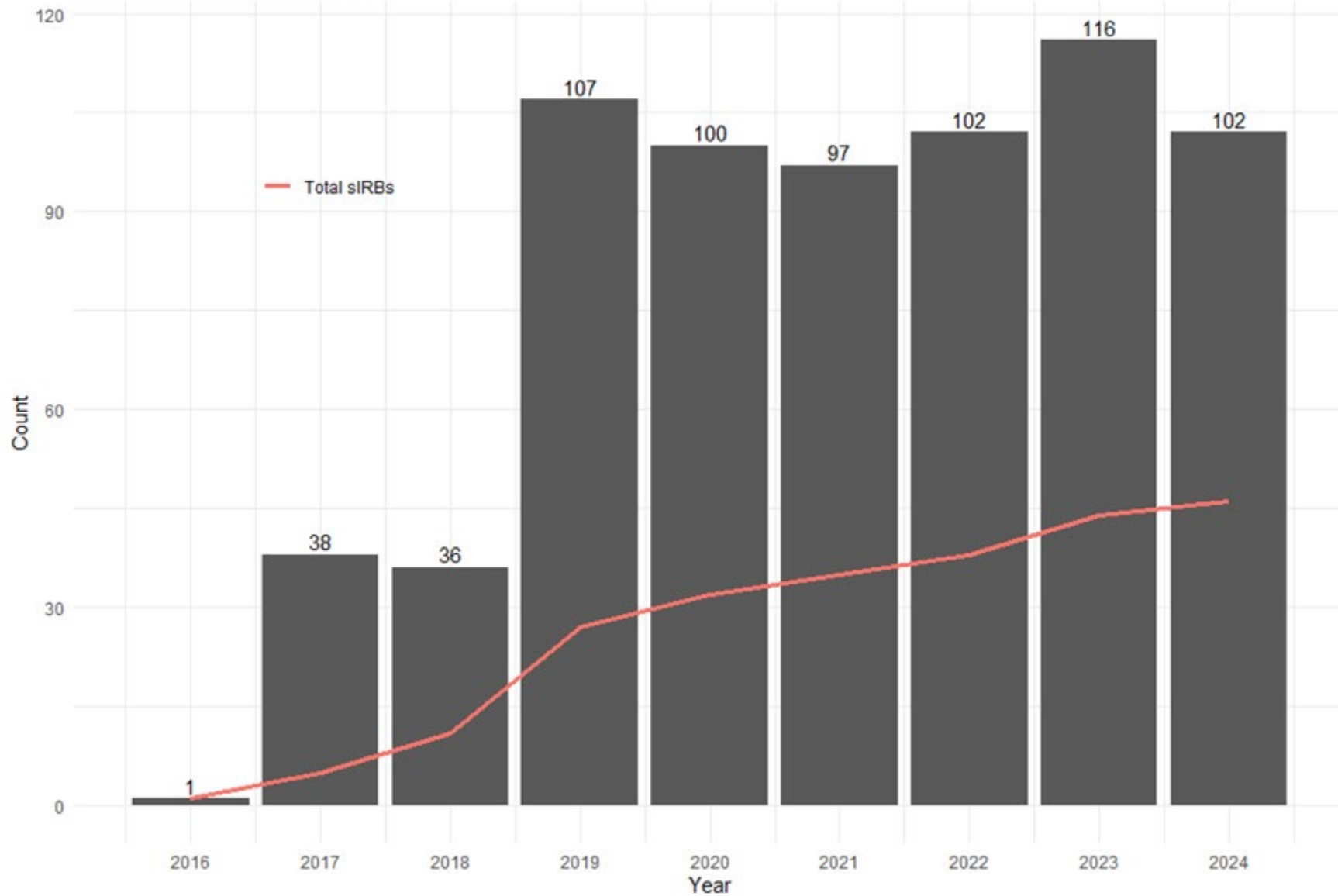
- **92%** of sites in IREx have completed their Institutional Profile
- **88%** of IREx sites have indicated reliance
- **88%** of sites have ceded review and have approval posted to IREx
- **34 out of 46** single IRBs are using IREx for more than one study
- **12** median days from initial sIRB submission to sIRB approval for relying sites (*not including local review time*)

2024 Q3 Metrics Update



- **517** unique participating sites
- **4263** total reliances across all studies
- **7** sites per study on average
- **85%** of studies created after 2018 collecting local considerations
- **33** days between lead site initial approval to submission (median)

Studies Created by Year

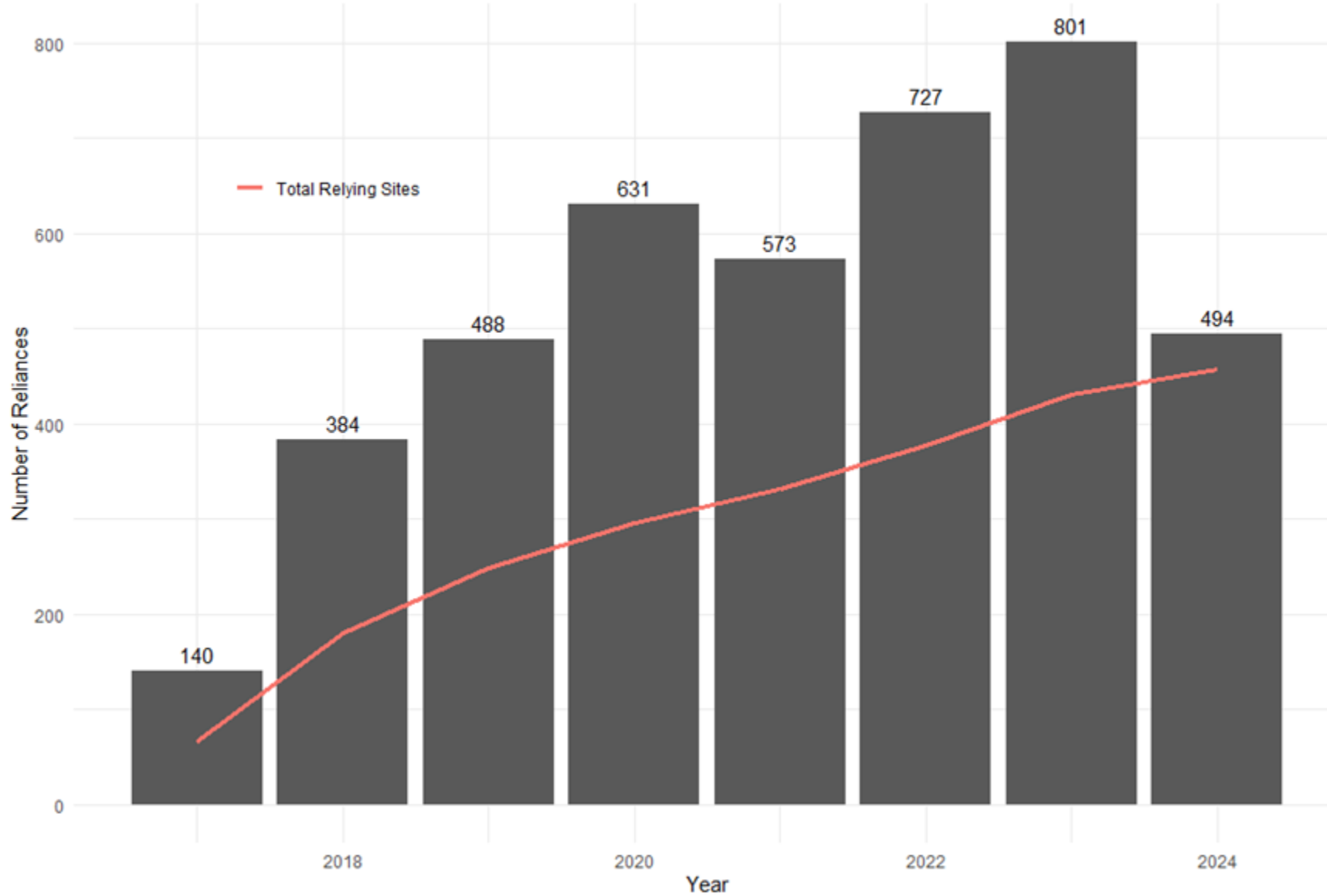


+

•

○

Relying HRPPs Use of IREx



+

•

○



Upcoming Features

Upcoming Feature



Upcoming Features	Est. Timeline
Enhance IREx API to accommodate 1. Component sites on studies 2. EFIC: CCP acceptance + submission of summary of results	November 2024
Support for studies where sIRB is PSite, but NOT Lead Site	December 2024
Support Importing PSite Contacts	January 2024
sIRB & Study Managers turn on/off notification	February 2025
Incorporating satisfaction surveys into IREx	March 2025
Automating Local Considerations	July 2025

PREVIEW: Automating Local Considerations Documentation

Goals: simplify Relying HRPP Process + Improve Information Quality for sIRB

sIRB documents unique study criteria

Vulnerable Populations

- Children
- Pregnant women
- Prisoners
- Individuals with impaired decision-making capacity

Other populations that may require additional requirements

- LGBTQIA
- Elderly
- Non-English speaking
- Students, staff, or faculty of the research institution
- Student athletes
- Legally authorized representatives

Unique documentation requirements

✓ Assent

- Waiver of consent
- Use of eConsent
- Select potential ancillary reviews
- Imaging
- Patient contact prior to consent
- Sharing of specimens
- HIPAA status and procedure
- Compensation?

OTHER – allow sIRB to list the issue and that would populate on the HRP survey for the HRPP to respond to

Unique Protocol Elements

- Standard of care with description from protocol
- Pregnancy testing
- Genetic testing

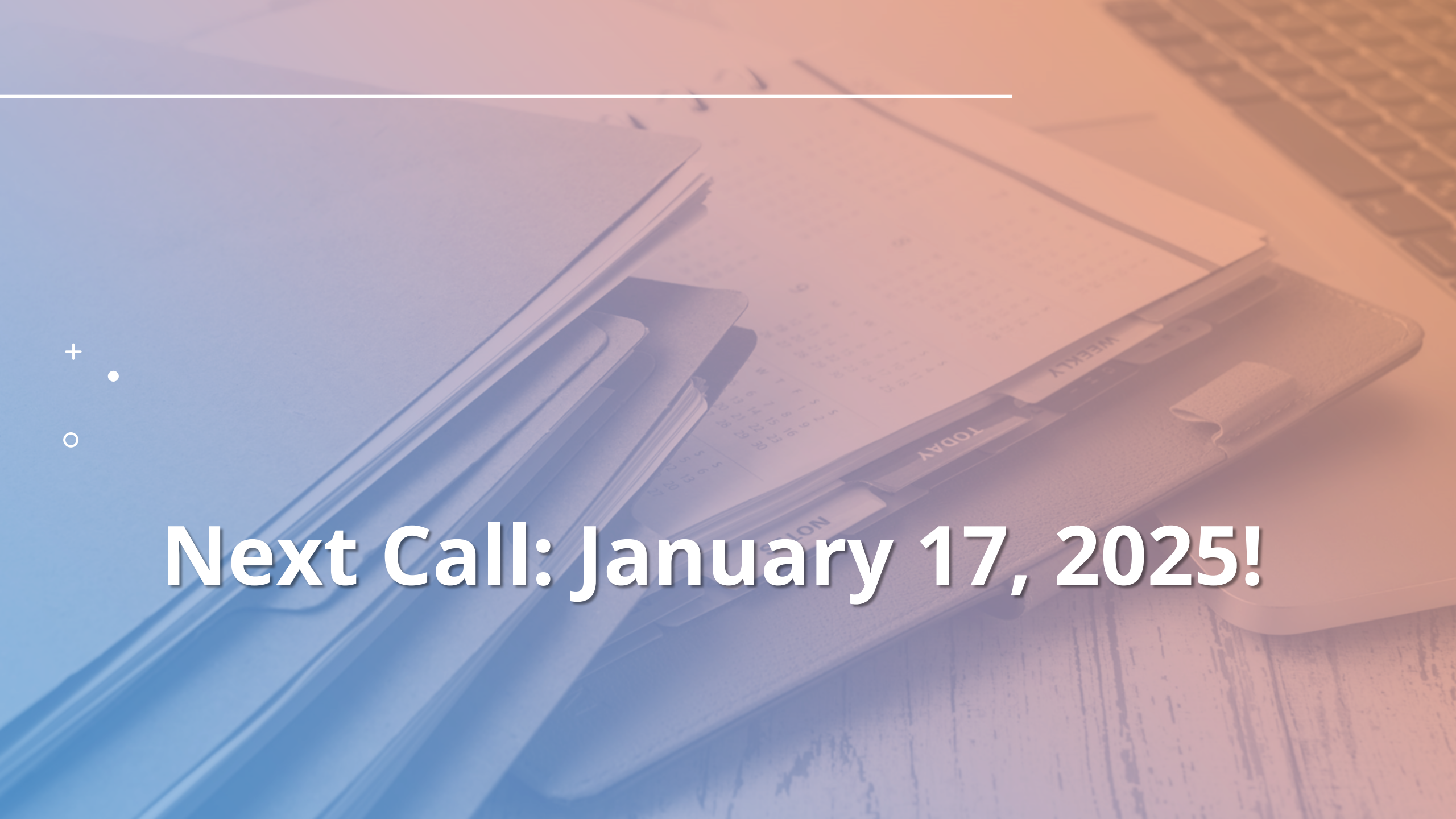
IREX Checks for related IREx IP Questions

- State and local laws that establish age of majority
- Institutional policies that affect any applicable assent process
- Community Info (e.g., Populations likely to be enrolled at a site or by a study team that could affect the assent process, such as in terms of language, religious or cultural consideration)



Relying Site confirms/edits on HRP Survey

Age of majority in your state?	18
What circumstances affect age of consent in your state? For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment	• Emancipated minors • Self-Sufficient minors • Care related to the prevention or treatment of pregnancy • Minors, 12 years or older, seeking care for: 1. Out-patient mental health treatment or counseling, excluding drugs 2. Care related to the diagnosis or treatment of reportable infectious, contagious, or communicable/sexually transmitted diseases 3. Care provided to the victims of sexual assault or rape



- +
-
-

Next Call: January 17, 2025!