

07.17.2026 QUARTERLY CALL AGENDA



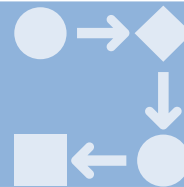
Welcome &
Announcements



IREx Mid Year Metrics



New IREx Features



Feature Highlight: EFIC
Workflow



Current & Upcoming
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



October 16, 2026

+

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Welcome *The Guthrie Clinic* - NEWEST sIRB in IREx!



Who Else Created Studies in Q2?



- Nationwide Children's Hospital – 2
- Pennington Biomedical Research Center – 2
- The Guthrie Clinic – 2
- The Ohio State University – 1
- UCLA – 1
- **UCSF – 18** 
- University of North Texas HSC – 1
- University of Utah – 2
- Vanderbilt Health – 6
- Wake Forest University Health Sciences – 2

+ Updated IREx • Resource Pages!



Why change the IREx Resource Pages?



- **Feedback from users**

- Resources are helpful, but...
- Pages were difficult to navigate
- “Takes more time to find the guide I need than to actually use it and do the task”

- **Solution**

- Simplify pages
- Break up resources by study ‘phase’
- Highlight most requested resources
- Better navigability overall

Old...

Cluttered
Too much
information

The screenshot shows the IREx website homepage. At the top is a navigation bar with links: ABOUT, RESOURCES, USER TRAININGS, NEWS & ANNOUNCEMENTS, CONTACT US, JOIN IREx, and LOGIN. Below the navigation bar are statistics: Institutions (671), Studies (904), Reliances (5,379), HRPP Liaisons (1,236), and Lead Study Members (1,231). The main content area features a large banner titled "USING IREx AS THE REVIEWING IRB" with a "Join a Training" button. Below the banner are four sections: "DOCUMENT RELIANCE ARRANGEMENTS", "FACILITATE COMMUNICATIONS WITH SITES", "CAPTURE SITE-SPECIFIC LOCAL CONSIDERATIONS", and "PROVIDE TOOLS FOR LEAD STUDY TEAMS AND COORDINATING CENTERS". At the bottom is a section titled "SINGLE IRB RESOURCES FOR YOUR STUDY" with six sub-sections: "Serve as the Single IRB", "Use a Study Manager (SM) on a study", "Initial Approval for Lead Site or Overall Study", "Study-wide Amendment Approvals", "Continuing Review Approvals", and "Site Amendment Approvals".

The screenshot shows a more organized version of the IREx website. It features a grid of cards with clear titles and concise content. The top row includes "Approval Documents Captured in IREx", "Closing a Study in IREx", and "Closing a Site in IREx". The middle row includes "IREx Template Instructions", "Fulfill SMART IRB Documentation & Notification Requirements in IREx", and "Exemption from Informed Consent (EFIC) Studies". The bottom section is titled "GENERAL RESOURCES FOR USING IREx" and includes "Institutional Profile", "HRPP/ IRB Access", "Study-Specific Reliance Plan (SSRP)", "FWA Components", "Agreements", "Letters of Indemnification (LOI)", and "Study-specific Local Considerations (LC)". Each card contains a list of items with checkmarks and a "Download" or "Watch Video" button.

May not
make sense
to folks new
to IREx /
Too much
IREx lingo

NEW!

+

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○

Sleeker
More
intuitive

**IRB Reliance Exchange**
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

[ABOUT](#) [RESOURCES](#) [USER TRAININGS](#) [NEWS & ANNOUNCEMENTS](#) [CONTACT US](#)

[JOIN IREx!](#) [LOGIN](#)

Q

Institutions
675

Studies
909

Reliances
5,391

HRPP Liaisons
1,241

Lead Study Members
1,237

REVIEWING IRB HELP

MOST REQUESTED RESOURCES:

- [How to Add / Remove HRPP Staff Access to IREx \[PDF\]](#)
- [How to Upload the Lead Site / Overall Study Initial Approval \[PDF\] \[Video\]](#)
- [Managing Agreements in IREx \[PDF\] \[Video\]](#)
- [What is the Study-Specific Reliance Plan \(SSRP\)? \[PDF\] \[Video\]](#)

[— START HERE!](#)

The [Reviewing IRB Quick Guide](#) gives a comprehensive tutorial on all your IREx tasks. If you are not ready to create a study in IREx and would like a demo, please click 'Request a Demo' below.

[Reviewing IRB Quick Guide \[PDF\]](#)

[How to Create a New Study \[Video\]](#)

[How to Add / Remove HRPP Staff Access to IREx \[PDF\]](#)

[Request a Demo](#)

[How to Use the sIRB Dashboard \[Video\]](#)

[Using IREx to fulfill SMART IRB Documentation and Notification Requirements \[PDF\]](#)

[+ Institutional Preferences \(Institutional Profile; Staff Access; Component Sites; Agreements & Indemnification\)](#)

[+ Study Start Up \(Delegating Tasks to the Lead Study Team; Capturing Local Considerations; Uploading Initial Approval\)](#)

[+ Ongoing Study Activities \(Amendments and Continuing Reviews\)](#)

[+ Site and Study Closure](#)

Easier to
take in and
navigate



• IREx Mid-Year Metrics

Notable Metrics



Active Studies

IREx supports **902** active studies



Single IRBs

51 unique sIRBs oversee these studies



Participating Sites

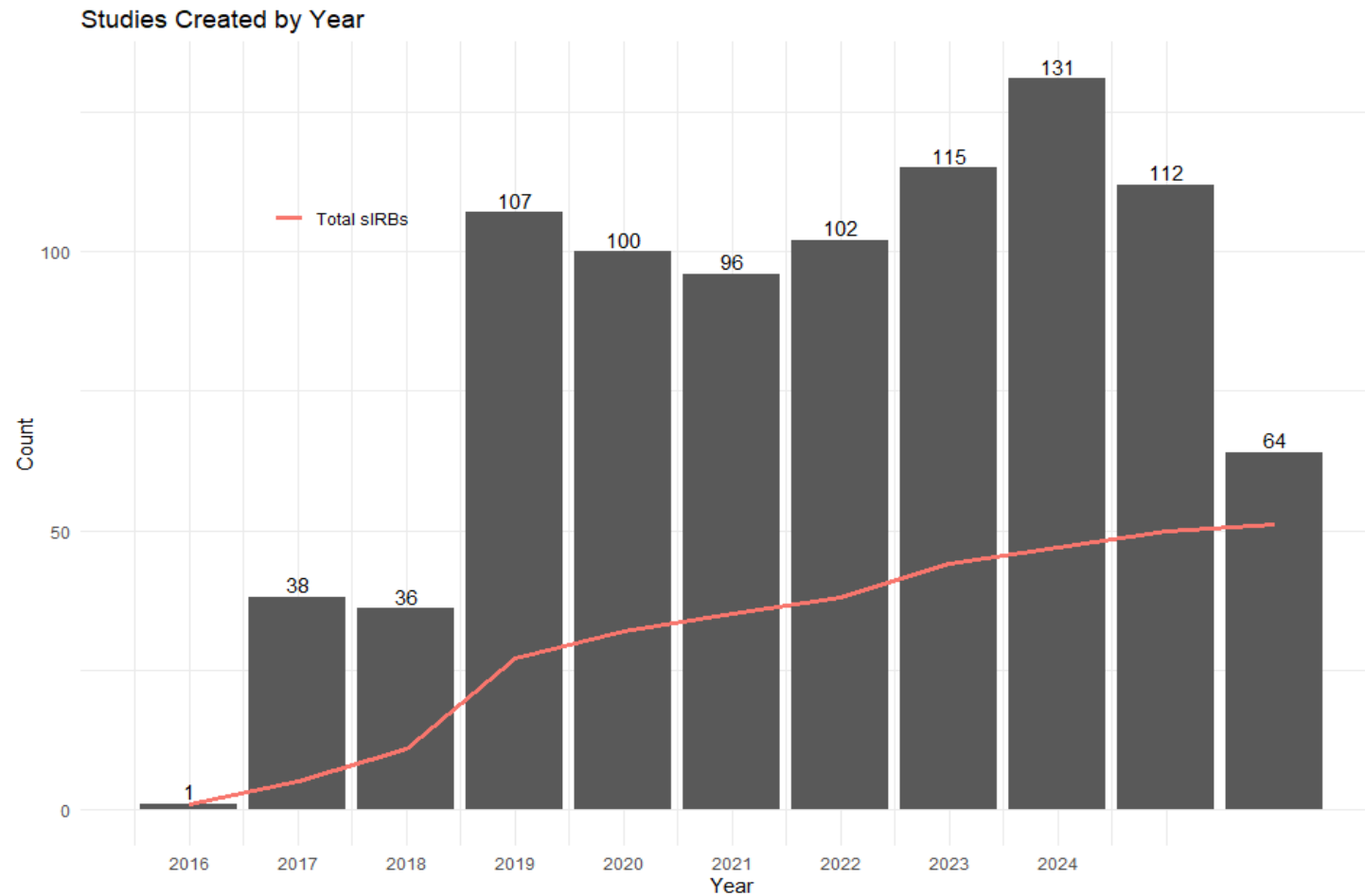
5,850 participating sites across all studies



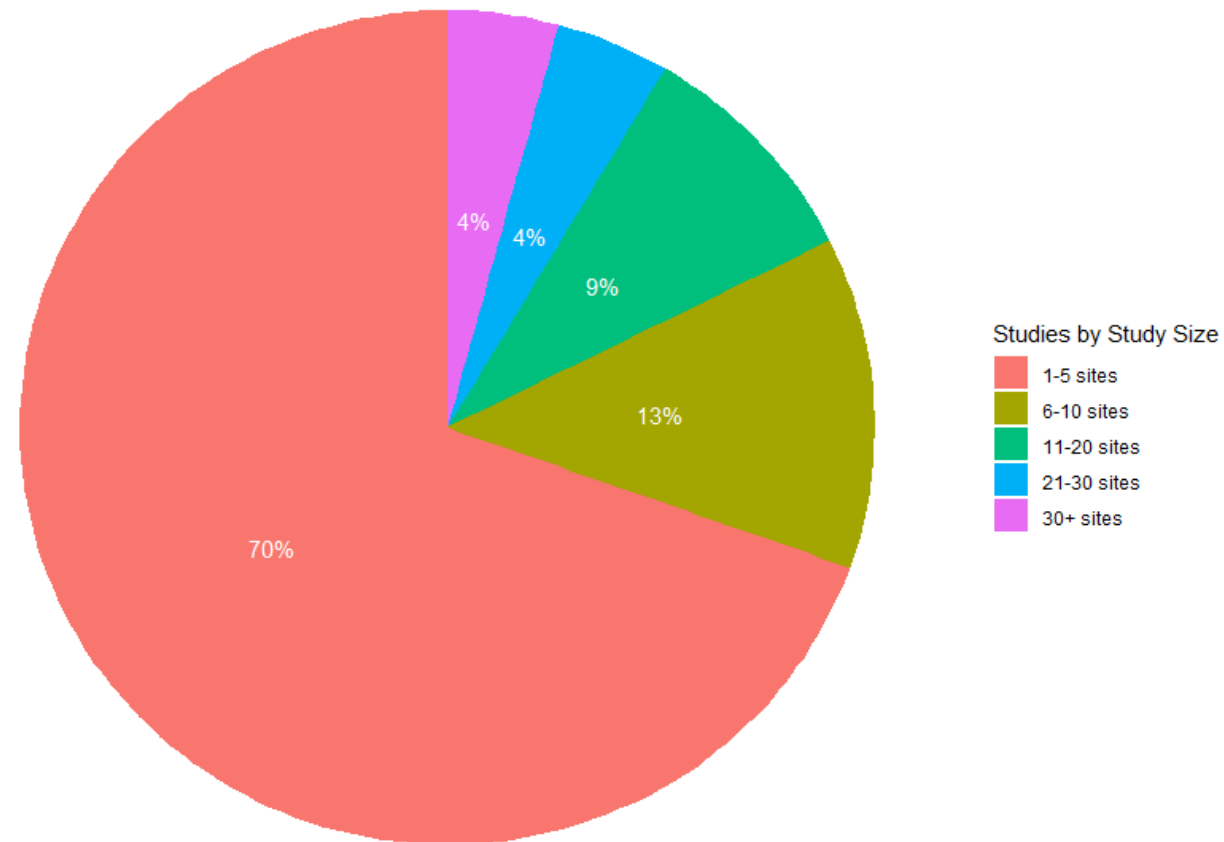
Institutional Diversity

570 **unique** participating institutions

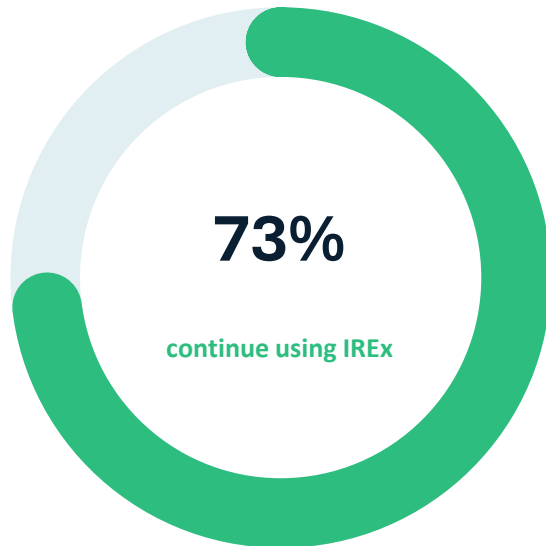
IREx studies growing steadily in 2026



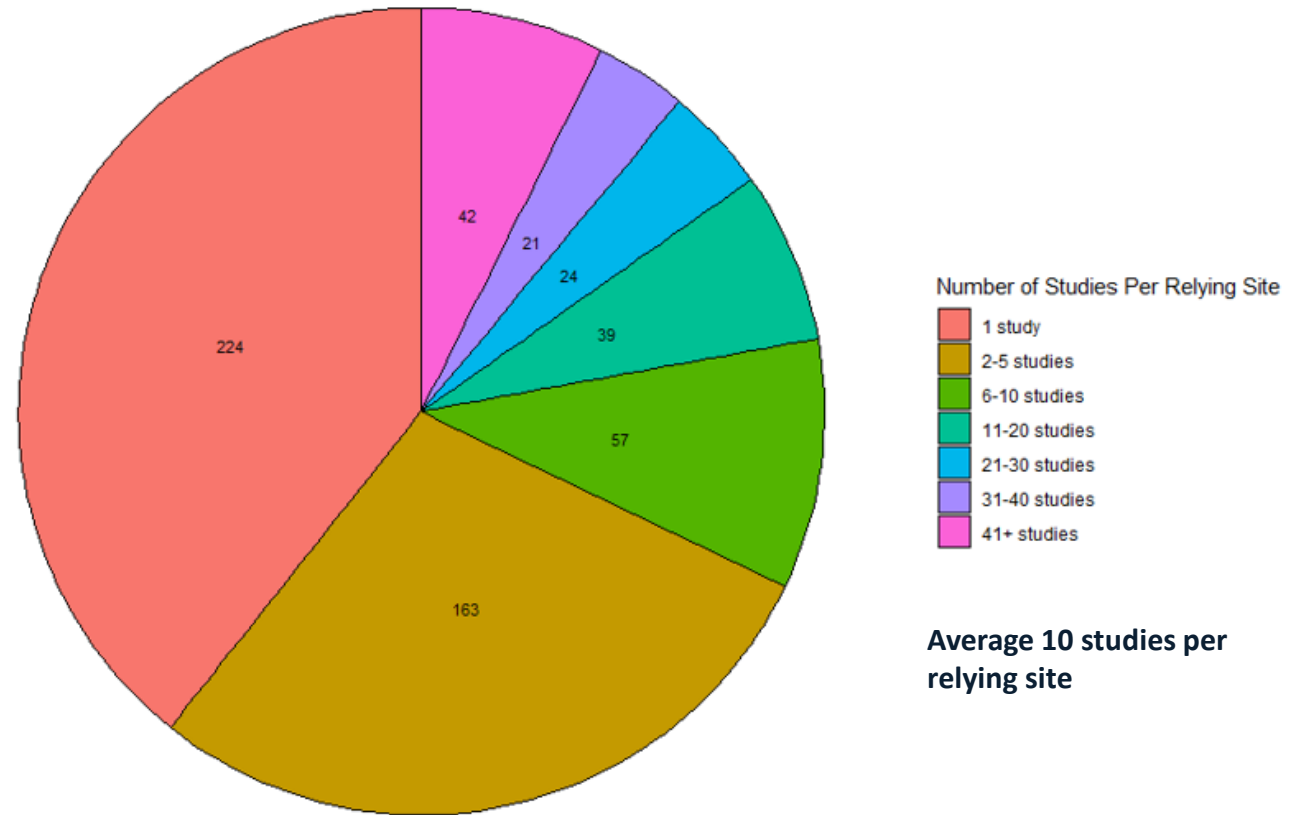
IREx is useful for studies of all sizes



IREx maintains high adoption and retention



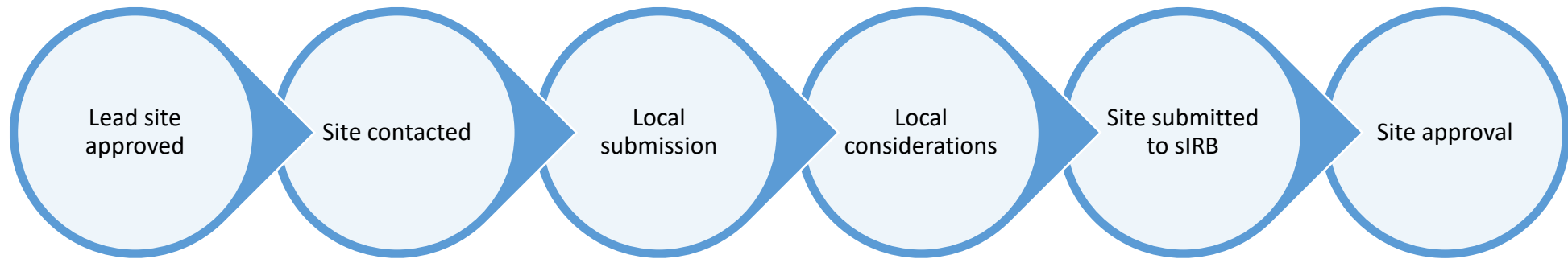
IRBs with >1 studies
in IREx



Sites are moving through the process efficiently



92% of sites have made it through the sIRB process and received initial approval, up from 90%



Median of **13 days** from submission to approval for relying sites



+ . New IREx ○ Features

NEW: Reviewing IRB # Included on sIRB Emails

IREx: Notification of Reliance

 admin@irbexchange.org
To

☺

↩ Reply

↩ Reply All

➡ Forward

⋮

Wed 7/15/2026 4:35 PM

🛡 General

12565200-4487406-IREx_Reliance_Notification-2026-07-09-110052.pdf 63 KB ▾

Study Specific Smart v3 Reliance Plan - VUMC.pdf 76 KB ▾

Dear all,

This email confirms that **Blueberry University** has agreed to rely on the **Vanderbilt University Medical Center** IRB using the following agreement(s):

- SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement

Study Title	A testing demo study
IREx Project ID	12565200
Reviewing IRB	Vanderbilt University Medical Center (FWA #00005756)
Reviewing IRB Number:	123456
Relying Institution	Blueberry University (FWA #00043543)
Study Link	https://staging.irbexchange.org/project/12565200

NOTE: This is not a notice of IRB approval. A separate email will be sent when the study is approved by the reviewing IRB.

Thank you,
The IREx Team

NEW: Local reliance instructions included in email



Notification Preview — Blueberry University will receive the email below

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.

Your local HRPP's instructions for investigators:

Investigators should email hrpp@blueberry.edu and schedule a consult.

Study Title	Combos Again
Study Link	https://staging.irbexchange.org/project/9590435
Reviewing IRB	Vanderbilt University Medical Center
Reviewing IRB Contact	Liaison Test (liaison@hotmail.com)
Study Manager	Kaysi PI
Sponsor	Center for Information Technology (CIT)

Next Steps:

- Local reliance instructions piped from Institutional Profile into first relying site email
- This will help investigators know their first step and save the Relying HRPP from having to follow up
- **Reminder:** Update Section 3 of your Institutional Profile!

New Indemnification Enhancements

- Indicate use of SMART IRB Indemnification Addendum
- Offer multiple indemnification agreements (e.g., LOI and SMART IRB Addendum)
- Archive previous agreements
- Option to no longer offer indemnification on existing study

The screenshot shows the 'IREx Project Settings' window. At the top is a progress bar with five icons: a gear, a document, a pie chart, a clipboard, and a checkmark. The current step is 'Identify Required Agreements', indicated by a blue document icon and a 'Help' button. The form contains the following sections:

- What reliance agreement(s) can be used by relying sites?** (Check all that apply)
 - ☒ SMART IRB Agreement Version 3.0
 - ☐ Other Reliance Agreement
- Is Indemnification required of any relying site?** (Radio buttons)
 - ☒ Yes
 - ☐ No
- Do you want to track whether sites have executed an indemnification agreement (e.g., Letter of indemnification, SMART Addendum) in IREx?** (Radio buttons)
 - ☒ Yes
 - ☐ No
- Letter(s) of Indemnification** (List)
 - A dropdown menu with '+ Add Indemnification'.
 - A list item: 'SMART IRB Indemnification Addendum (SMART Addendum)' with an 'Available' status and a close button 'x'.
- A blue informational box: '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.'

At the bottom right is a green 'Continue →' button.

Automating Local Considerations Improvements



Study Elements

In the list below, select element(s) that are relevant to this study to help Relying Institutions identify potential aspects that may need particular attention. The list is not exhaustive. Select the "Other" element to include additional questions on the HRP and/or PI Surveys.

Relying HRPPs remain responsible for communicating all their pertinent local review information to you, as the sIRB, even if a relevant study element is not marked in this list.

Federally Regulated Study Elements

- ☐ Informed consent forms
- ☐ Assent forms
- ☐ e-Consent
- ☐ Exception From Informed Consent (EFIC)
- ☐ Waiver or alteration of informed consent
- ☐ Children/Minors
- ☐ Pregnant women
- ☐ Prisoners
- ☐ Other vulnerable populations (e.g., students)
- ☐ Drugs/devices
- ☐ Genetic Testing
- ☐ HIPAA applies to this study

Other Elements Related to State Laws/Local Policies

- ☐ Drug or device that could impact billing
- ☐ Drug storage or distribution
- ☐ Individuals with impaired decision making
- ☐ Investigational biosafety review
- ☐ Involves radiation of any kind
- ☐ Is federally funded
- ☐ Mandatory reporting (e.g., testing for infectious disease, abuse/neglect)
- ☐ Non-English speaking individuals
- ☐ Pregnancy testing or collecting pregnancy status
- ☐ Other (e.g., Future Use of Data, Standard of Care, etc.)

- Screening questions added to HRP Survey to allow the relying HRPP to indicate it does not apply to their site.

STUDY ELEMENTS RELEVANT TO LOCAL REVIEW

Will your site enroll participants? ☐ Yes ☐ No
* must provide value reset
If you change your answer from 'No' to 'Yes', close survey and re-open to include piped information from the IP

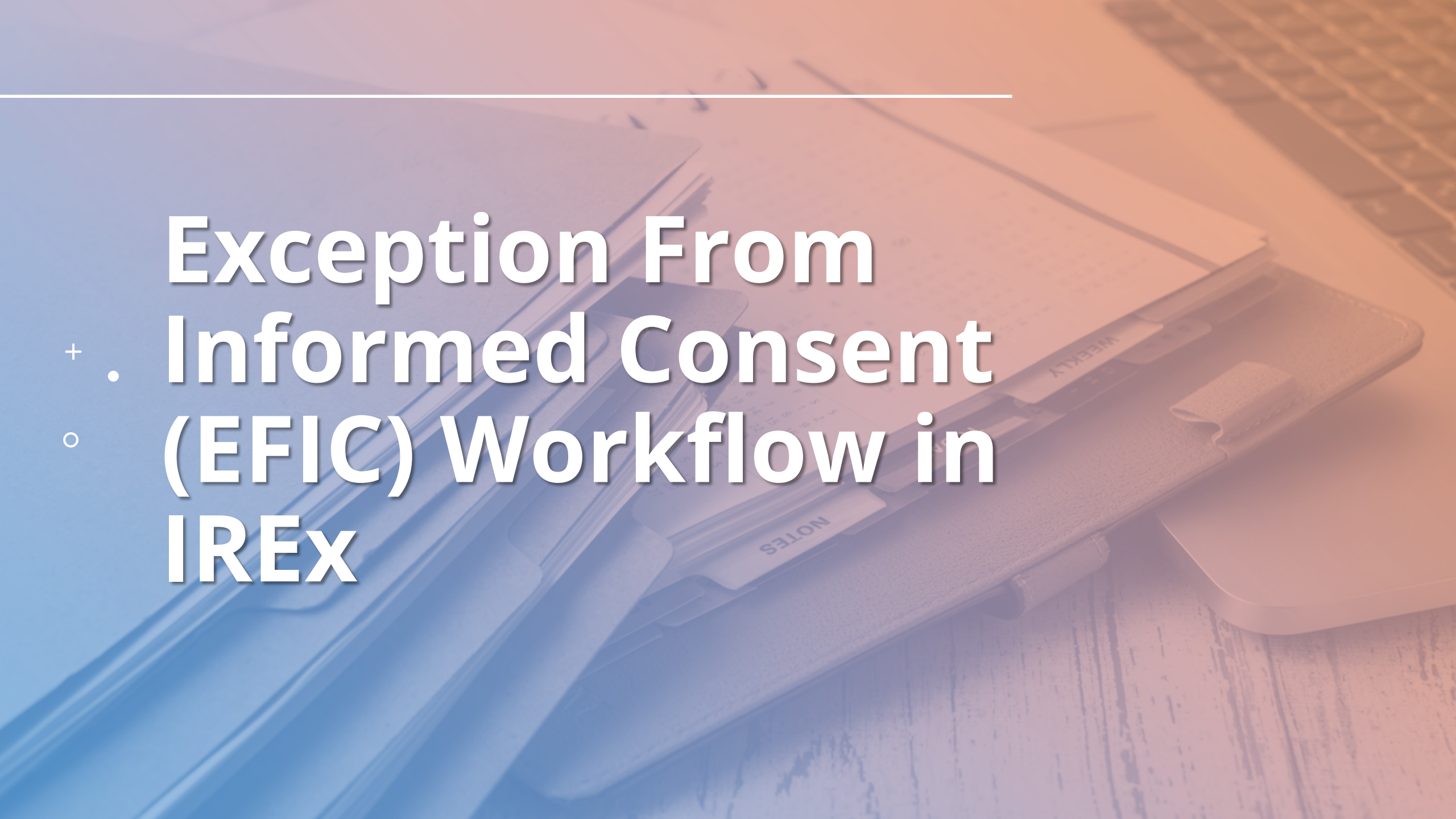
Does your institution have a posted policy for the following?

- ☒ Consent Process for those with Impaired Decision-Making Capacity
- ☒ Use of short forms for non-English speaking individuals
- ☒ Translation of consent forms for non-English speaking individuals
- ☐ We do not have a posted policy/guidance for any of these

NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.
* must provide value

- Other study elements will have a "N/A for this study" for related questions

If a study drug is not FDA approved, does your institution require specific language in the consent form around unknown risks? ☐ Yes ☐ No ☐ N/A for this study
* must provide value



A background image showing a desk setup. On the left, a blue folder is partially visible. In the center, a notebook with a dark cover and a white tab labeled 'NOTES' is open. To the right, a laptop is partially visible. The entire scene is overlaid with a semi-transparent blue and orange gradient. A white horizontal line is positioned near the top of the image.

Exception From Informed Consent (EFIC) Workflow in IREx

EFIC in IREx Refresher



- Launched September 2024
- **Goals:**
 - Support lead study teams as they track sites in various stages of the EFIC process
 - Standardize and centralize EFIC documentation (based on IREx User Feedback Group input)
 - Provide sites with clear EFIC processes and approval statuses
- **Update:**
 - 2 EFIC studies; 10 total relying sites, all with initial approval
 - Look forward to a Lead Study Team presentation on a future Quarterly Call!

sIRBs 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).

⚠ Required

Upload Community Consultation Plan (CCP) Template

+

sIRB indicates study is EFIC

sIRB/SM uploads
Community
Consultation Plan
Template (CCP) with
lead site approval

Relying HRPP
confirms review of
local CCP & Study
Team Uploads

SM uploads sIRB's
acceptance of CCP –
ready to implement

Study Team uploads
CCP Summary of
Results

SM submits CCP
Summary to sIRB for
approval

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

Consultation Plan Template

Grant Application

Meeting Notes

Investigators Brochure

Device Manual

Package Insert

Measures

Recruitment & Advertisements

Additional IRB Approved Documents

Others

Optional: Include on the Onboarding Tab

Onboarding

Approvals

Status Summary

Sites

Contacts

Edit Study Info

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 confirm review of CCP in HRP Survey

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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

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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

Status Summary: After Site Completes Initial Documentation†



Status Summary				
Export Data ▼ Q Search:				
Site	Agreements	Reliance Decision ?	Local Considerations	Approval Status
Apple Health	2 / 2 Agreements Complete ▼	Completed 7/18/2024	3 / 4 Surveys Complete ▼ ✓ 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	Awaiting CCP Acceptance

- ✓ 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

Community Consultation Plan

Status

Initial Review

Status

Review Type

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

Study Info
IRB Number:
Type of Study: Greater than Minimal Risk
Reviewing IRB Decision: pending
Review Cycle:

Key Dates

Community Consultation Plan Submitted 5/20/2024
Community Consultation Plan Reviewed 5/21/2024
Community Consultation Plan Accepted 5/22/2024

Submitted for Local Review:
Local Review Conducted:
Local Review Completed: 5/11/2024
Reviewing IRB Submitted:
Reviewing IRB Reviewed:
Reviewing IRB Approved:

Status Summary: After CCP Accepted

+



Status Summary

Export Data ▼

Q Search:

Site	Agreements	Reliance Decision ?	Local Considerations	Approval Status ?
Apple Health	2 / 2 Agreements Complete ▼	Completed 7/18/2024	3 / 4 Surveys Complete ▼	CCP Accepted

Status Updated

✓ 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

Next Step: Upload of
CCP Summary of
Results

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



- + .
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Current & Upcoming Feature Development

Upcoming IREx Features

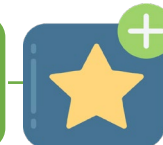


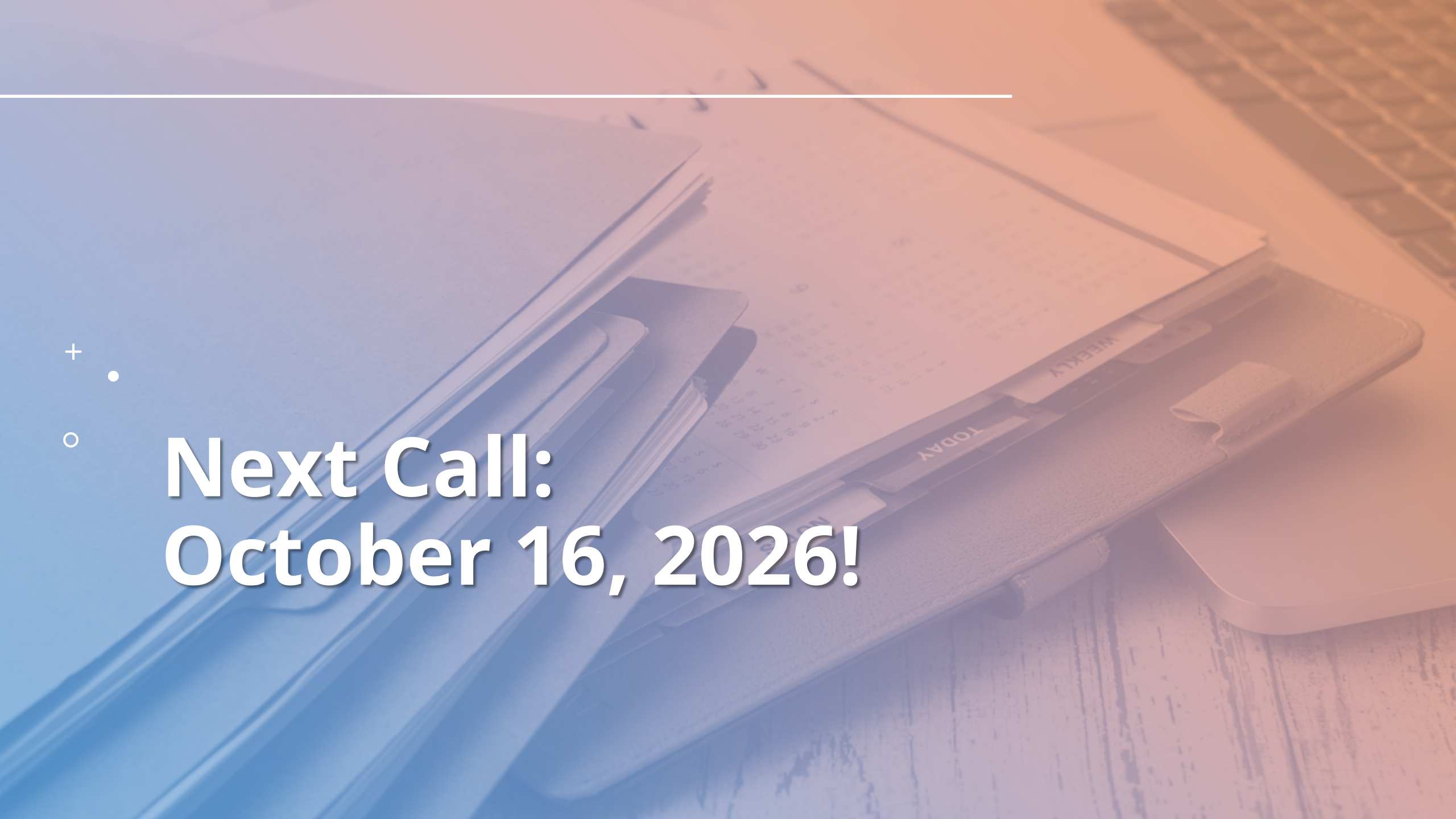
Improve relying site usability via progress bar

Allow Lead Study Teams to request changes to HRP / PI Surveys within IREx

Allow Lead Study Teams to create studies in IREx (to save sIRBs 1 step)

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





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Next Call: October 16, 2026!