04.17.2026 QUARTERLY CALL AGENDA

- Welcome & Announcements
- New IREx Features
- Featured Speakers – IREx Study Managers
- 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

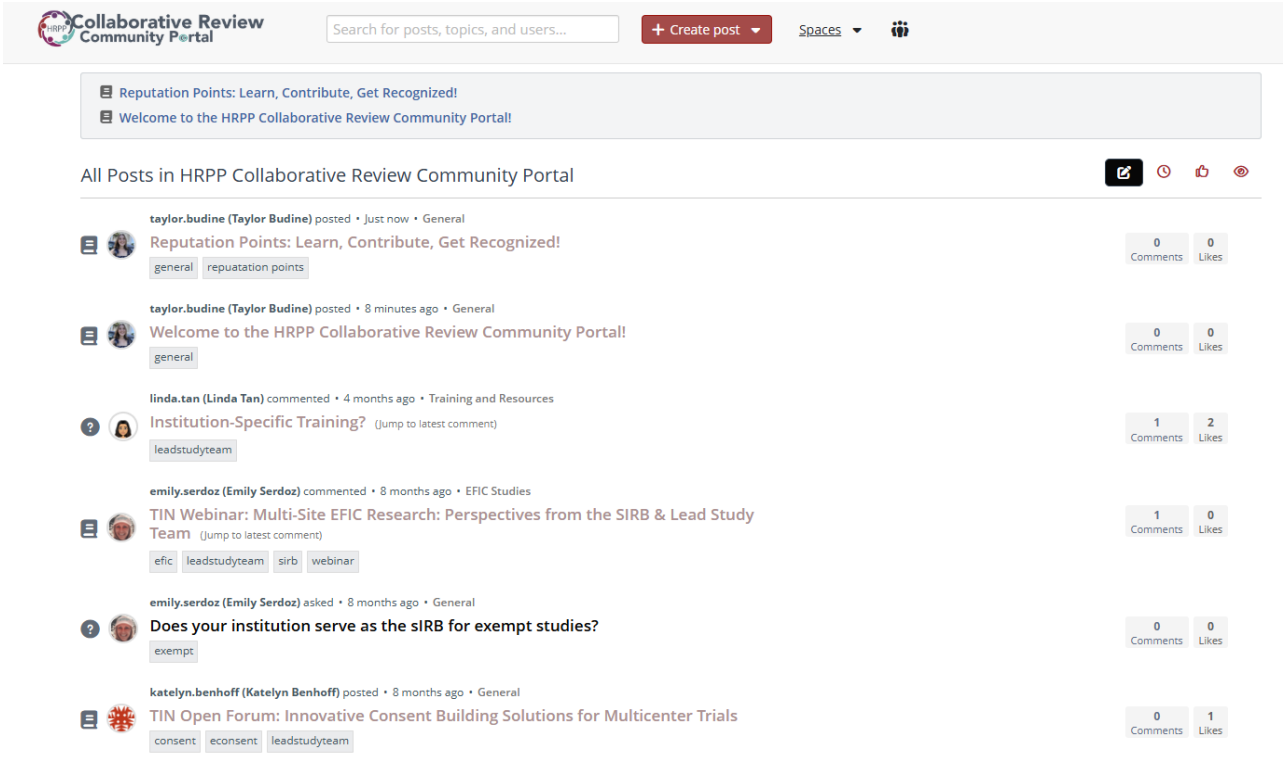
July 17,2026

October 16, 2026

Announcement: HRPP Collaborative Review Community Portal

Introducing the HRPP Collaborative Review Community Portal!

HRPP Collaborative Review Community Portal



Purpose of the Portal

Facilitate meaningful collaboration among IRB/HRPP professionals involved in single IRB (sIRB) review and oversight by enabling consistent communication and shared learning

Serve as a centralized, trusted forum for asking questions, exchanging experiences, and discussing challenges, policies, and best practices related to sIRB processes

Promote consistency, efficiency, and transparency in sIRB operations through peer engagement and collective problem-solving

Support the development of long-term, cross-institutional professional relationships that strengthen the broader IRB/HRPP community

Introducing the HRPP Collaborative Review Community Portal!

Metrics

Launch: April 16, 2026 (yesterday!)

So Far:

- Portal Users: 76 (excluding admin)
- Portal Users interested in joining the Steering Committee: 28

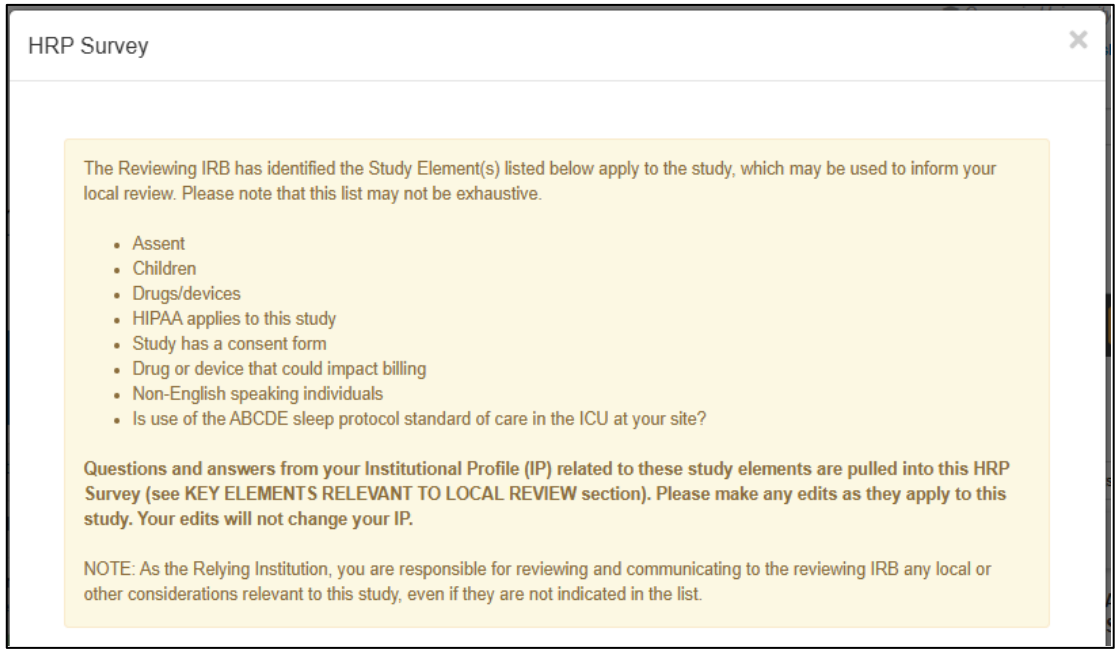
Scan QR Code to join the HRPP Portal!

Update: Automating Local Considerations Metrics

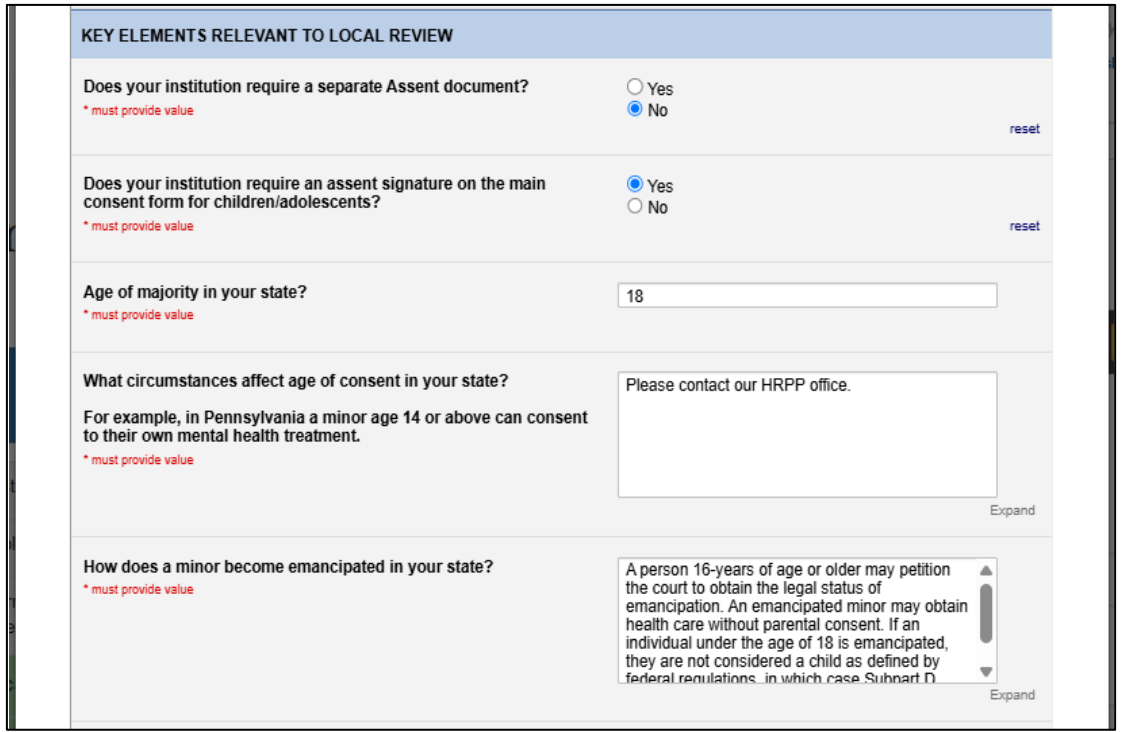
Automating Local Considerations Reporting for HRPPs

REMINDER OF NEW FEATURES FOR RELYING HRPPS

1. Key Study Elements listed at the top of the HRP Survey to inform the HRPP Review



2. Relevant info about Key Study Elements are piped in from the Institutional Profile to the HRP Survey to streamline reporting



Update on Time Savings from Automating Local Considerations

Feature Released in October 2025

	BEFORE Automating LCs	AFTER Automating LCs	Results
Avg Days to Complete HRP Survey *Site Contacted -- HRP Survey Completed*	**82** Days	**62** Days	**20** days faster!
Avg Days to PSite Approval *Site Contacted -- Relying Site's Initial Approval*	**118** Days	**105** Days	**13** days faster

Studies Included in Analysis

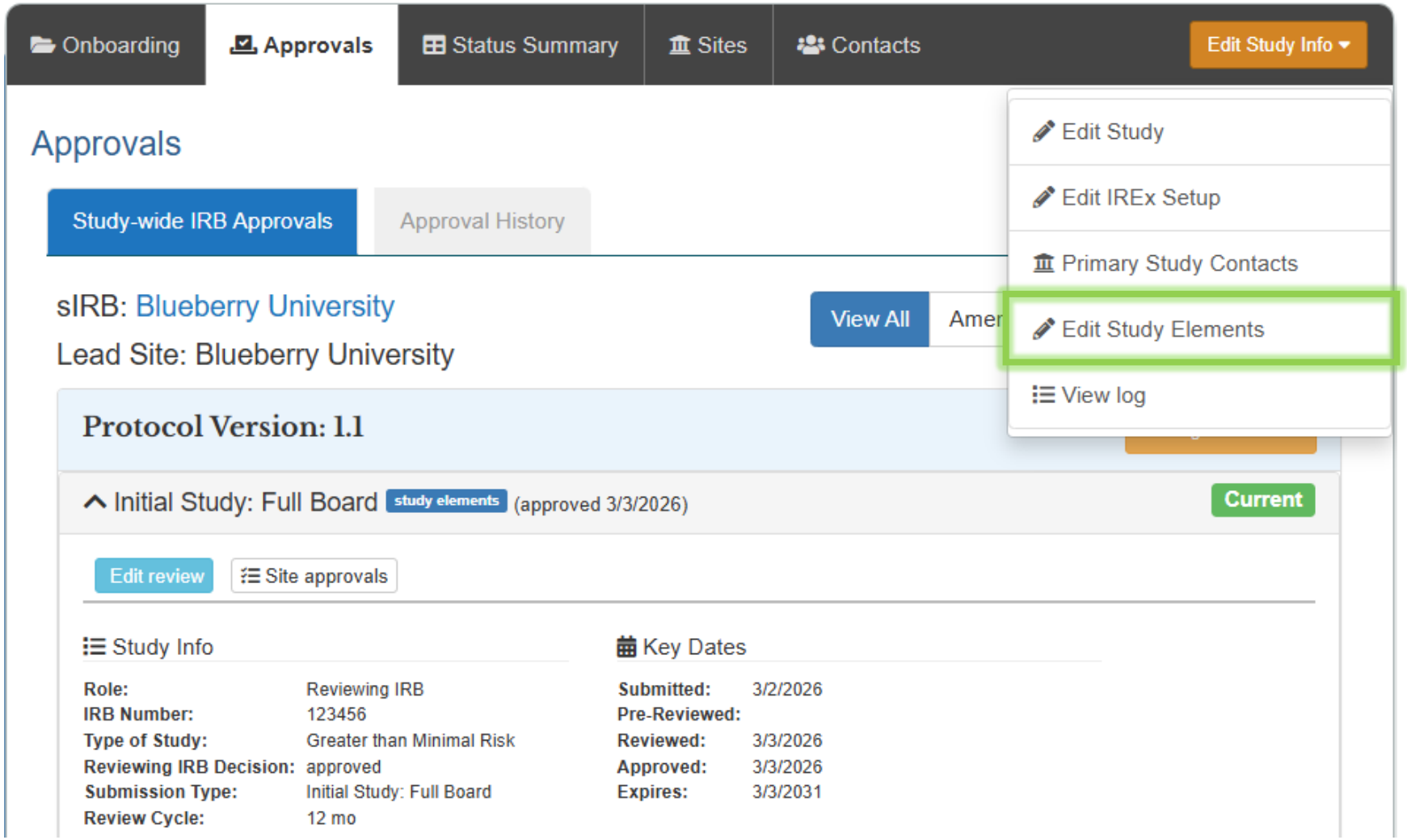
	BEFORE	AFTER
Studies	57	106
Total Relying Sites	269	277
Unique Relying Sites	120	135

Automating Local Considerations

Feedback – Thoughts, Comments, Questions, Suggestions?

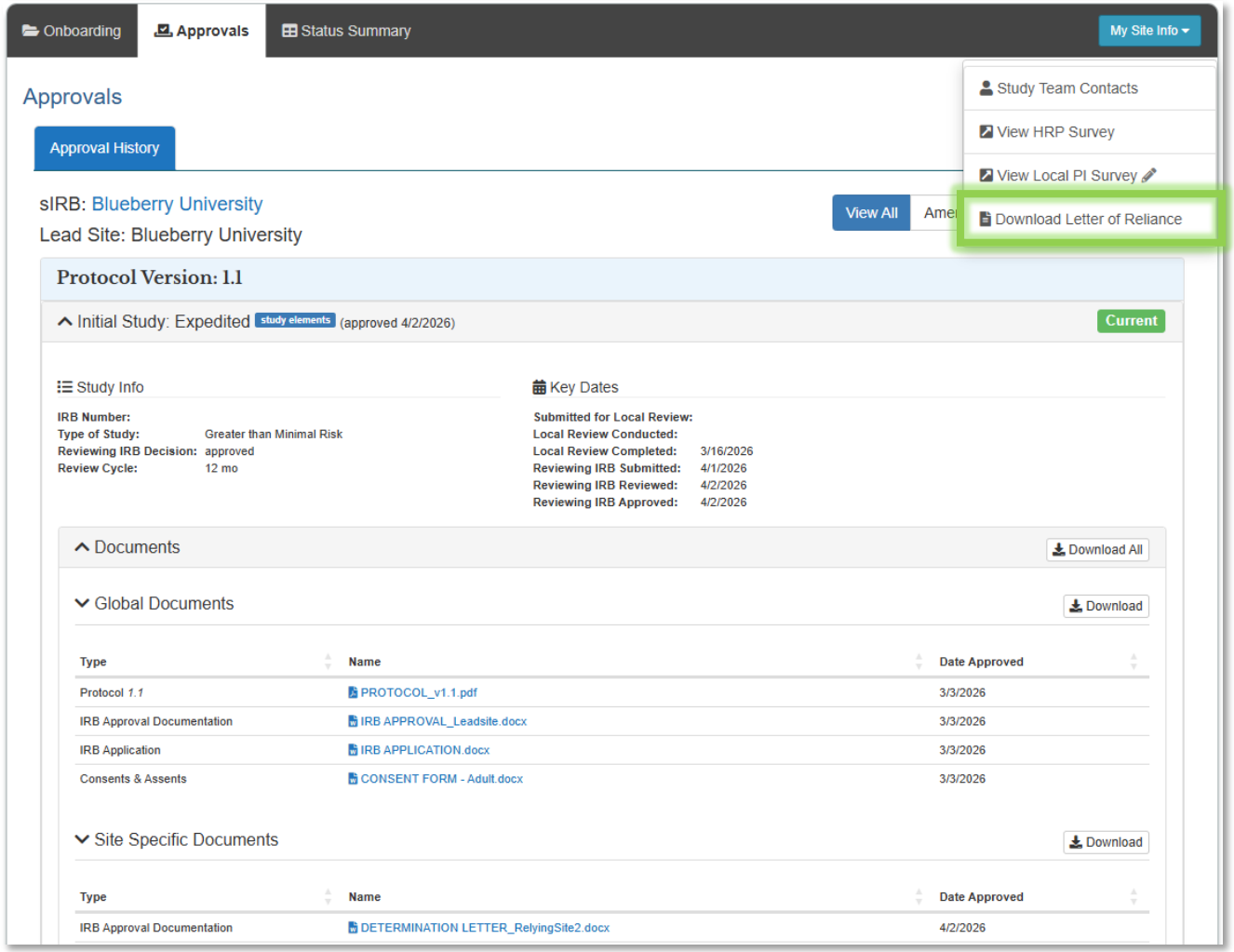
New IREx Features

Reviewing IRBs can now Edit Study Elements at any time



- Completed surveys do *not* change when study elements are edited.
- **Tip:** Email sites that have completed their HRP Survey to edit their HRP Survey if new elements are indicated!

Letter of Reliance Available for Relying Sites



IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Official Documentation of Reliance

March 16, 2026

Dear all,

This letter serves as documentation that **Carnegie University Medical Center** has agreed to rely on the **Blueberry University** IRB using the following agreement(s):

- SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement
- Blueberry Broad Indemnification

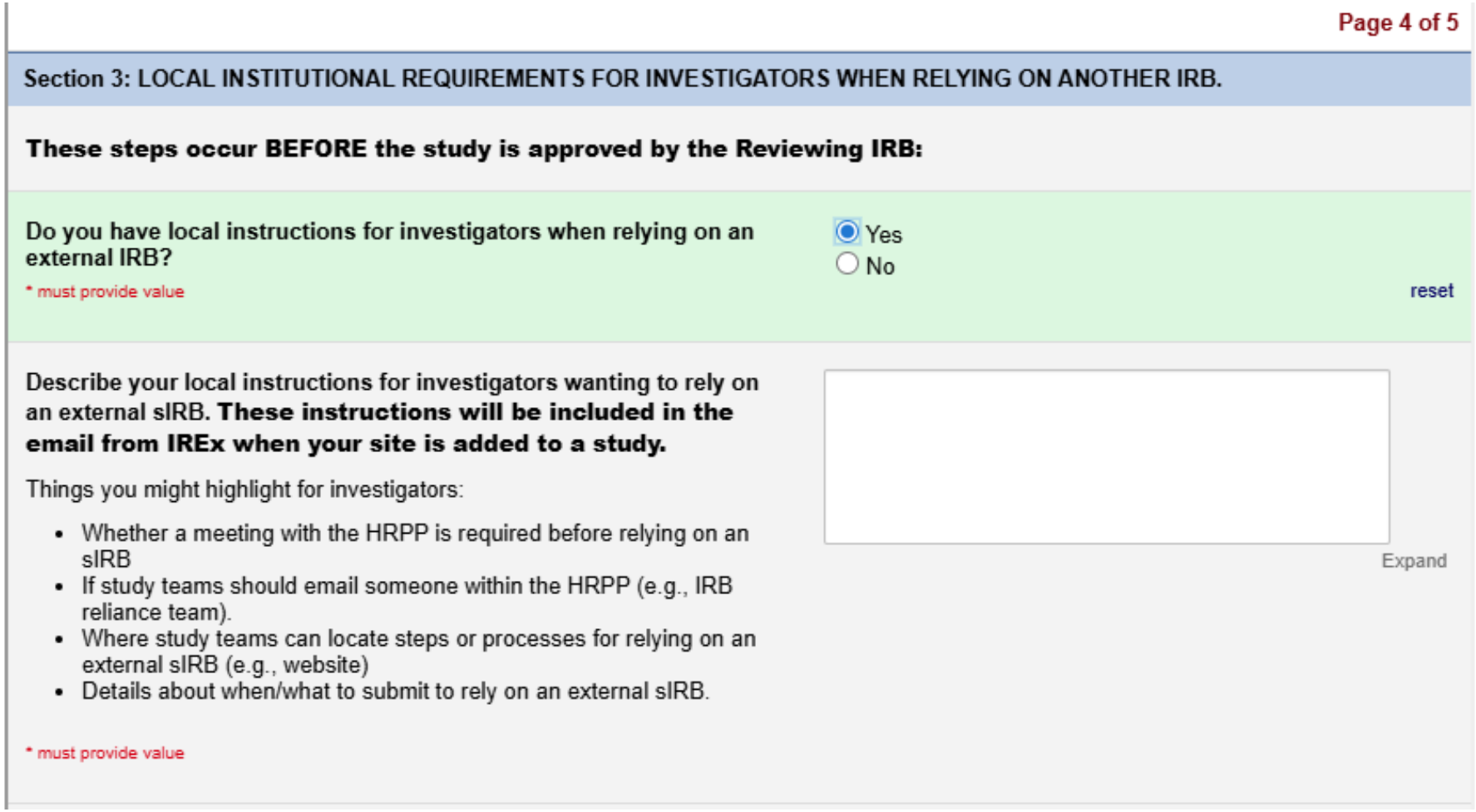
Study Title	A dashboard demo study
IREx Project ID	11919771
Reviewing IRB	Blueberry University *(FWA #00043543)*
Relying Institution	Carnegie University Medical Center *(FWA #12345678)*
Study Link	https://www.irbexchange.org/project/11919771

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

Institutional Profile Section 3 Updated

- Study teams often need ***extra guidance*** on initial steps to initiate reliance.
- We want to automate this process.
- Starting in July, the information entered here will be included on the 'IREx Access and Single IRB Instructions' email.
- Action required: HRPPs, update your IP Section 3!



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

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

Do you have local instructions for investigators when relying on an external IRB?

* must provide value

(•) Yes
( ) No

reset

Describe your local instructions for investigators wanting to rely on an external sIRB. These instructions will be included in the email from IREx when your site is added to a study.

Things you might highlight for investigators:

- Whether a meeting with the HRPP is required before relying on an sIRB
- If study teams should email someone within the HRPP (e.g., IRB reliance team).
- Where study teams can locate steps or processes for relying on an external sIRB (e.g., website)
- Details about when/what to submit to rely on an external sIRB.

Expand

* must provide value

Institutional Profile Section 3 Updated

- Sample of your local instructions for investigators within the institutional profile

Example of your local IRB instructions that will be inserted in IREx's "IREx Access and Single IRB Instructions" email when your site is notified about a study in IREx.

Next Steps:

The overall/lead site approval is available in IREx on the Approvals tab of the study page. Use the Onboarding tab to view any additional documents shared by the sIRB and/or lead study team. Use these documents to prepare your local submission and initiate the reliance process at your site.

1. **LOCAL HRPP facilitates agreement execution:**
   The study requires the following items to be completed, which can be facilitated by the local HRPP, as needed:

Agreement/Resource	Status
SMART IRB V3 Agreement: A national, master reliance agreement supporting single IRB review.	Completed
Frog Letter of Indemnification	Completed
IRB Reliance Exchange (IREx): A single IRB documentation and communication portal. *This is a web-based platform, not a reliance agreement.*	Completed

2. **STUDY TEAM prepares local consent form and submits to local HRPP for review.**
   a. If applicable for the study, review the approved informed consent template(s) in IREx and insert your site-specific information.
   b. Seek guidance from your HRPP/Research Office/IRB regarding what needs to be submitted to your local HRPP to rely on the Reviewing IRB. Most HRPPS require a local submission to complete their documentation in IREx.
   c. Your Local IRB's Instructions:

Investigators wishing to rely on an external IRB must FIRST contact the IRB office to schedule a meeting with the IRB. Email IRB@yoursite.org to schedule a consult.

Featured Speakers: IREx Study Managers

Featured Speakers

Mythili Murala, MS, ACRP-CP

Program Coordinator, CONNECT

Nationwide Children's Hospital

Kayleigh Humphries, MPH, CCRP

Operations Study Coordinator, CONNECT

Nationwide Children’s Hospital

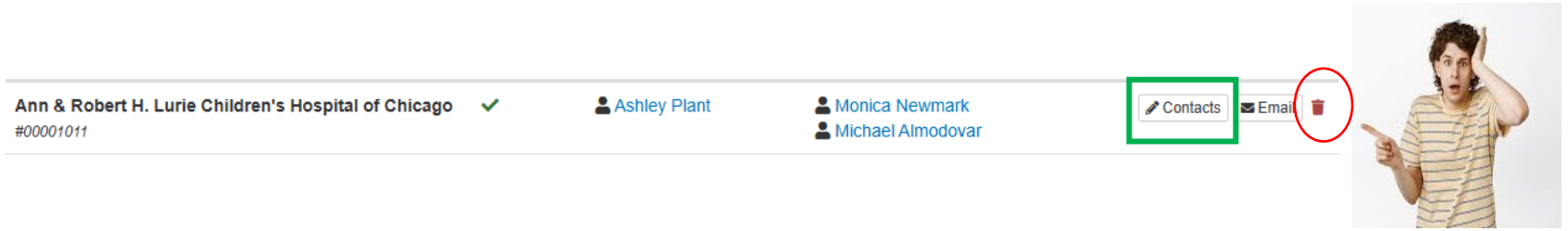
IREX

TIPS AND TRICKS

CONNECT Studies: Benefits of Using IREx

- Centralizes study site contacts and allows for edits
- Supports complex reliance arrangements (e.g., when 1 PI engages 2 FWAs)
- Allows for flexibility at the local sites – study teams can begin documenting in IREx and come back to make edits/changes after they discuss with their local IRB (as needed)
- Makes it easy to update the study information as things change (study names)
- Provides resources for relying sites
- Make it work for your team – IREx offers flexible set up options for coordinating centers / lead study teams

EDIT, OR REMOVE STAFF



When using the IREX system to add or update staff information, there is one important guideline to keep in mind:

Be cautious around the "Delete" button

A common mistake for new users is accidentally selecting *Delete* when intending to edit/Delete a staff entry. To update information, please use the **pencil icon** located next to the Contacts section. This ensures that existing records are modified rather than removed.

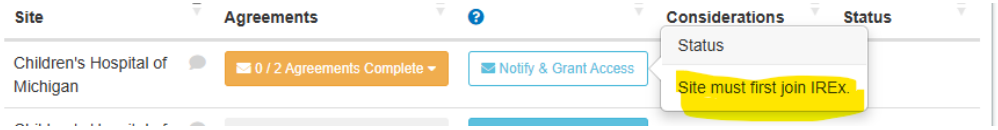
The good news is that IREX coordinators are typically able to assist with recovering deleted documents.

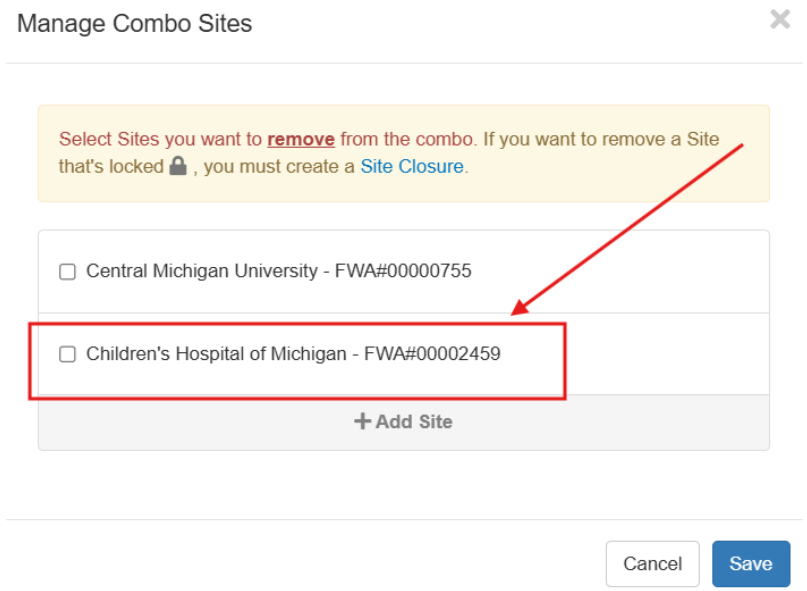
However, the process may involve unnecessary stress and delays before everything is restored.
Taking a moment to double check before clicking can help avoid these issues altogether.

TIP : So remember:
Pencil = edit.
Delete = chaos.

LINKED SITES-IRB

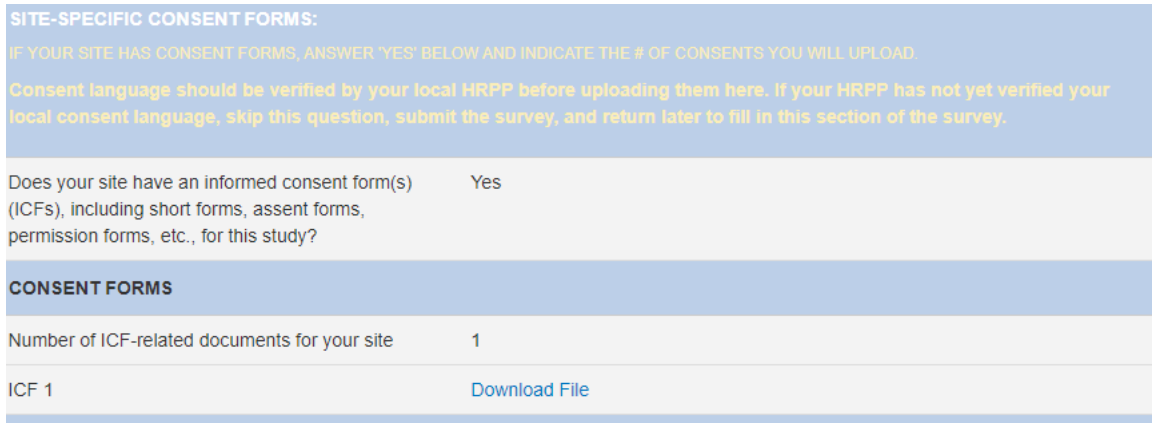
- When working with linked sites in the IREx system, it is important to remember that the sites are connected for a specific reason.
- If you connect two sites and one of the linked sites cannot establish reliance, for example, because it does not have its own IRB, this can affect the IRB reliance process for the site you intend to establish reliance with.
- When sites are linked, reliance is generally expected to be established for both sites. If one of the sites does not have its own IRB, it is important to contact the site that does have an IRB to determine whether they have the capacity and willingness to process the reliance documentation on behalf of the linked site as well.
- If the answer is no, then removing the linked site becomes necessary. Until the issue is resolved or the site can be removed, the reviewing IRB may not proceed with processing the approval.
- **TIP : Ensure your PI is from the same site where you can establish the reliance from and can enroll patients at.**





UPLOADING ICF-UNAPPROVED VERSION (SITE QUESTION)

- We recently received a question from a site about uploading the Informed Consent Form (ICF) in the IREx portal. This situation can sometimes be confusing because, when sites establish reliance in IREx, the full IRB approval process may not be completed yet.
- The site was concerned about uploading an unapproved ICF to the portal and was unsure whether it was appropriate to proceed.



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
CONSENT FORMS	
Number of ICF-related documents for your site	1
ICF 1	Download File

Here's the key guidance:

- It is perfectly acceptable to upload the ICF in IREx even if Single IRB of record approval is not yet finalized.
- If the local IRB /Site's IRB has already reviewed and approved the ICF, simply select "Yes" and upload the document.
- If the local IRB /Site's IRB has not yet reviewed the ICF, you can skip that question for now, submit the form, and come back to complete it later.

TAKEAWAY: This flexibility allows sites to continue progressing through the IREx workflow without delaying the reliance process.

STUDY TITLE CHANGE

- We recently had a study title change for one of our studies. When we requested the update, the study title in the IREx system was changed promptly. However, we noticed an issue when generating and sending IREx Agreements to participating sites.

- The generated email still showed the subject line:
  “CONNECT2111 - IREx Access and Single IRB Instructions” instead of the updated title:
  “TarGeT-L - IREx Access and Single IRB Instructions.”

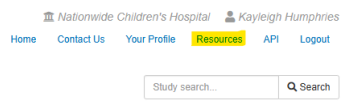
- When our IRB coordinator reviewed the study settings in IREx, she found that while the study title had been updated, the short title field still listed the old title (CONNECT2111).

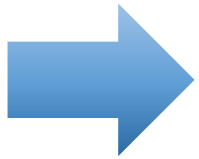
- **Tip: Updating the Short Title field to TarGeT-L resolved the issue. Once the short title was updated, the automatically generated emails reflected the correct study title moving forward.**

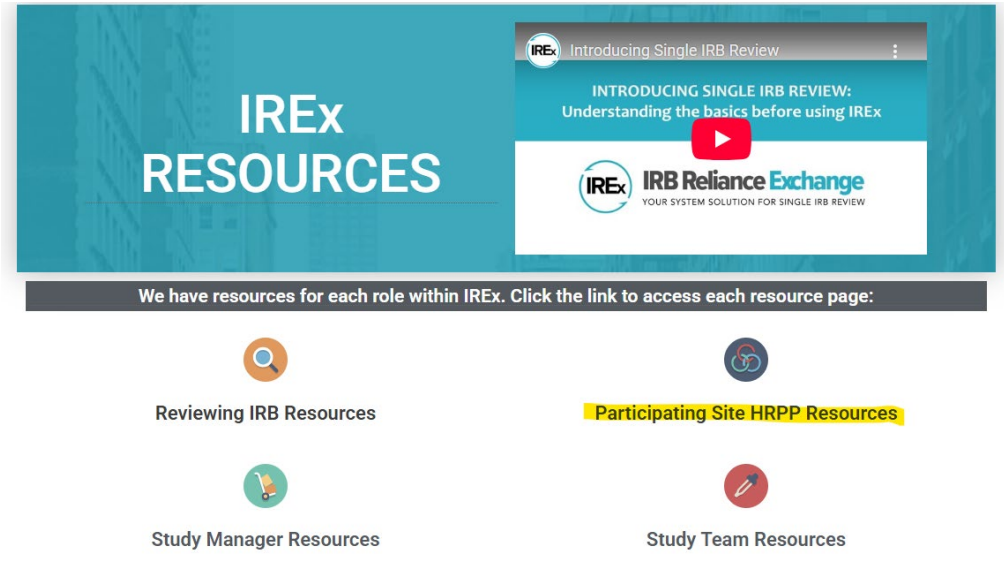
RESOURCES FOR SITES NEW TO IREX

- Issue: we recently had a new site come on board, but the staff hadn't worked with IREx before
  - This resulted in a lot of back and forth as I tried to instruct the site and they would come back with more questions
  - There was also confusion about how the site's IRB navigates IREx, which delayed establishing reliance with the site
- Solution: IREx has a lot of resources to help the site's IRB and site staff navigate IREx
  - Guides and videos for all stages of the process (agreements, surveys, etc.)

IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW







DIVVYING UP RESPONSIBILITIES

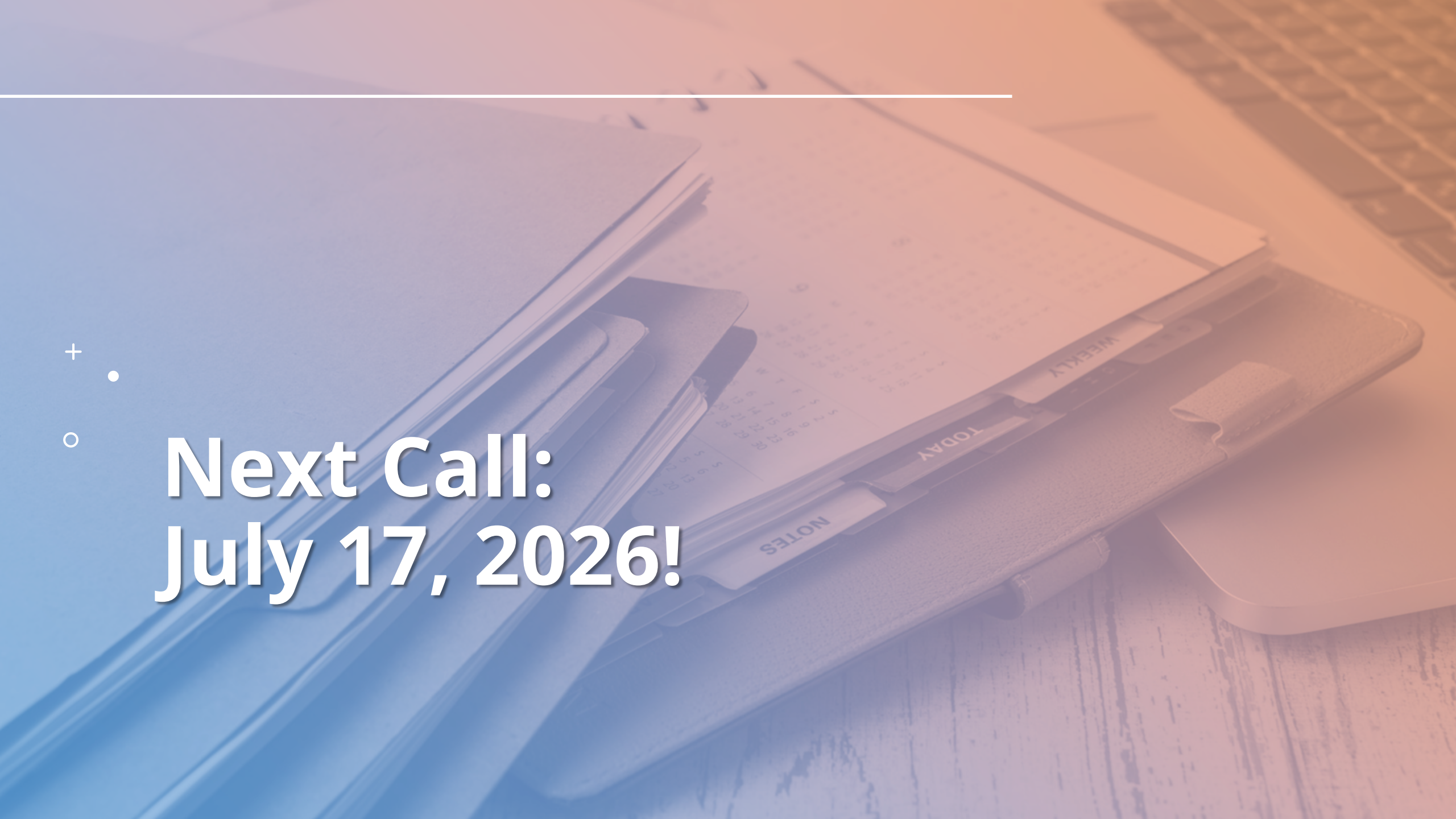
- CONNECT studies are typically assigned to one coordinator, but we add everyone as a study manager for coverage purposes
- However, there is one study (CONNECT1906) where, due to the shear number of enrollments we have had, we had divvy it up by site to help balance workload (and staff sanity)
- The best system is the one that **works best for your team**, but allows for your team to pivot if needed

Current & Upcoming Feature Development

Upcoming IREx Features

- SMART IRB Indemnification Addendum tracking
- Improve relying site usability via progress bar
- Allow Lead Study Teams to request changes to HRP / PI Surveys within IREx
- How can IREx better support you? Chat or email us your ideas or feature suggestions!

Poll: Allowing Lead Study Teams to Create Studies in IREx



Next Call: July 17, 2026!