



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



- System Website
- Development Support

Kaysi Quarles



- Manager, Application Development

Joshua Milford



- System Direction & Evaluation

Emily Serdoz



- System Development

Linda Tan



- Application Developer

Jason Tan



- Application Developer

Evan Wimberly



7.19.2024 QUARTERLY CALL AGENDA



Welcome & Announcements



System Enhancements / Features



IREx Metrics & Satisfaction Survey



Upcoming Feature:

Supporting Exception from Informed Consent (EFIC) studies in IREx

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



October 18, 2024

January 17, 2025

(new Zoom information will be sent)



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Announcements

New Team Members



- Study Support
- User Training

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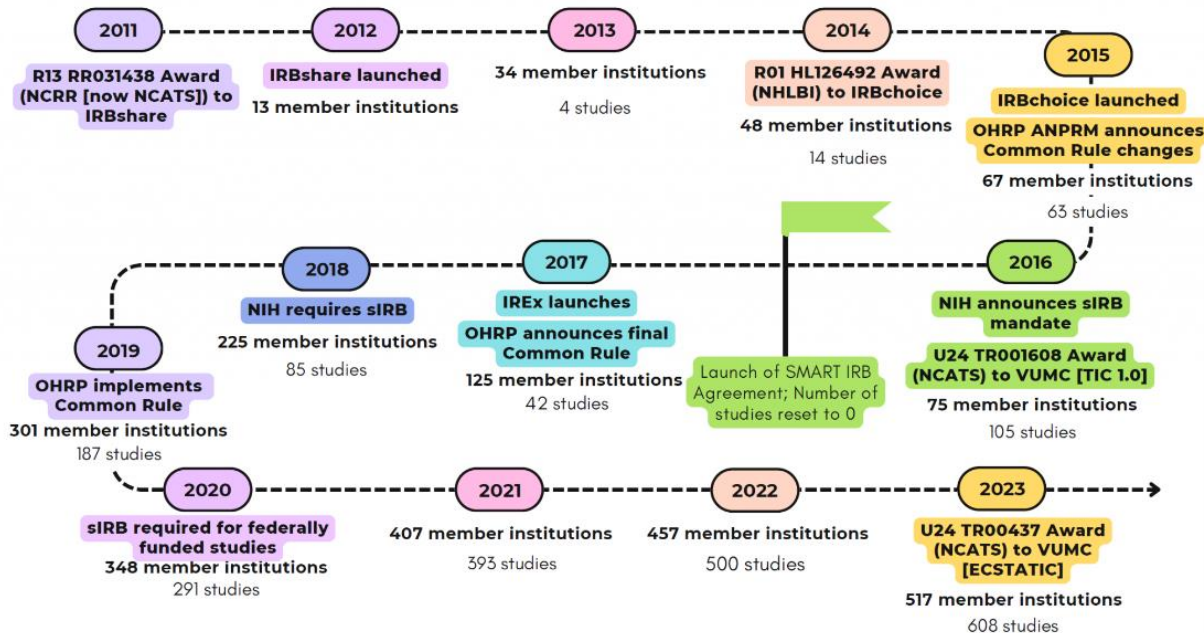


New / Revised IREx Materials



FOR ALL USERS: [IREx History](#)

History of NIH Support for Vanderbilt's Single IRB Platform



FOR STUDY MANAGERS

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





FOR REVIEWING/SINGLE IRBS

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

For RELYING SITE HRPPs: [Relying Site HRPP Workflow](#)

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

Updated Videos Available via IREx YouTube Channel



FOR ALL USERS: *NEW* [Capturing Local Considerations in IREx for the Life of the Study](#)

FOR STUDY MANAGERS

- [Using IREx as the IREx Study Manager](#)
- [Intro to sIRB Review & IREx Steps for Relying Site Study Teams](#) *(Send to your study teams!)*
- [How do I add a Site Amendment approval in IREx?](#)
- [How to add and edit Relying Sites in an IREx Study](#)

The screenshot displays the YouTube channel for IRB Reliance Exchange 'IREx'. The channel has 43 subscribers and 30 videos. The video list includes:

- 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 Approval in IREx** (1:51)
- Using IREx as the Lead Study Team or Coordinating Center - AKA - The IREx Study Manager** (14:25)
- Introduction to Single IRB Review and IREx -For Relying Site Study Teams-** (6:40)
- How to add a Continuing Review Approval** (4:25)
- How to Create a Study in IREx** (7:27)
- How to add a Study-wide Amendment Approval** (4:06)

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What's New?

The IREx Onboarding Tab

About The IREx Onboarding Tab

- **Goal:** To allow the sIRB and Lead Study Team/Study Manager (LST/SM) to share supplemental documents or guidance to help PSites complete their local submission and initiate the reliance process.
- **Why do PSites need these documents?**
 - PSites receive single IRB instructions from IREx when contacted about a study
 - PSites access the lead site approval (protocol, consent template, etc) by logging into IREx
 - But sometimes sites need extra guidance or other documents that aren't in the lead site's 'approval' documents
- **Sample Document Types:**
 - Single IRB Instructions (generated by IREx or uploaded by the sIRB)
 - sIRB SOPs/Communication Plans
 - Consent form instructions
 - Template consents/Part 2 Consent (if an sIRBs does not share with the lead site's initial approval)
- **Released May 2024**

Onboarding Tab: Uploading Documents

➔ Complete IREx Setup

IREx Project Settings

Confirm Site Instructions for completing the Single IRB Process

Please confirm the instructions sites should receive when they are granted access to the study in IREx. This email is triggered from the Status Summary tab.

Would you like to send sites the default IREx instructions for completing the sIRB process or attach custom instructions?

Use default IREx instructions
 Attach custom instructions

Would you like to provide additional documents to facilitate the site's local submission process (e.g., Part 2 consent form, SOPs, instructions)?

Yes
 No

Upload Additional Document(s)

Choose a file or drag it here (Required)

Additional Documents

Site-specific consent form guidance.docx	✕
sIRB Communication Plan.docx	✕
sIRB SOP.docx	✕
Part II Consent.docx	✕

Onboarding

Approvals Status Summary Sites Contacts Edit Study Info

Onboarding

sIRB Instructions

sIRB Instructions

+ Add Document

Additional Documents

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.

Site-specific consent form guidance.docx	Archive
sIRB Communication Plan.docx	Archive
sIRB SOP.docx	Archive
Part II Consent.docx	Archive

Archived Documents

DeviceManual.docx	Restore
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Onboarding Tab: Directing PSites

SIRB Instructions now reference the Onboarding tab.



Dear HRPP(s) and Study Team,

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

PI Goodall has been listed as an investigator at Goodall University (FWA: 4563287895). All study team members included on this email now have access to the study in IREx.

Study Title	SMARTv3_disabled_v2_LC_2024May14
Study Link	https://test.irbexchange.org/feature-branch/public/project/8550460
Reviewing IRB	Mellon University Medical Center
Reviewing IRB Contact	Mellon Liaison (liaison@mellon.cdu)
Study Manager	Study Manager Mellon

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

Onboarding Tab: Relying Site Access

Onboarding Approvals Status Summary My Site Info

Onboarding

sIRB Instructions

[sIRB Instructions](#)

Additional Documents

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.

- [Site-specific consent form guidance.docx](#)
- [sIRB Communication Plan.docx](#)
- [sIRB SOP.docx](#)
- [Part II Consent.docx](#)

Archived Documents

Onboarding Approvals Status Summary My Site Info

Approvals

Study-wide IRB Approvals

sIRB: [Carnegie University](#) View All Amendments Continuing Reviews

Lead Site: Carnegie University

Protocol Version: 1.1

Initial Study: Full Board (approved 2/2/2024) Current

Study Info

Role: Reviewing IRB
IRB Number: 654321
Reviewing IRB Decision: approved
Submission Type: Initial Study: Full Board
Review Cycle: 12 mo

Key Dates

Submitted: 2/1/2024
Pre-Reviewed: 2/2/2024
Reviewed: 2/2/2024
Approved: 2/2/2024
Expires: 2/2/2025

Global Documents

Type	Name	Date Approved
Protocol 1.1	PROTOCOL_v1.1.docx	2/2/2024
IRB Approval Documentation	IRB APPROVAL_Leadsite.docx	2/2/2024
IRB Application	IRB APPLICATION.docx	2/2/2024
Consents & Assents	CONSENT FORM - Assent.docx	2/2/2024
Consents & Assents	CONSENT FORM Spanish.docx	2/2/2024
Investigators Brochure	INVESTIGATOR'S BROCHURE_1.0.docx	2/2/2024

[Download All](#)



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IREx Metrics

July 2024

2024 Q2 Metrics Update



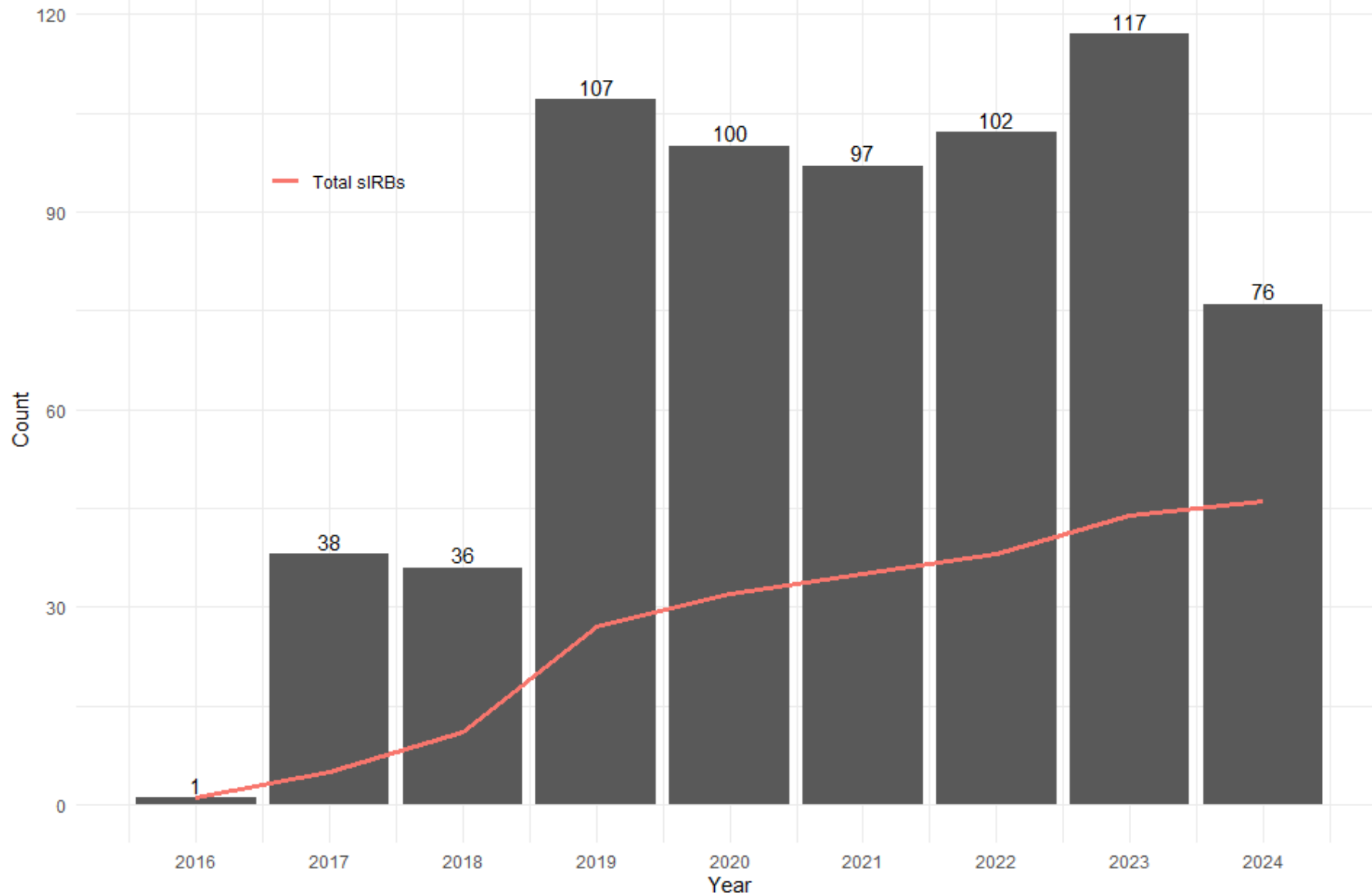
- **92%** of sites in IREx have completed their Institutional Profile
- **88%** of IREx sites have indicated reliance
- **87%** of sites have ceded review and have approval posted to IREx
- **33 out of 46** single IRBs are using IREx for more than one study
- **12** median days from initial sIRB submission to sIRB approval for relying sites (*not including local review time*)

2024 Q2 Metrics Update



- **512** unique participating sites
- **4076** 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

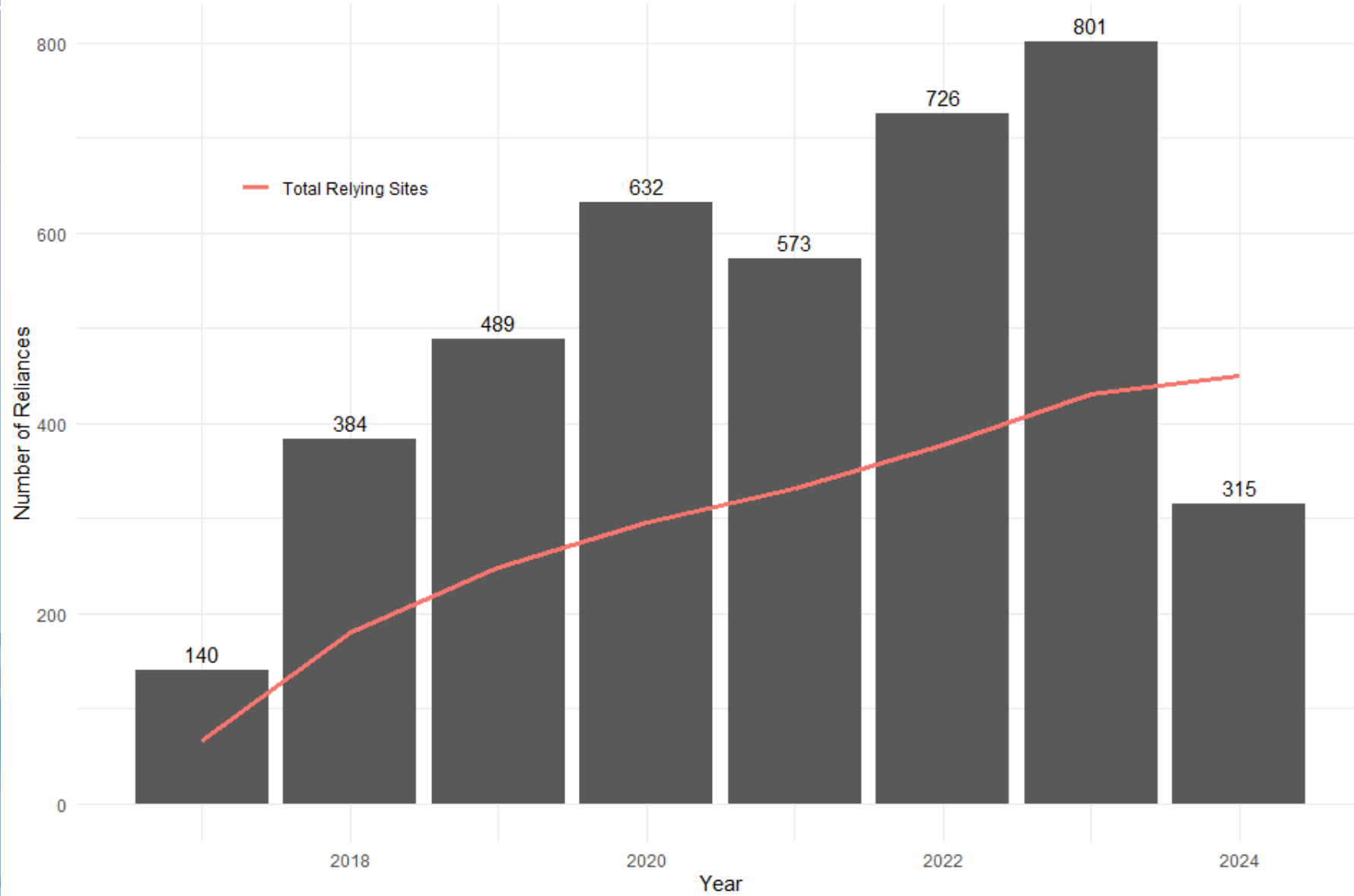


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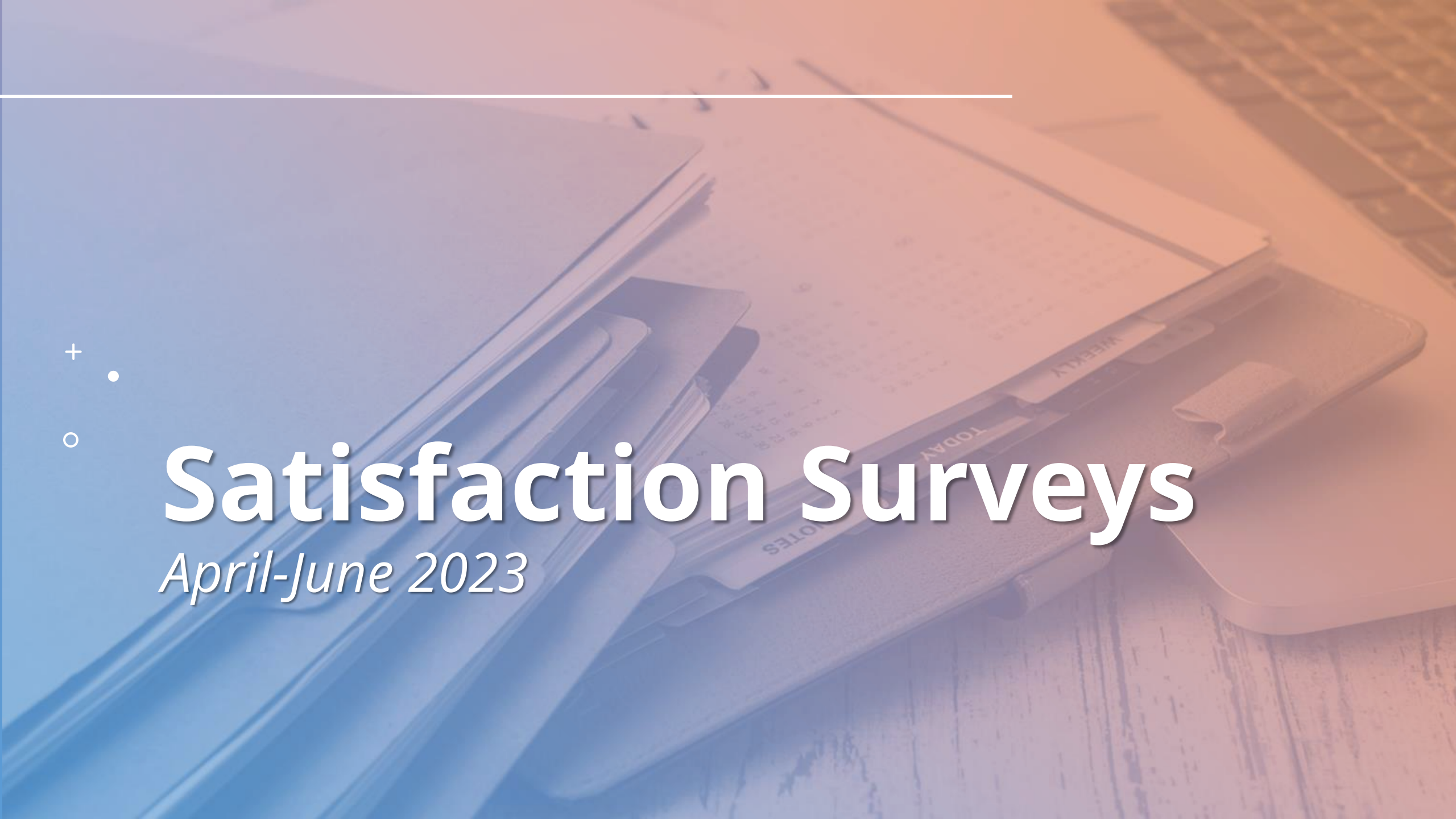
Relying HRPPs Use of IREx



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Satisfaction Surveys

April-June 2023

Satisfaction Survey: Methods & Response Rates



- **WHO to survey**

- For the **sIRB**, survey sent to the Primary Contact listed on the study
- For the **Relying HRPP**, survey sent to the Relying HRPP contact who signed the HRP Survey
- For the **LST/SM**, survey sent to the 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** surveyed after lead site approval posted to IREx
- **Lead Study Teams (LST)/Study Managers (SM)** surveyed after ~25% of their PSites received initial approval
- **Relying HRPPs** surveyed after receiving initial approval on a study

- **Survey Completion by Respondent**

- **sIRBs**: 6 completed/15 sent; 40% response rate
- **LST/SM**: 20 completed/40 sent; 50% response rate
- **Relying HRPPs**: 22 completed/55 sent; 40% response rate

sIRB Feedback



- Both sIRB and LST reported that they:
 - Add/remove sites
 - Upload initial approval
 - Grant site access
 - Export local considerations
- Most common difficulty factor: educating lead study team
- Tasks reported as easy
 - Completing IP
 - Using getting started checklist
 - Indicate required reliance agreements
 - Confirming SSRP

How satisfied are sIRB users?



- 4/4 respondents who reported having to use **admin support** were very satisfied
- 5/6 respondents were **satisfied/very satisfied** with IREx for their study
- 5/6 respondents reported IREx **made their role easier/significantly easier**
- Majority of respondents said **using IREx takes less time** than for studies where IREx is not used

When is IREx a good fit?



- 5/6 reported they use IREx when they feel a study is a good fit
 - At least 4-5 sites
 - Appropriate site type (e.g. primarily CBOs relying = not a good fit)
 - When participating sites are already using IREx

*“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.**”*

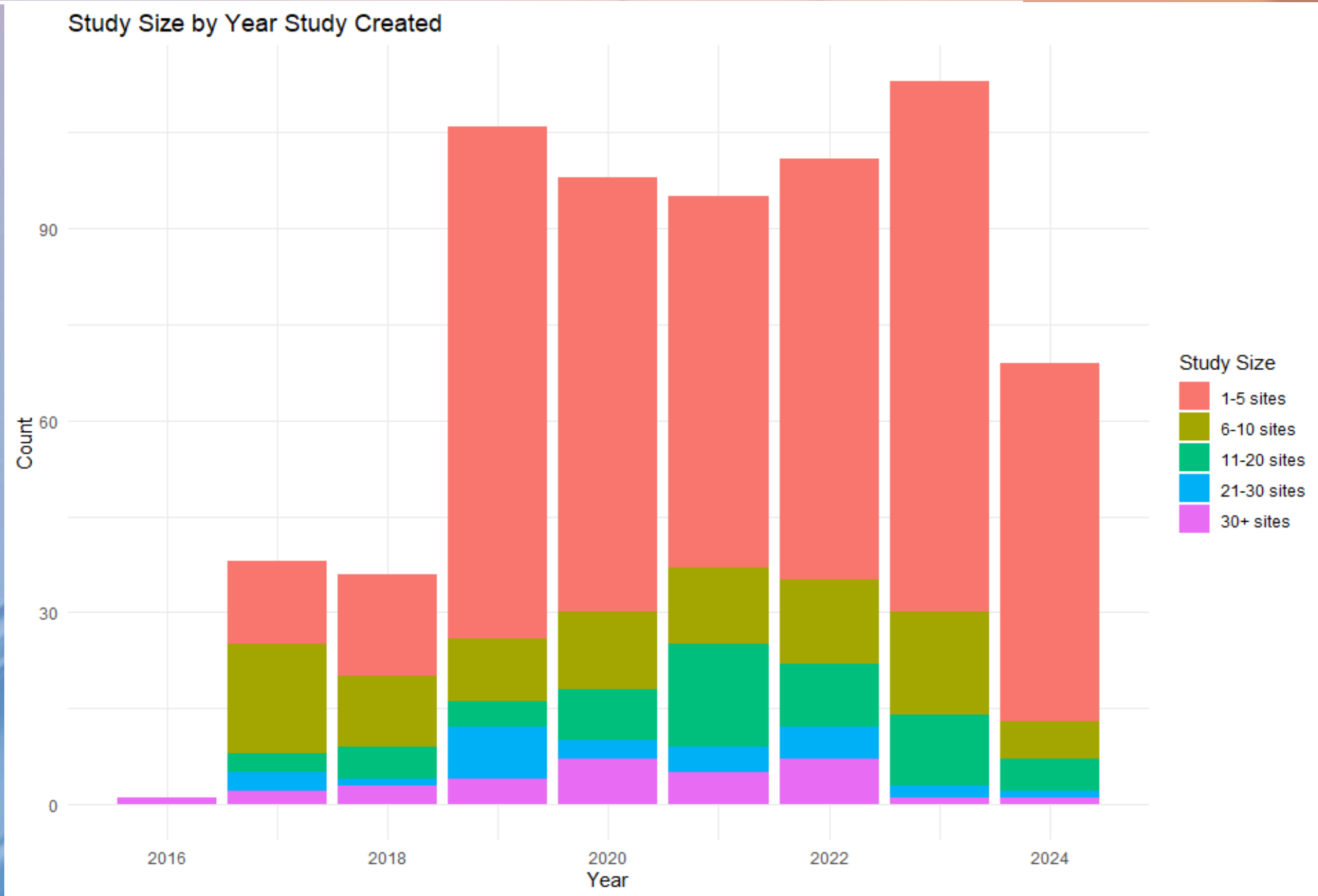
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*We have had a few of our larger study teams and consortiums begin to use IREx within the last year. **They have indicated that they can't imagine having to do the reliance process any more through email like they had in the past.** One consortium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

IREx is used for studies of all sizes!



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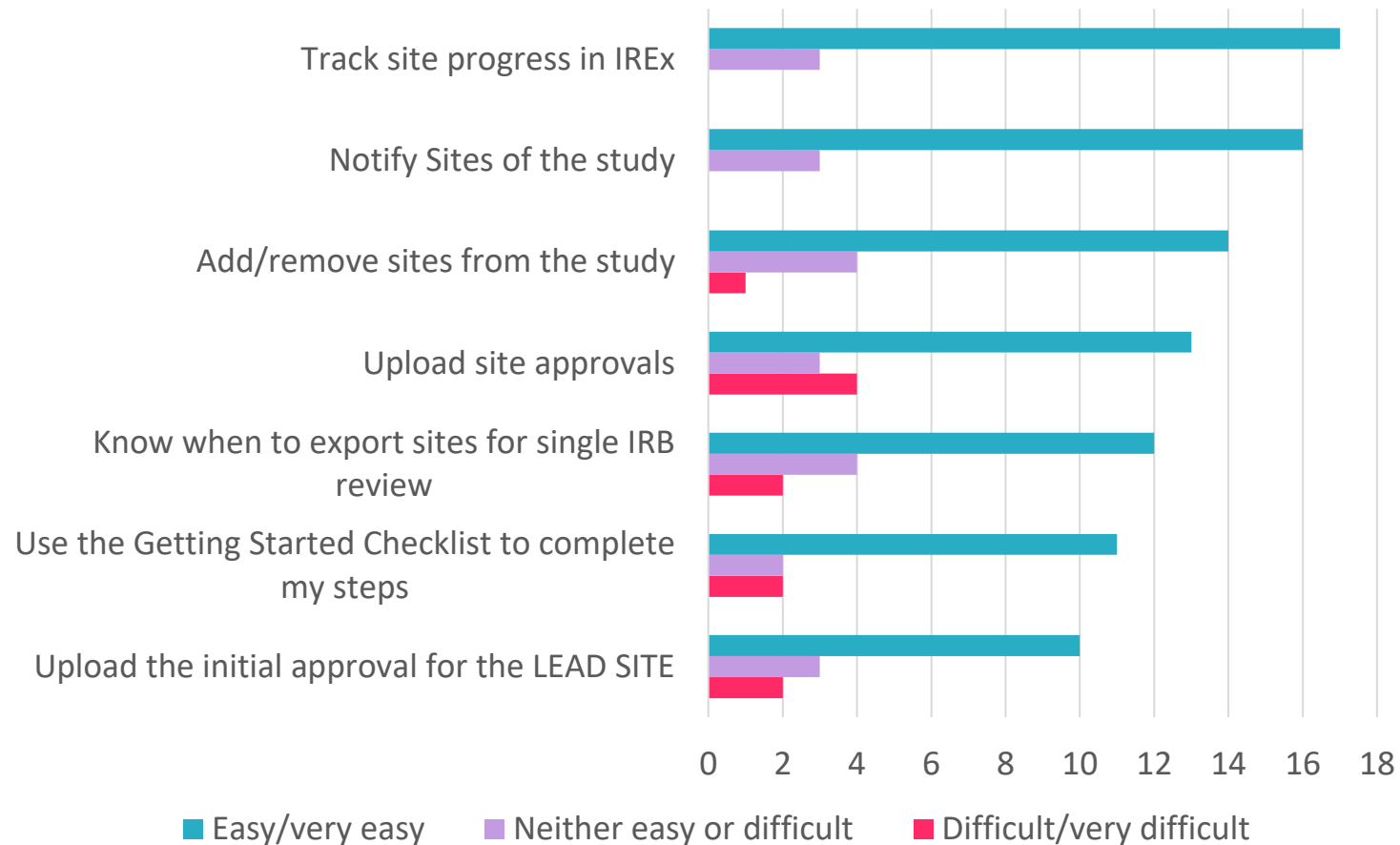
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How satisfied are Study Managers?



- 85% of respondents reported:
 - Being satisfied/very satisfied with using IREx for their study
 - IREx made role of LST easier
 - **Would recommend** other LSTs use IREx
- 60% of respondents reported that IREx takes **the same or less amount of time** as studies that do not use IREx

How easy are SM tasks?



Sticking points for SMs



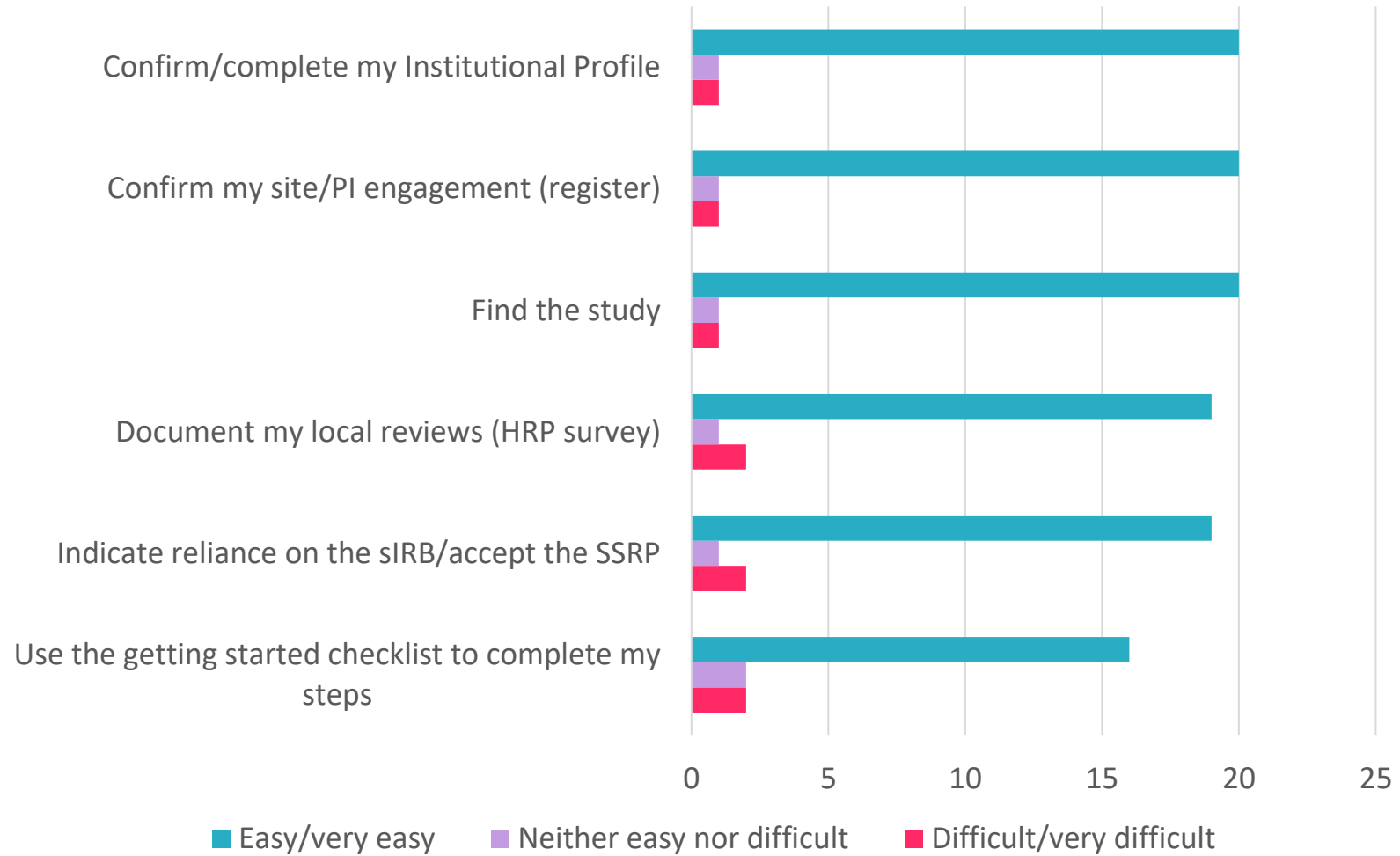
- Most commonly reported factors that make IREx difficult to use
 - Getting sites to complete their steps in IREx
 - Local site variation in process for relying on an sIRB
 - Resistance from site HRPPs
- Difficulties with the way approvals are organized and uploading study-wide/site-specific amendments

Relying HRPPs



- 73% of respondents reported their institution is a relying site on **50+ studies**
- 86% reported using IREx **made their steps easier**
- 90% of respondents **satisfied/very satisfied** with using IREx
- Difficulty factor: helping the study team use IREx or its resources, communication with study teams

How easy are relying HRPP tasks?



Requested Features / Comments

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Feature Request/Comment	Addressed?
Allow study teams to be responsible for several elements of the questionnaires – such as uploading consent forms	Yes
Site staff being able to register themselves; being able to share study documents with sites once they are registered to the study (protocol, SIRB study approval	Yes
[As the LST, when initially adding sites and study contacts,] Adding other coordinators to IREx for each of our sites would be helpful	Yes
We'd like the local context forms to be editable through the life of the study as amendments are added	Yes
Providing cover letters and steps to send to sites to know how to complete reliance and submit to the SIRB for approval. Even if the site's HRPP is familiar with IREx, many study coordinators are not familiar with the process especially with study coordinator turn over	Yes

Requested Features / Comments



Feature Request/Comment	Addressed?
SSRP cannot be revised by relying institution, which leads to a lot of discussion off-line and requests to make edits with the reviewing IRB admin - oftentimes delaying the reliance process	Not yet
Perhaps have a way early on to include local study ID#	Not yet
Make linking sites easier to understand - especially if a site has previously been approved then wants to add an additional site (or remove).	Not yet
Frequency of email notifications (more vs. less)	Not yet

Next Steps



- Continue working on solutions for suggestions/comments
- Continue integrating satisfaction/feedback mechanisms into IREx
- Evaluate whether using IREx reduces approval times compared to studies that DO NOT use IREx

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 - **Upcoming Feature:**

Supporting Exception from Informed Consent (EFIC) studies in IREx

Upcoming Feature: Supporting EFIC studies in IREx

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Need	Feature
Capture Reviewing IRB's community consultation plan (CCP) template for sites	<ul style="list-style-type: none">• Indicate EFIC study in IREx Setup• Add document type: CCP template to lead site approval docs
Document relying HRPP acknowledgement of site's CCP	New question added to HRP Survey
Allow Relying Site PI to upload CCP	New file upload field on PI Survey
Capture Reviewing IRB acceptance of CCP for site	<ul style="list-style-type: none">• Capture submission/review/acceptance of CCP by Reviewing IRB• New "Approval Status" for CCP Accepted (distinct from "approved")• New notification noting CCP acceptance
Capture CCP Summary of Results	<ul style="list-style-type: none">• New local considerations survey: CCP Summary of Results• New notification to lead study team of CCP Summary upload complete
Capture Reviewing IRB initial approval for site	Require CCP acceptance and summary of results upload before site approval can be indicated

sIRBs can turn on EFIC study in IREx setup



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?

(Recommended) 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

When a study-wide amendment is posted to IREx, do you want IREx to notify sites to update their local considerations if necessitated by the study changes?

Yes

No

⚠ Required

Upload Community Consultation Plan (CCP) template to Lead Site Approval



The screenshot shows a document upload interface. At the top, a progress bar consists of four circular icons: a list icon, a calendar icon, a folder icon (which is highlighted with a blue arrow pointing down), and a checkmark icon. Below the progress bar, the heading "Upload Documents" is followed by the instruction "Drag file into document type or click a document type to upload." The main area contains a grid of document type buttons, each with an upload icon and a label. The "Consultation Plan Template" button is highlighted with a yellow border. The "IRB Approval Documentation" and "IRB Application" buttons are highlighted in red and marked as "Required" with a red warning triangle icon.

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			

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.

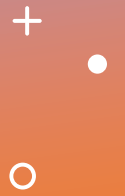
Expand

Have you REVIEWED and provided HRPP input into the Community Consultation Plan outlined by your study team? Yes No reset

* must provide value

Documentation of HRPP review/recommendations for plan (optional) Upload file

PI can upload 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

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

reset

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

* must provide value

 [Upload file](#)

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

After site completes all steps and 3/4 surveys, can capture Reviewing IRB's CCP acceptance



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 ▾	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

Capture Reviewing IRB acceptance of CCP for site



Relying Site Approvals

Anderson Med Ctr-
Anderson Outpatient

Baystate

Baystate

Baystate

Community Consultation Plan

Status

←

Date Reviewed

Date Approved

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

Capture Reviewing IRB dates around CCP submissions/review/acceptance



Onboarding Approvals Status Summary

Approvals

Study-wide IRB Approvals Approval History

View As: Baystate Health, Inc View All Amendments Continuing Reviews

Baystate Health, Inc

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>
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Display CCP Acceptance Status + Need for Upload of CCP Summary of Results



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	3 / 4 Surveys Complete ▾	CCP Accepted

- ✓ 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

Capture CCP Summary of Results on Study Team Checklist



PI 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

Study Team Member Checklist

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

Community Consultation Plan Summary

Community Consultation Plan Results

Please complete the survey below.

Thank you!

1) Please upload your Community Consultation Plan summary of results: [Upload file](#)

Submit

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

After site uploads CCP Summary of Results, display IRB approval status



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

EFIC SS Tab Approval Status

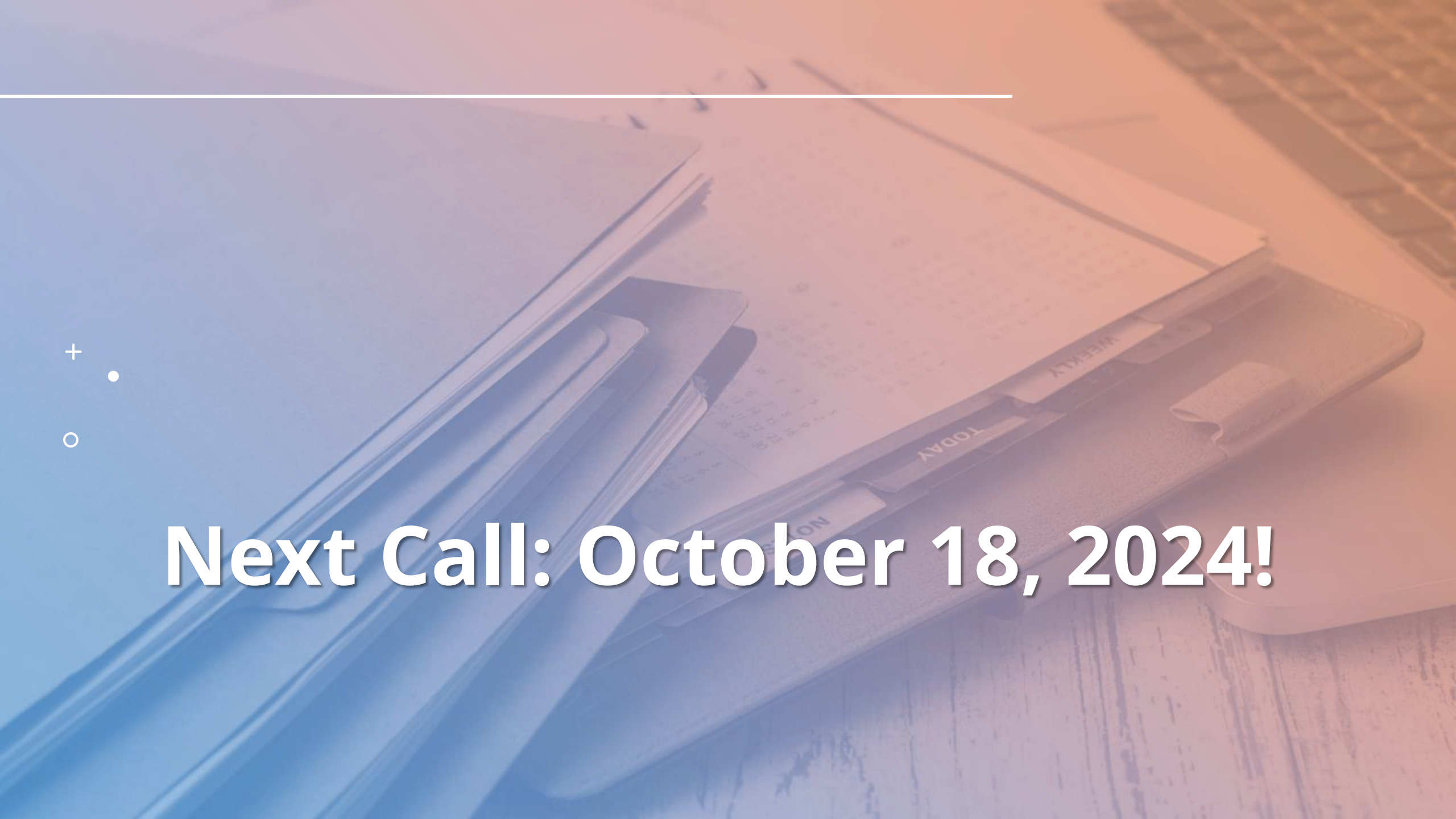


Status Summary

Export Data ▾

Search:

Site	Agreements	Reliance Decision ?	Local Considerations	Approval Status
Anderson Medical Center	2 / 2 Agreements Complete	<div style="border: 1px solid black; padding: 5px;"><p>✓ Institutional Profile <i>Confirmed: 7/10/2023</i></p><p>✓ HRP Survey <i>Completed: 7/10/2023</i></p><p>✓ PI Survey <i>Completed: 7/10/2023</i> <i>PI Attested: 7/10/2023</i></p><p>✗ CCP Summary of Results</p></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



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Next Call: October 18, 2024!