IRBRelianceExchange

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)

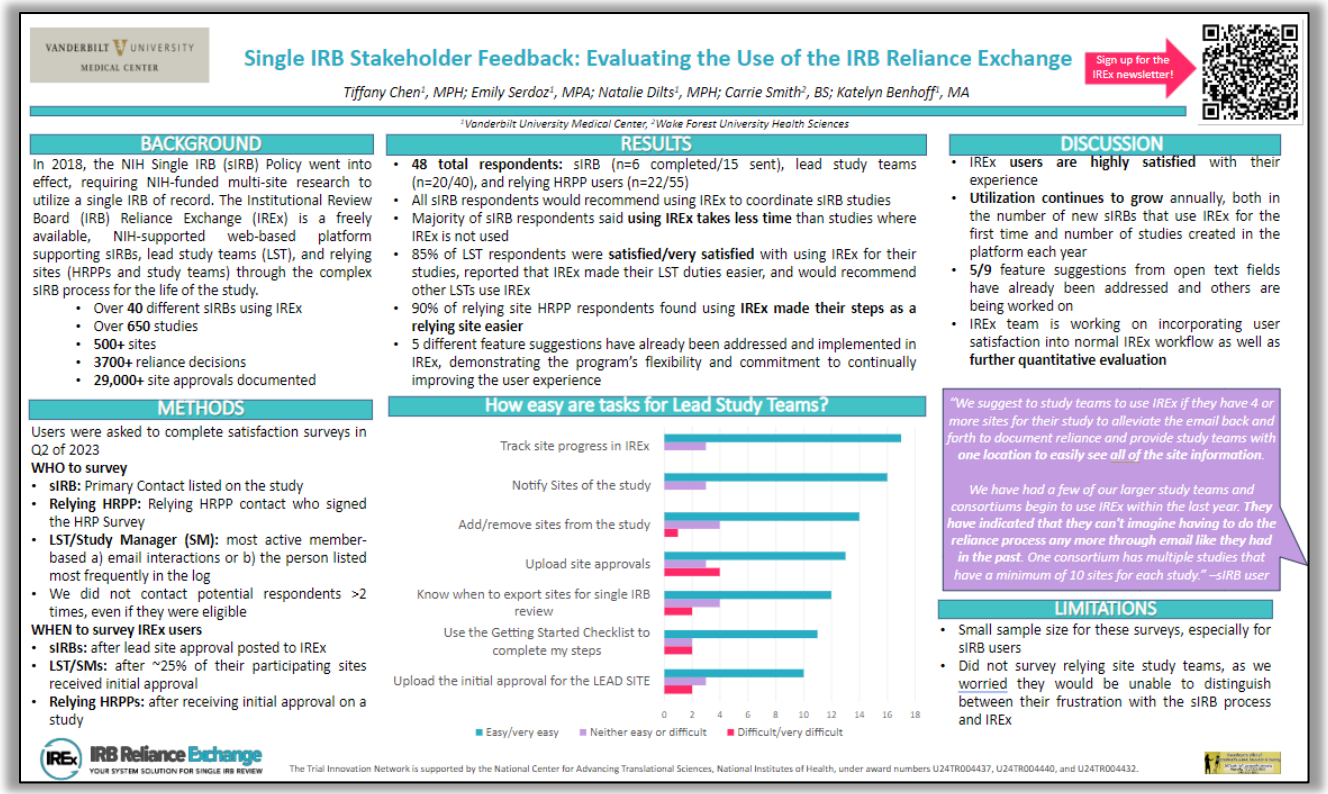
April 18, 2025

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	



VANDERBILT UNIVERSITY MEDICAL CENTER

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

Sign up for the IREx newsletter!

Tiffany Chen[1], MPH; Emily Serdoz[1], MPA; Natalie Dilts[1], MPH; Carrie Smith[2], BS; Katelyn Benhoff[1], MA

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

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

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

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

How easy are tasks for Lead Study Teams?

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**

*"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

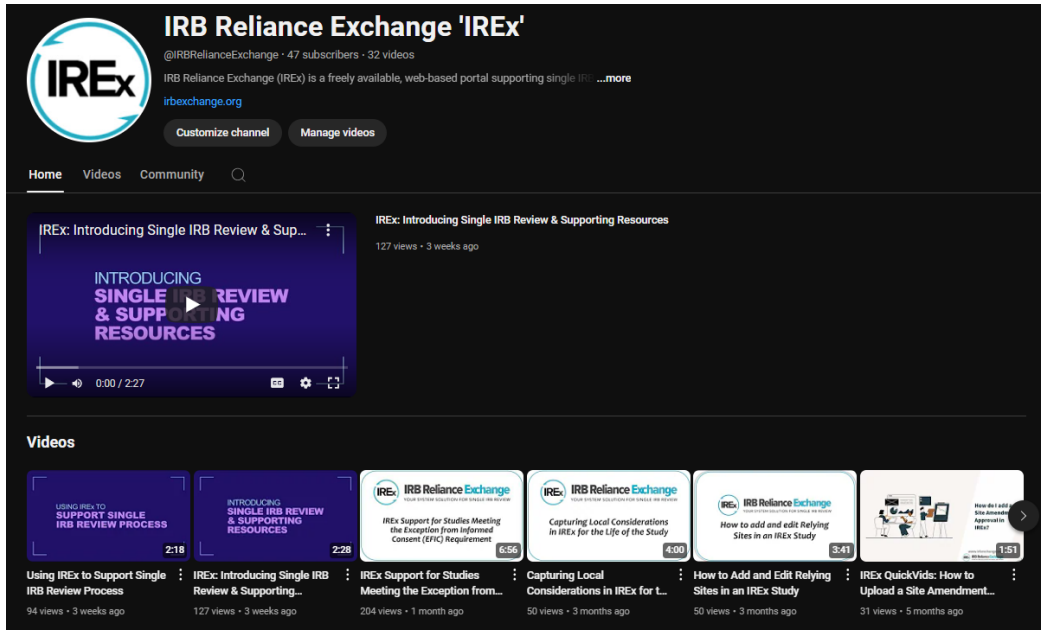
IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

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



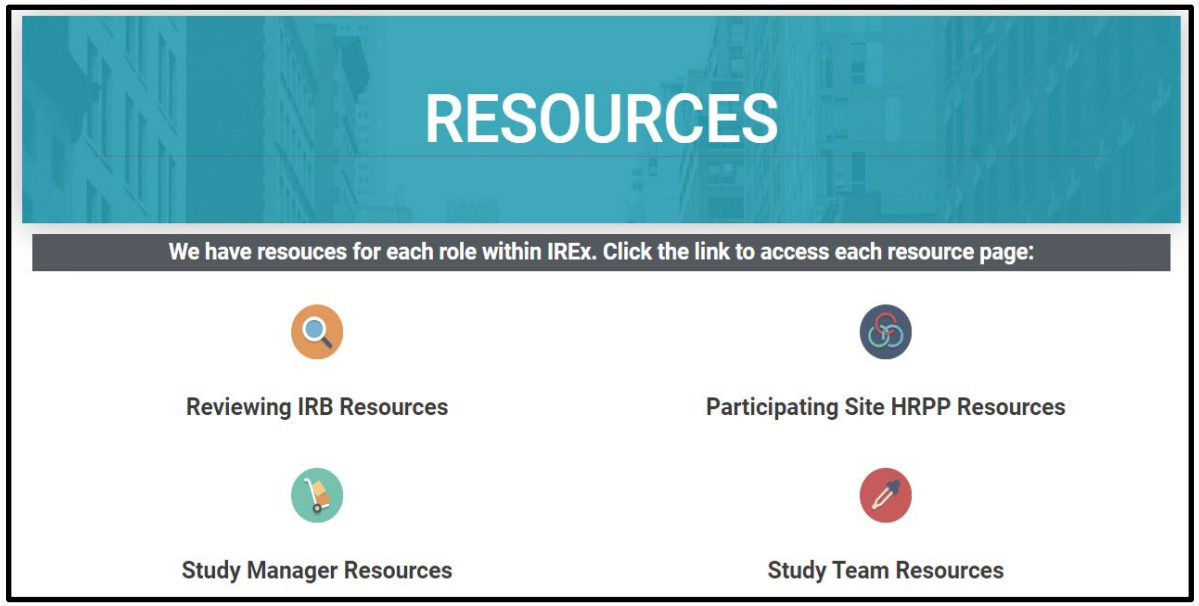
FOR STUDY MANAGERS

- 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



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?

* must provide value

(•) Yes
( ) No

reset

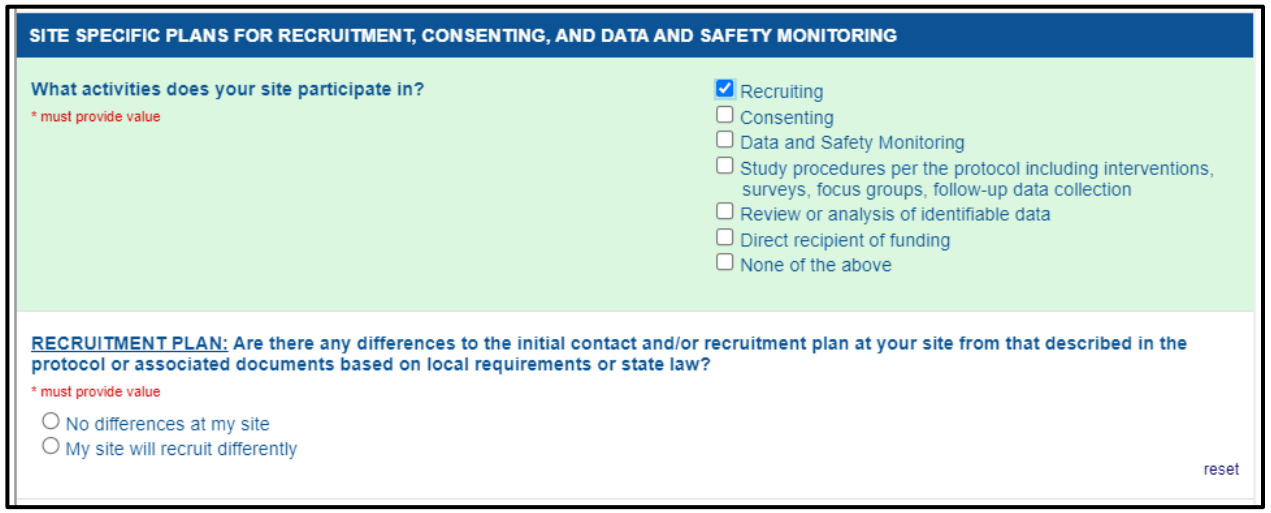
Local instructions for investigators when relying on another IRB

* must provide value

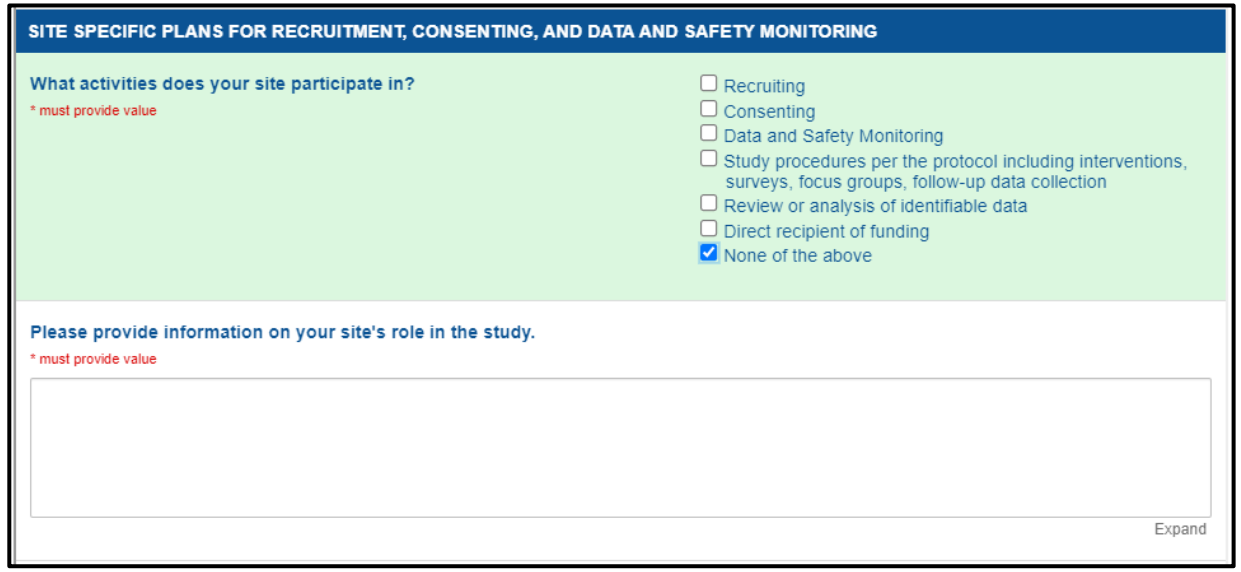
Upload file

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

Updated PI Survey

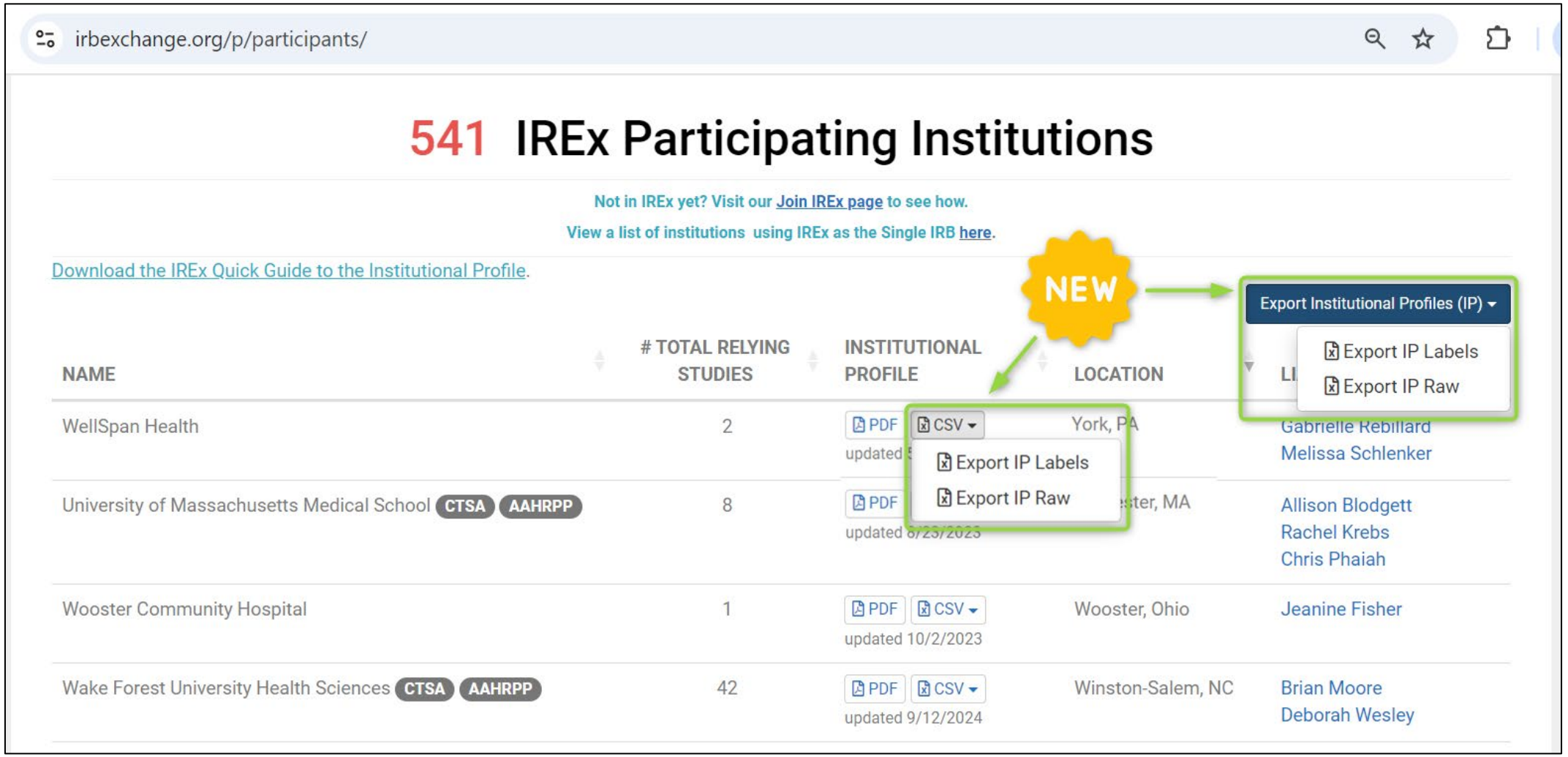


1. Better document what activities are happening at each site
2. Continue to capture whether the site has differences from the protocol

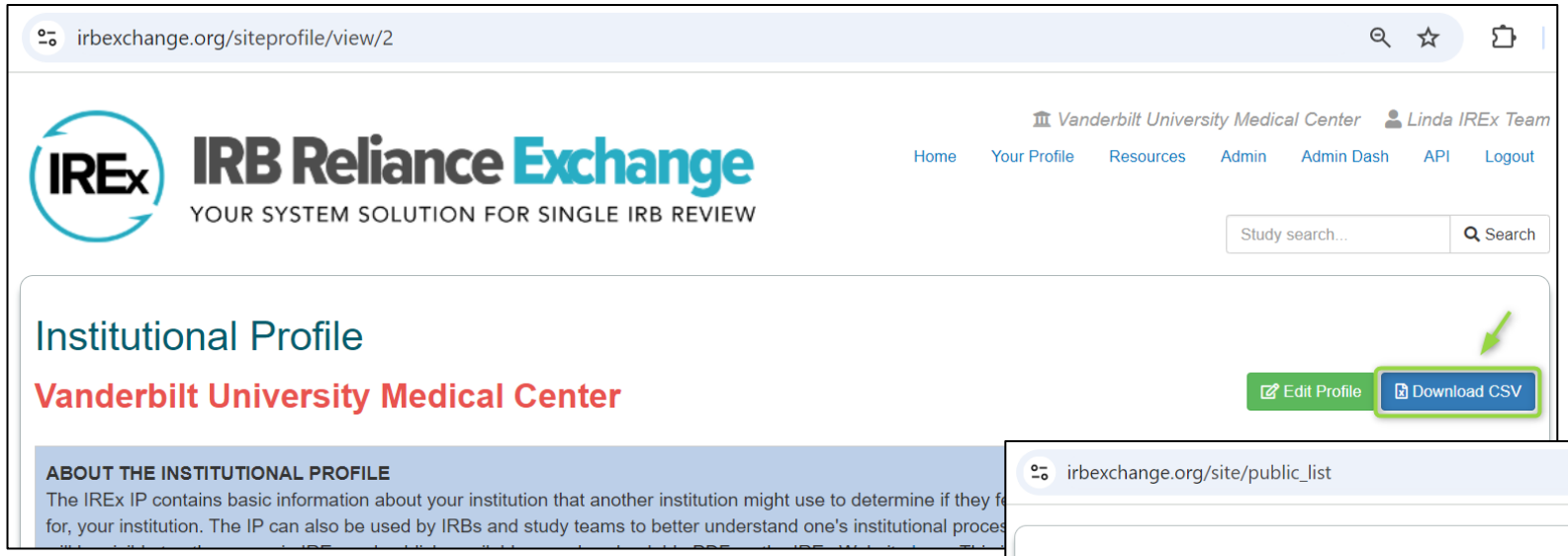


3. Allow sites to denote that they are engaged due to affiliations/institutional relations, but have not activities at their site.

Export Institutional Profile as CSV: From Public Website



Export Institutional Profile as CSV:
After logging into IREx

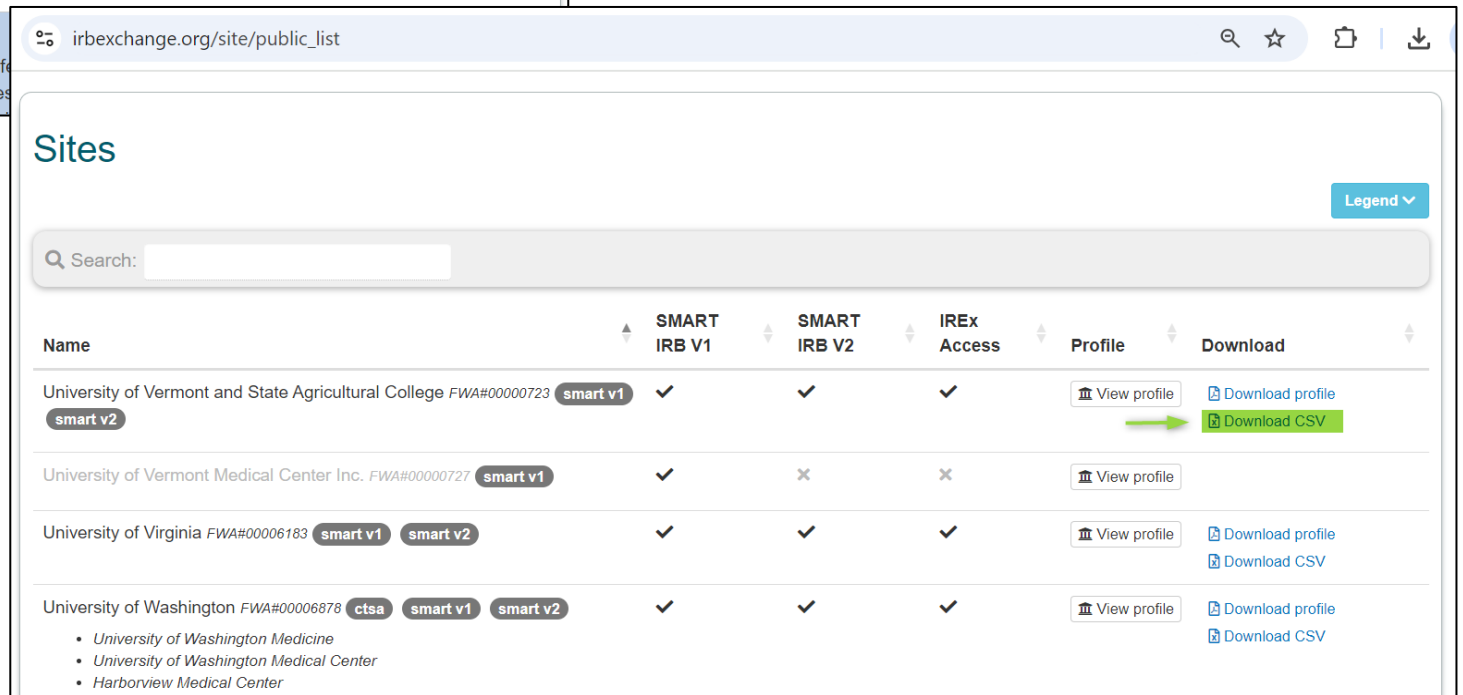


View your IP

- > Download CSV for your site

From Homepage:

- Find other Sites
- Search for site
- Download

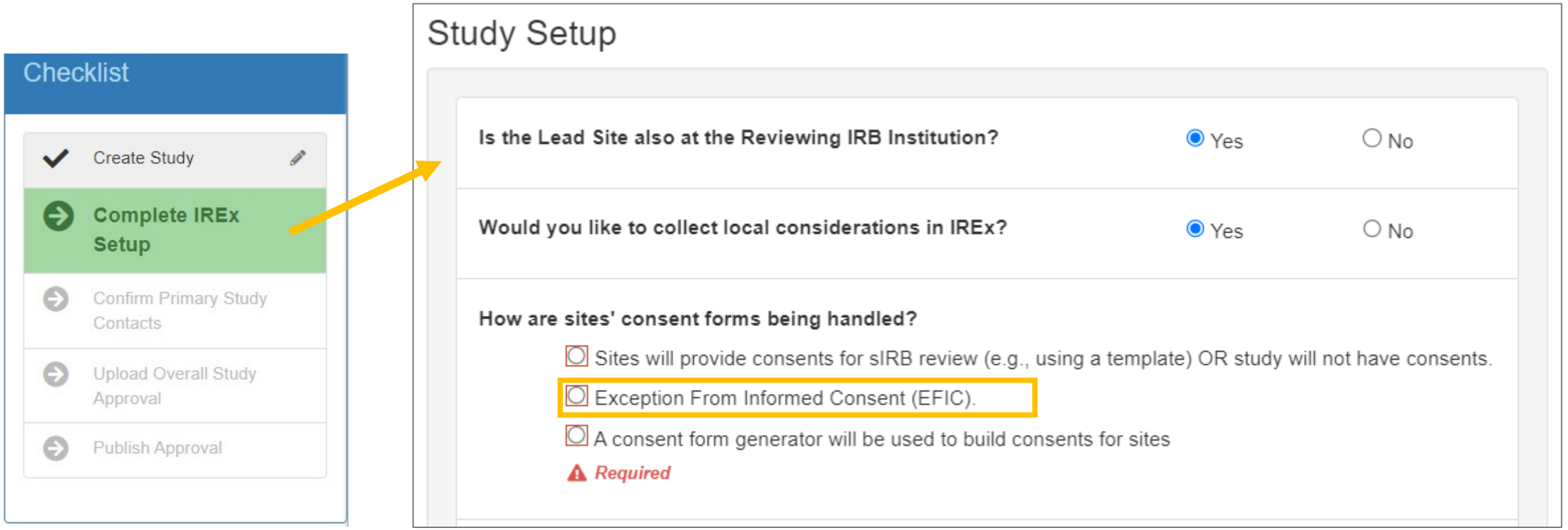


IREx Now Supports Studies with EFIC!

Goals

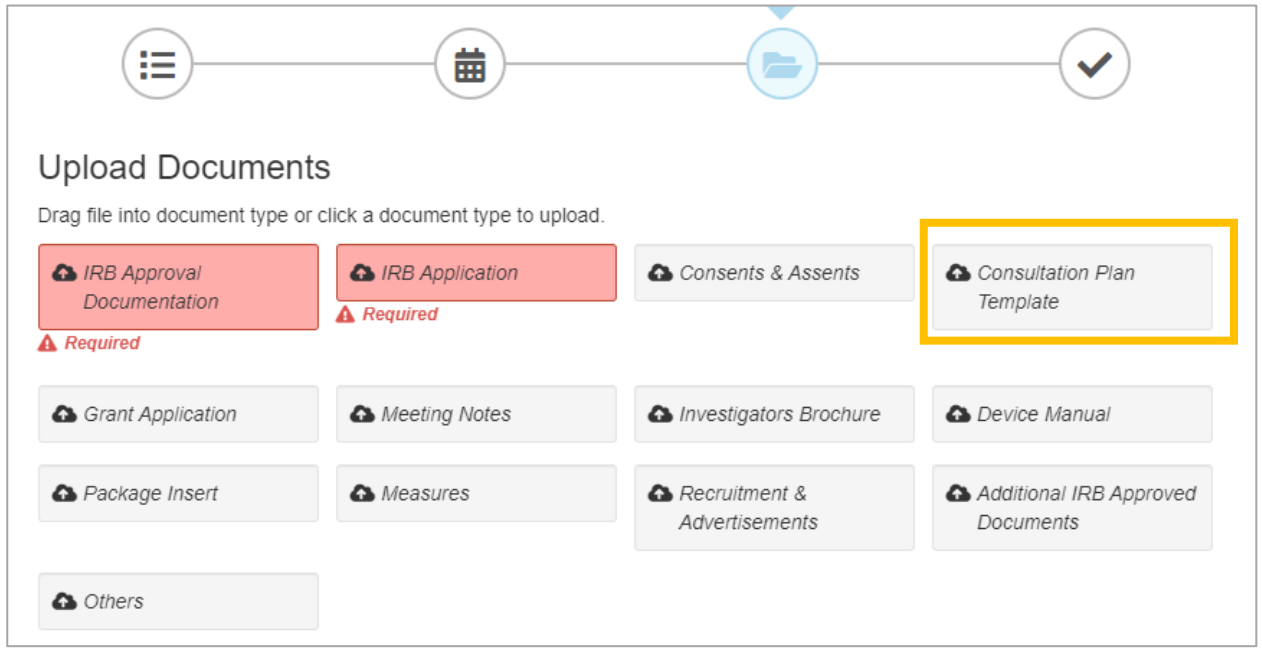
1. Support lead study teams as they track sites in various stages of the EFIC process
2. Standardize and centralize EFIC documentation (based on IREx User Feedback Group input)
3. Provide sites with clear EFIC processes and approval statuses

sIRBs can turn on EFIC study in IREx setup

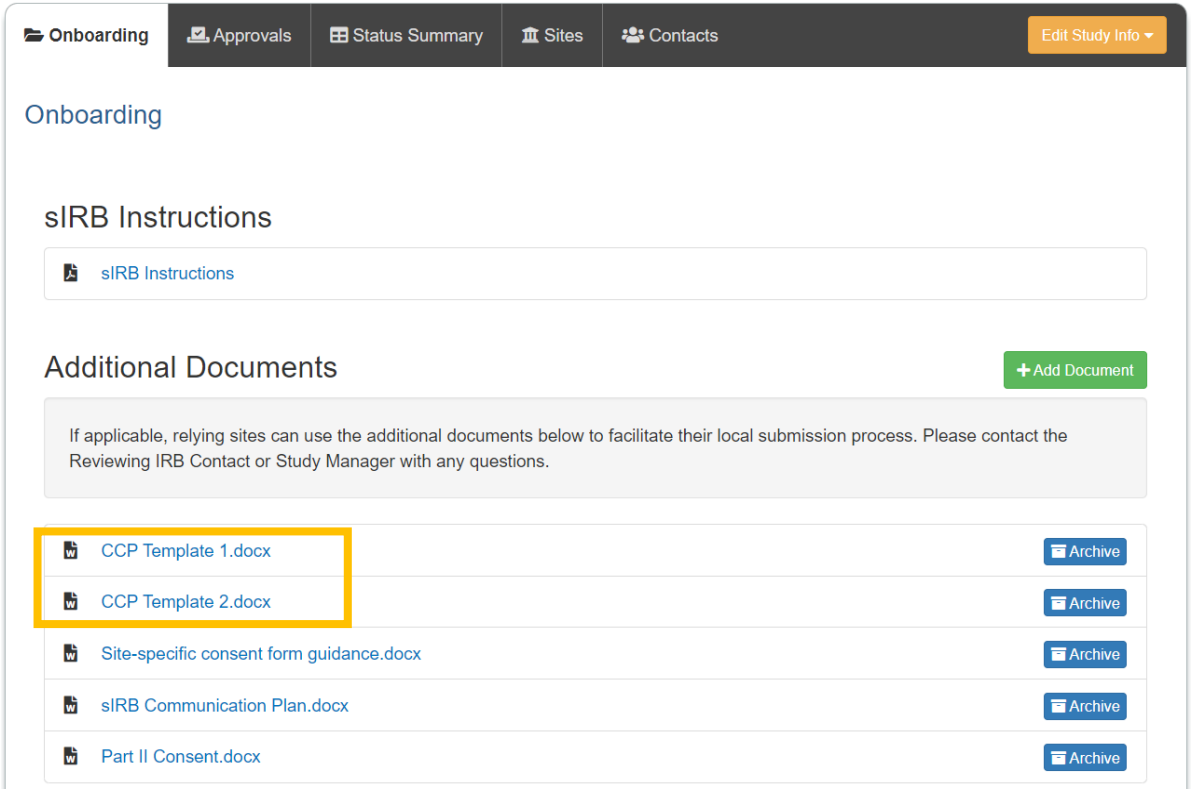


Upload Community Consultation Plan (CCP) Template

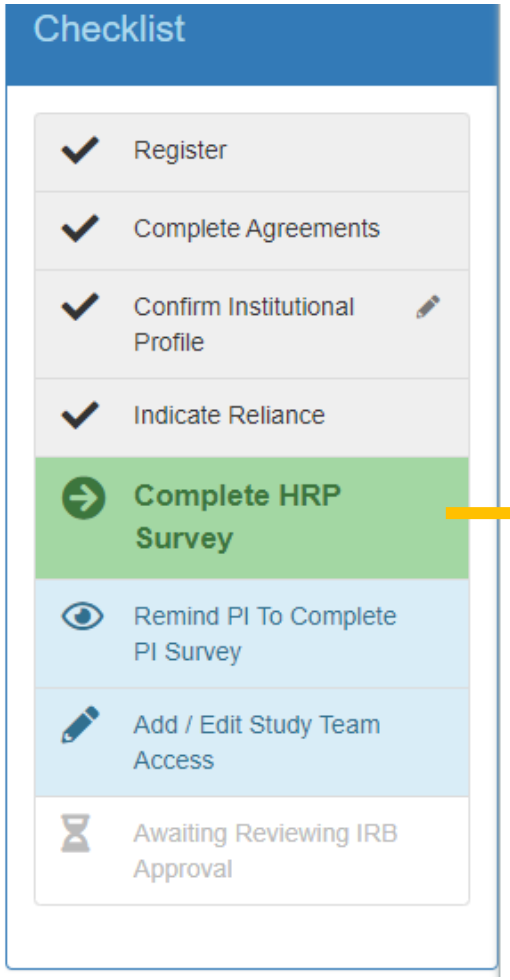
With the Lead Site Approval

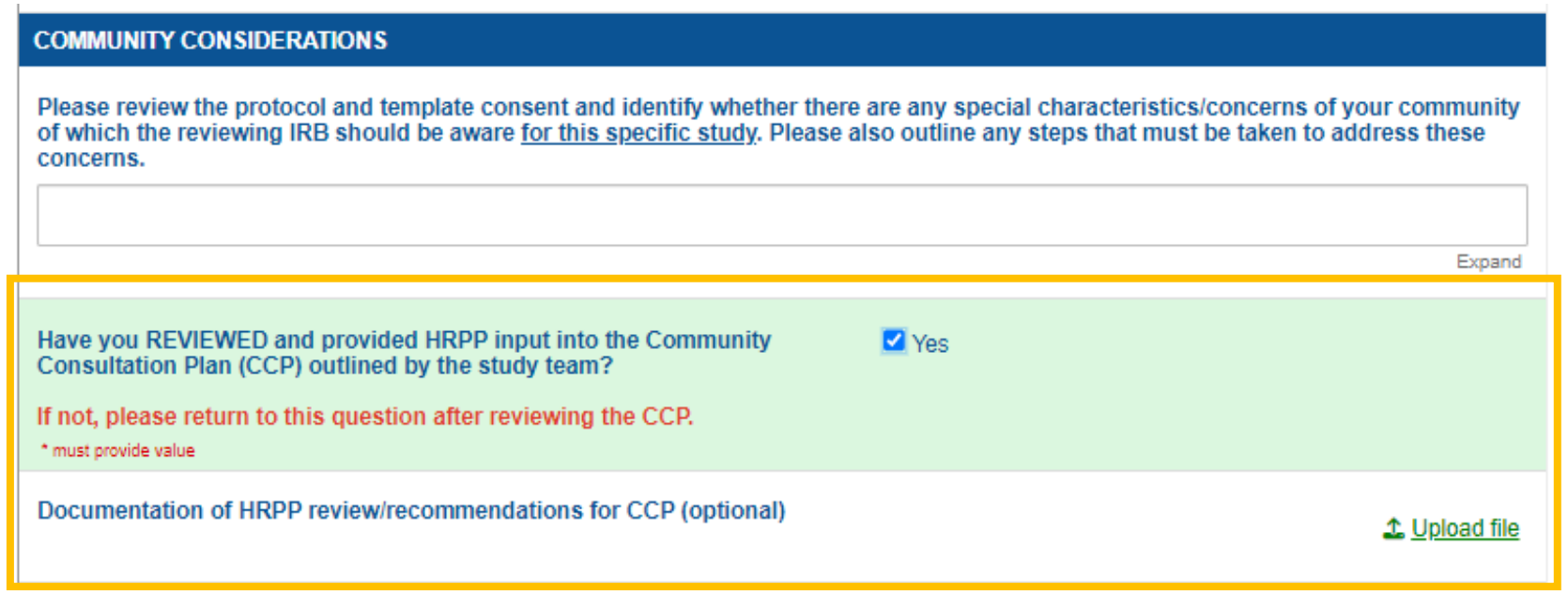


As a document on the Onboarding Tab

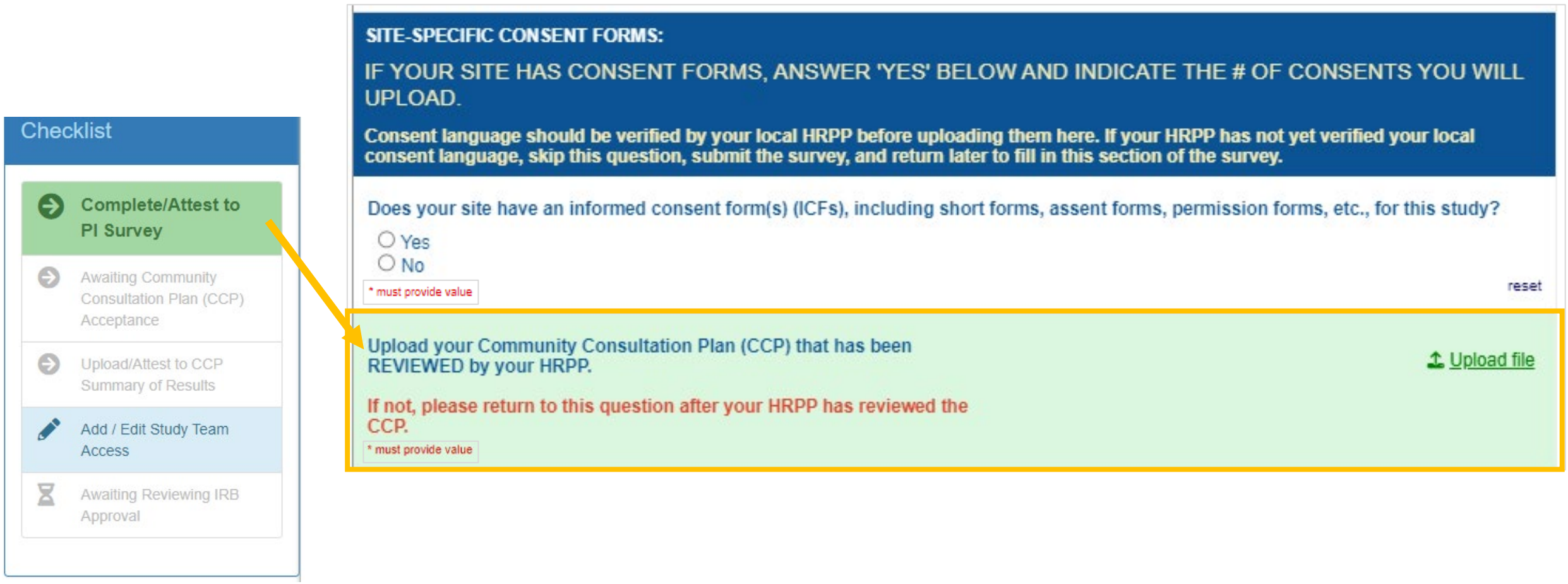


Relying HRPP must verify review of CCP in HRP Survey



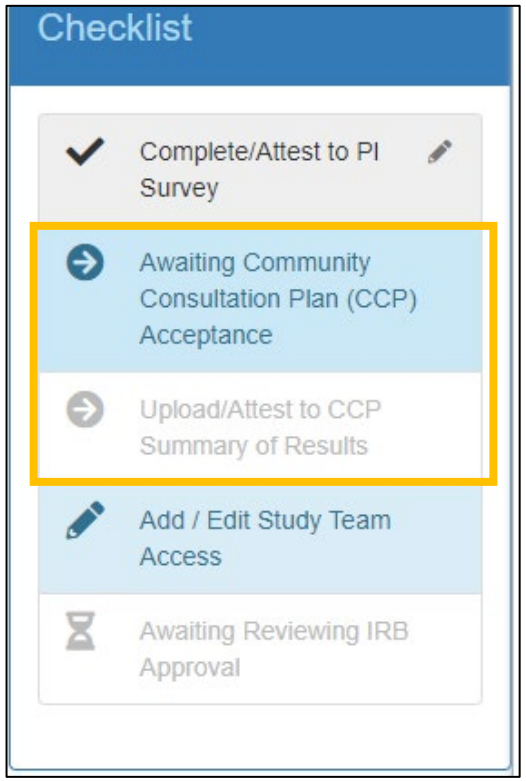


PI Uploads CCP to PI Survey

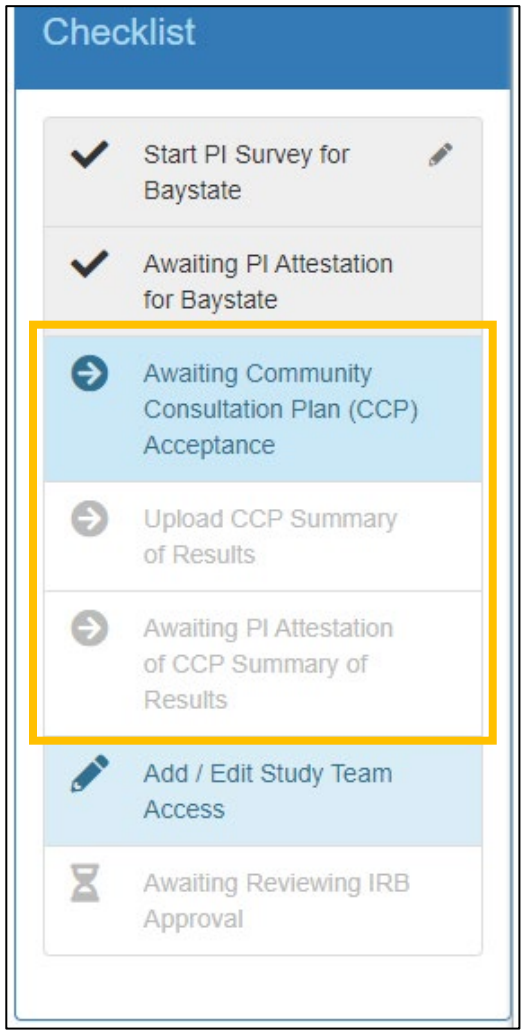


New Steps on Study Team Checklist

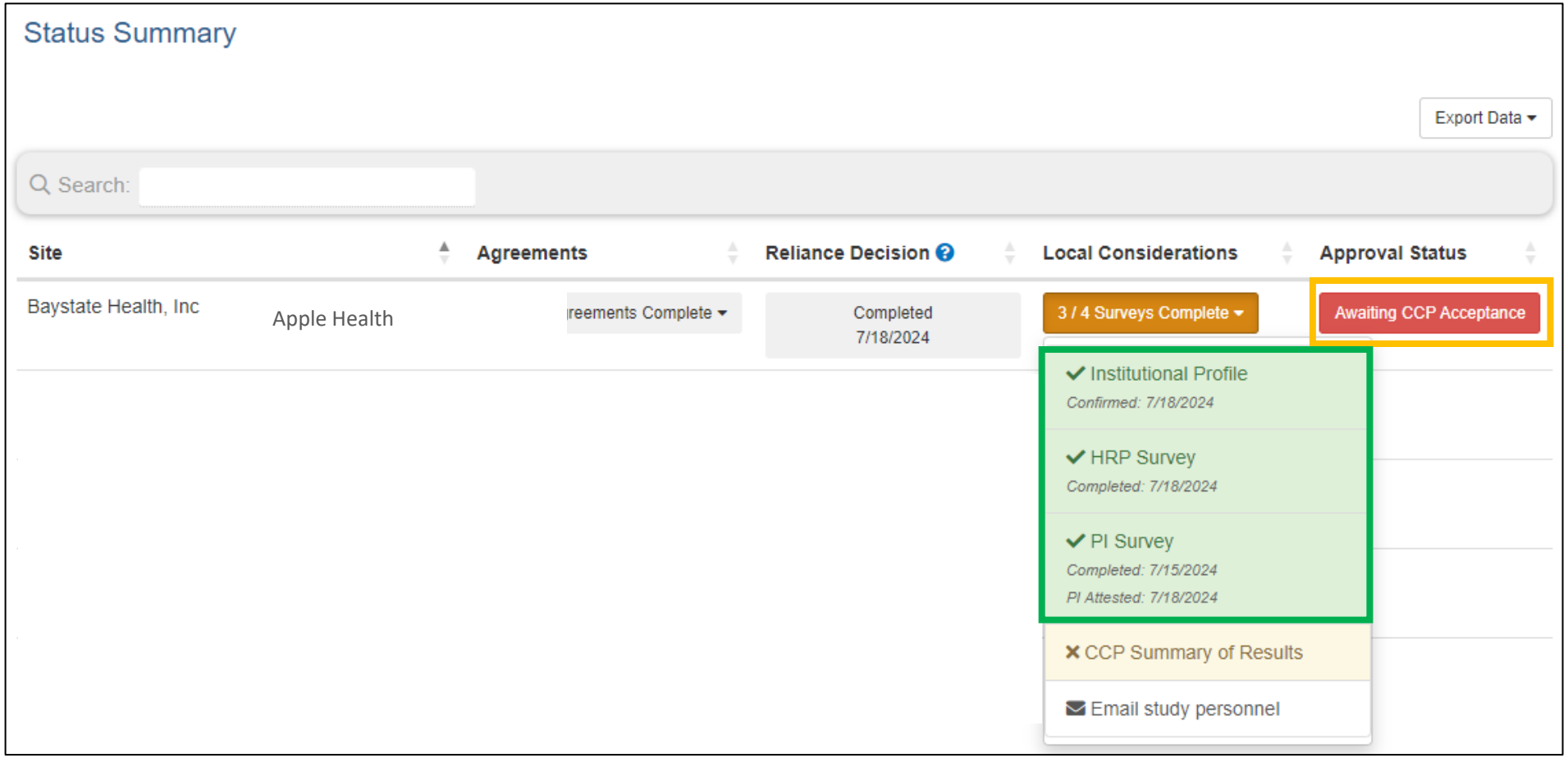
PI Checklist



Study Team Member Checklist

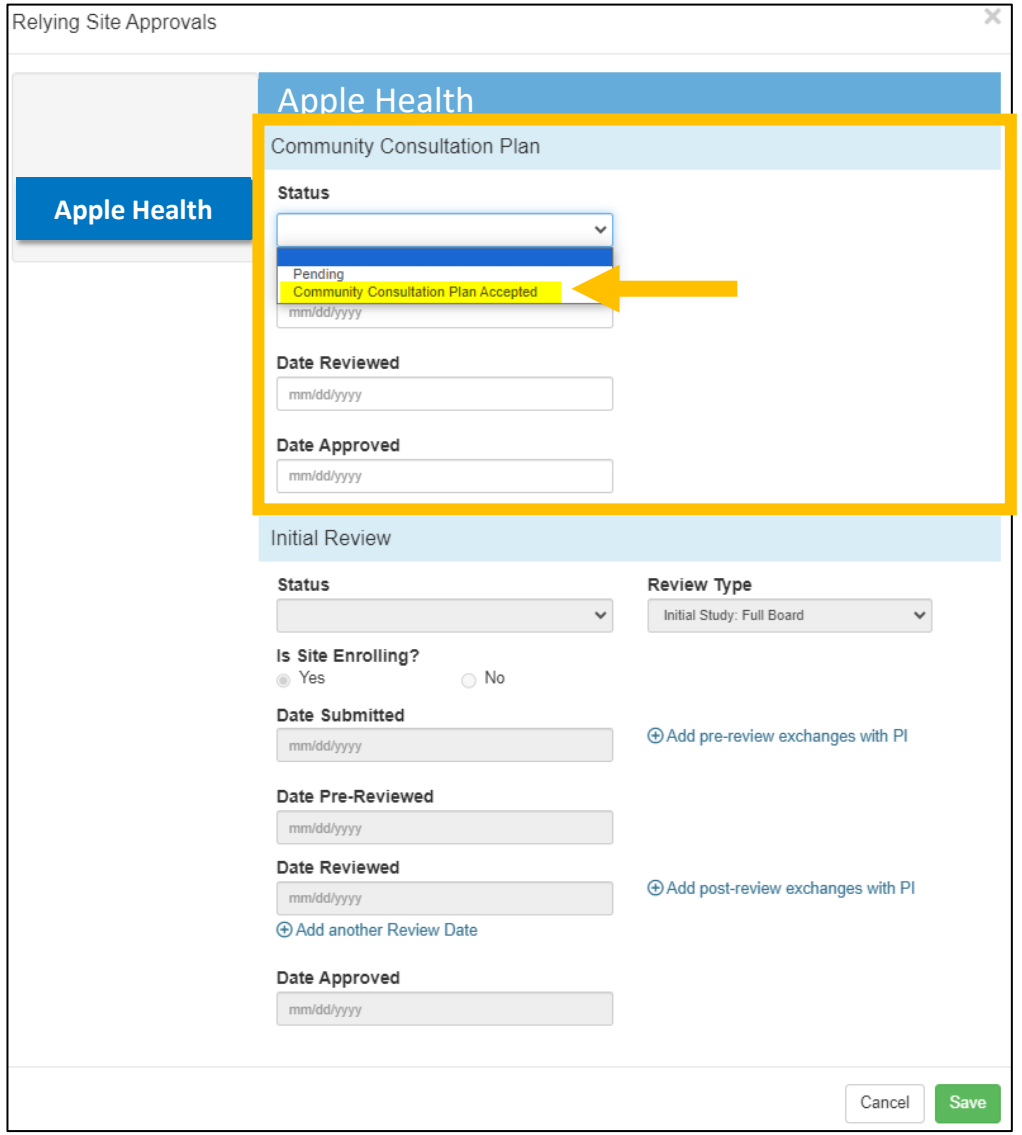


Status Summary:
After Site Completes Initial Documentation

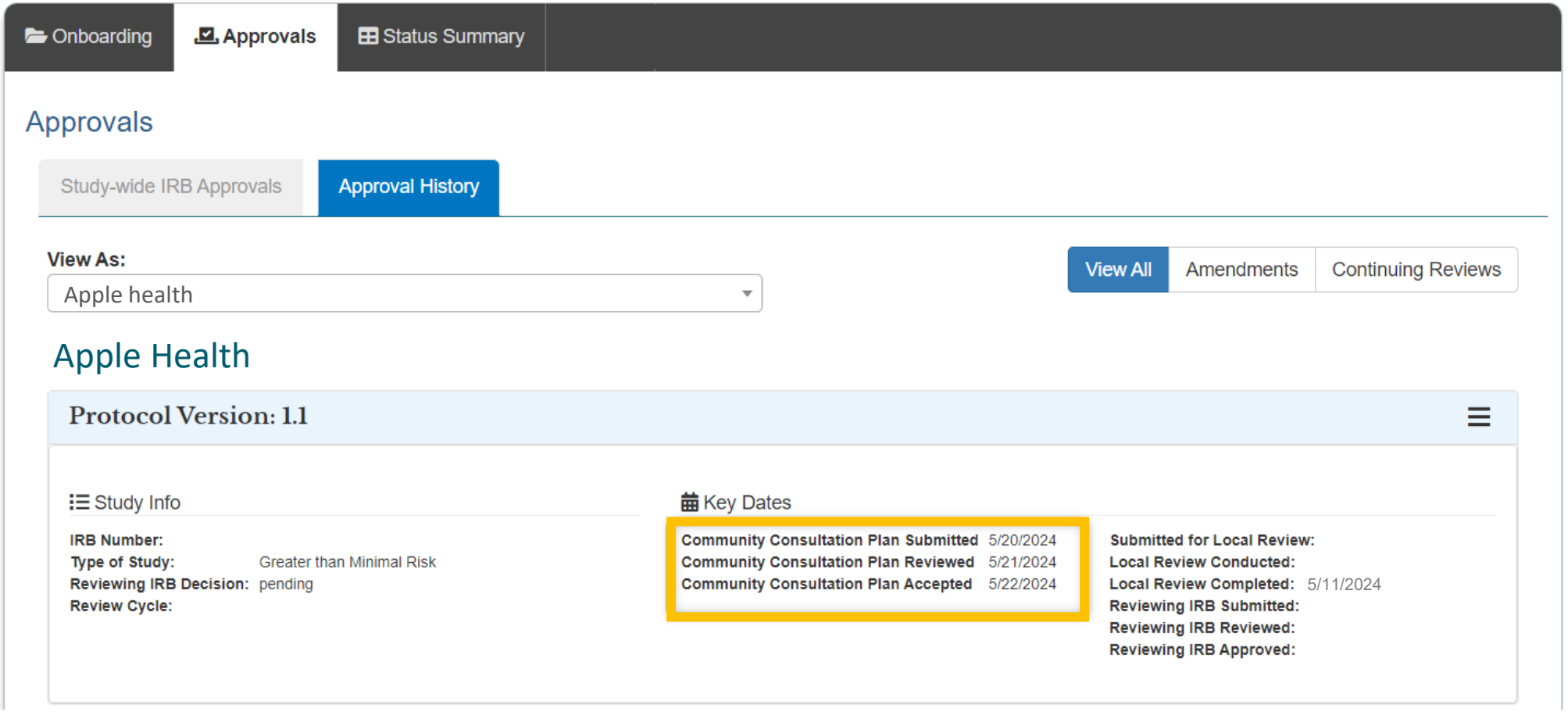


- ✓ **Relying Sites Completed Reliance Documentation and Local Considerations**
- ❑ **Site is ready for sIRB review of CCP**

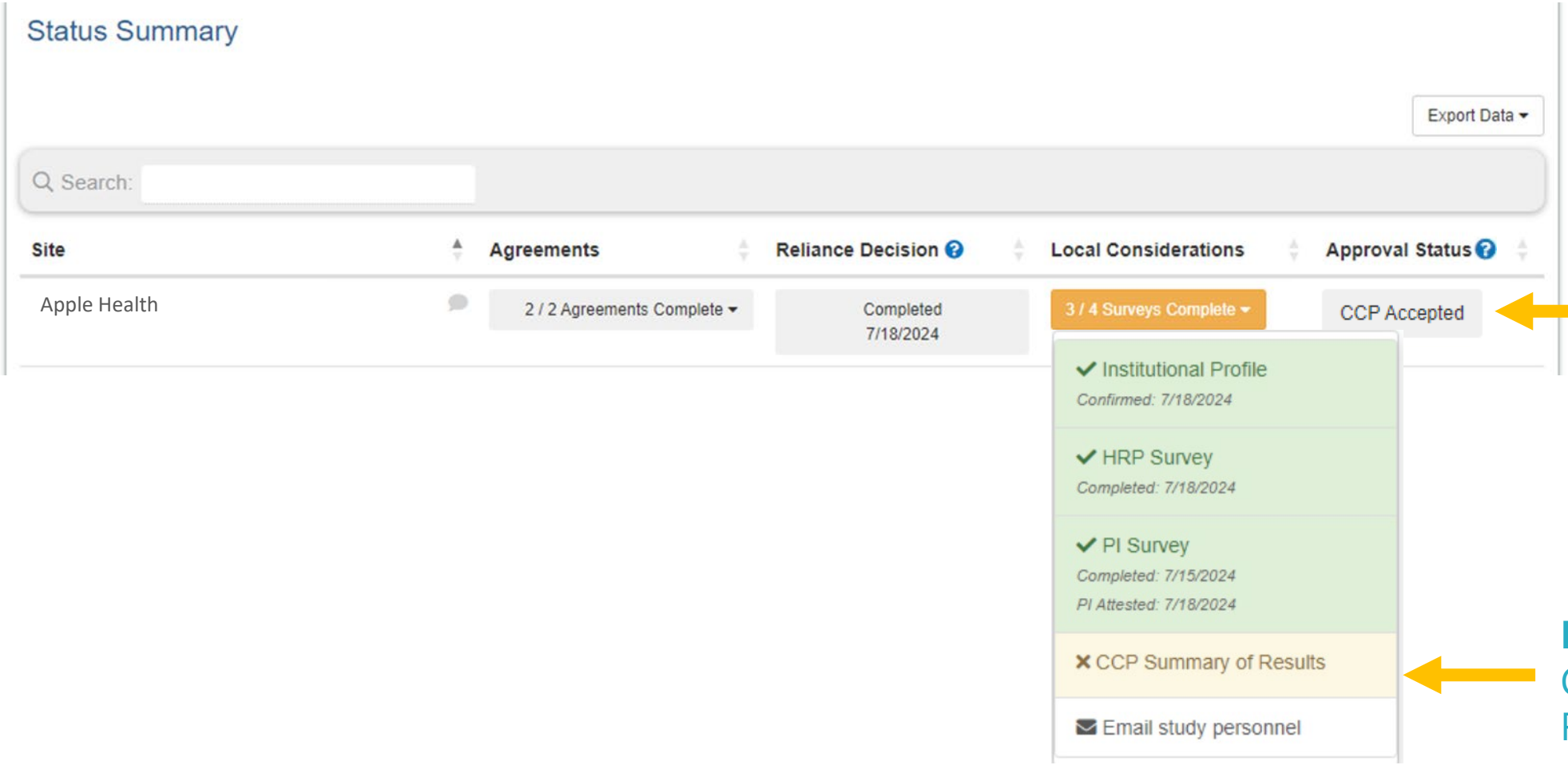
Lead Study Team Uploads CCP Acceptance from sIRB



Review dates captured:
CCP submissions + review + acceptance



Status Summary:
After CCP Accepted

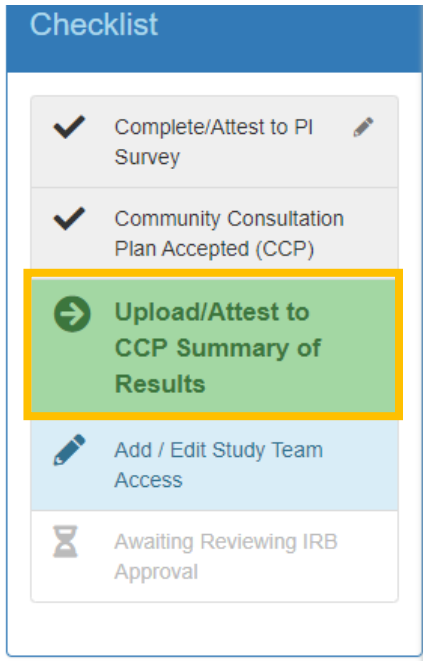


Status Updated

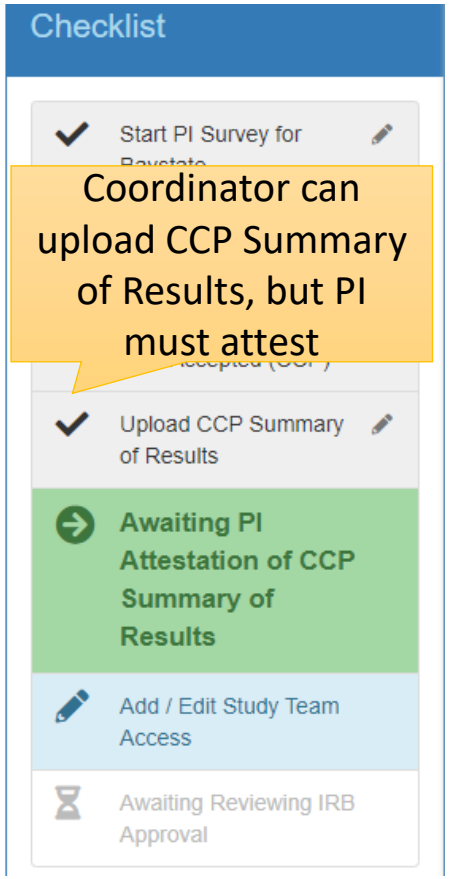
Next Step: Upload of CCP Summary of Results

After CCP implementation, Study Team Uploads CCP Summary of Results

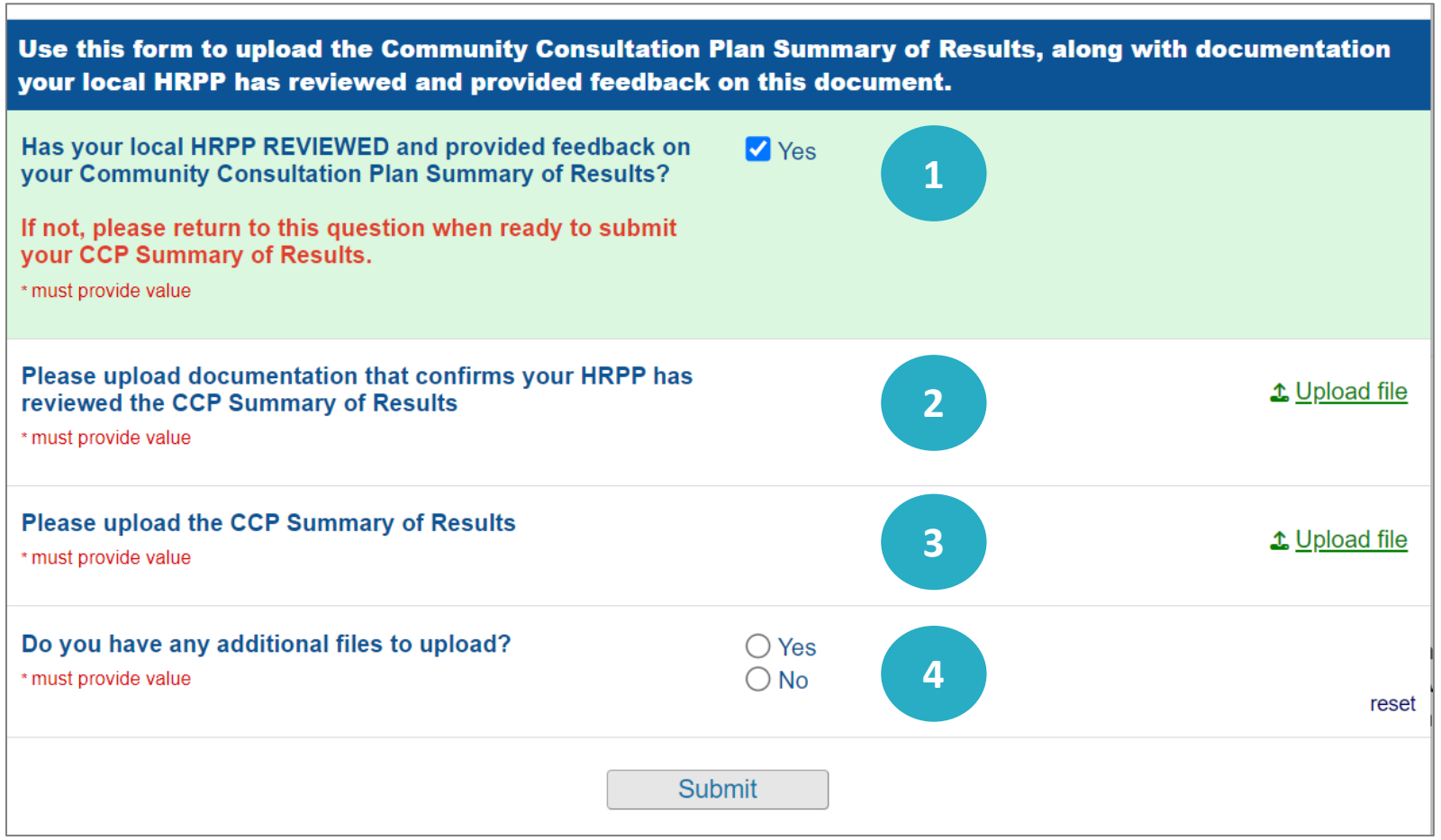
PI Checklist



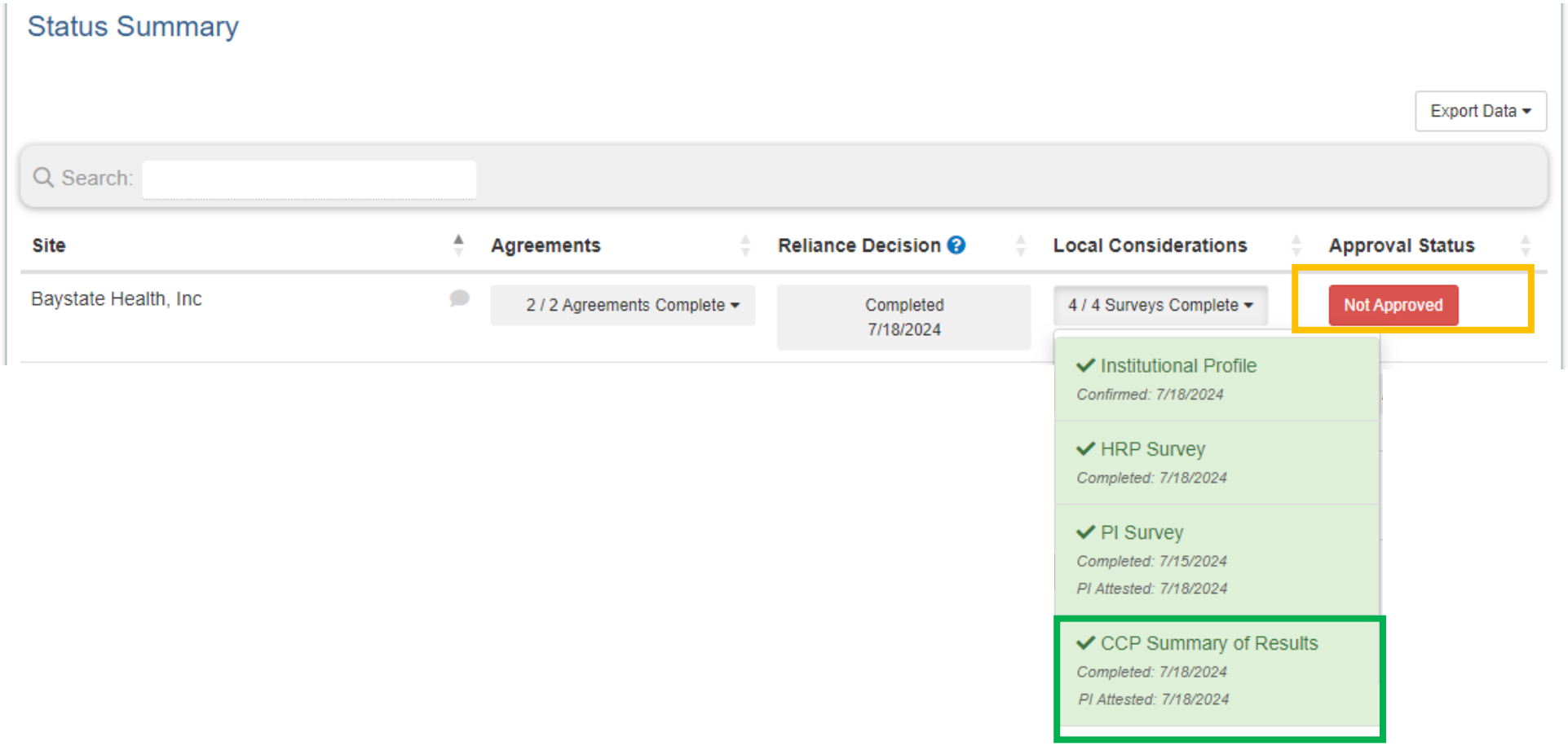
Study Team Member Checklist



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

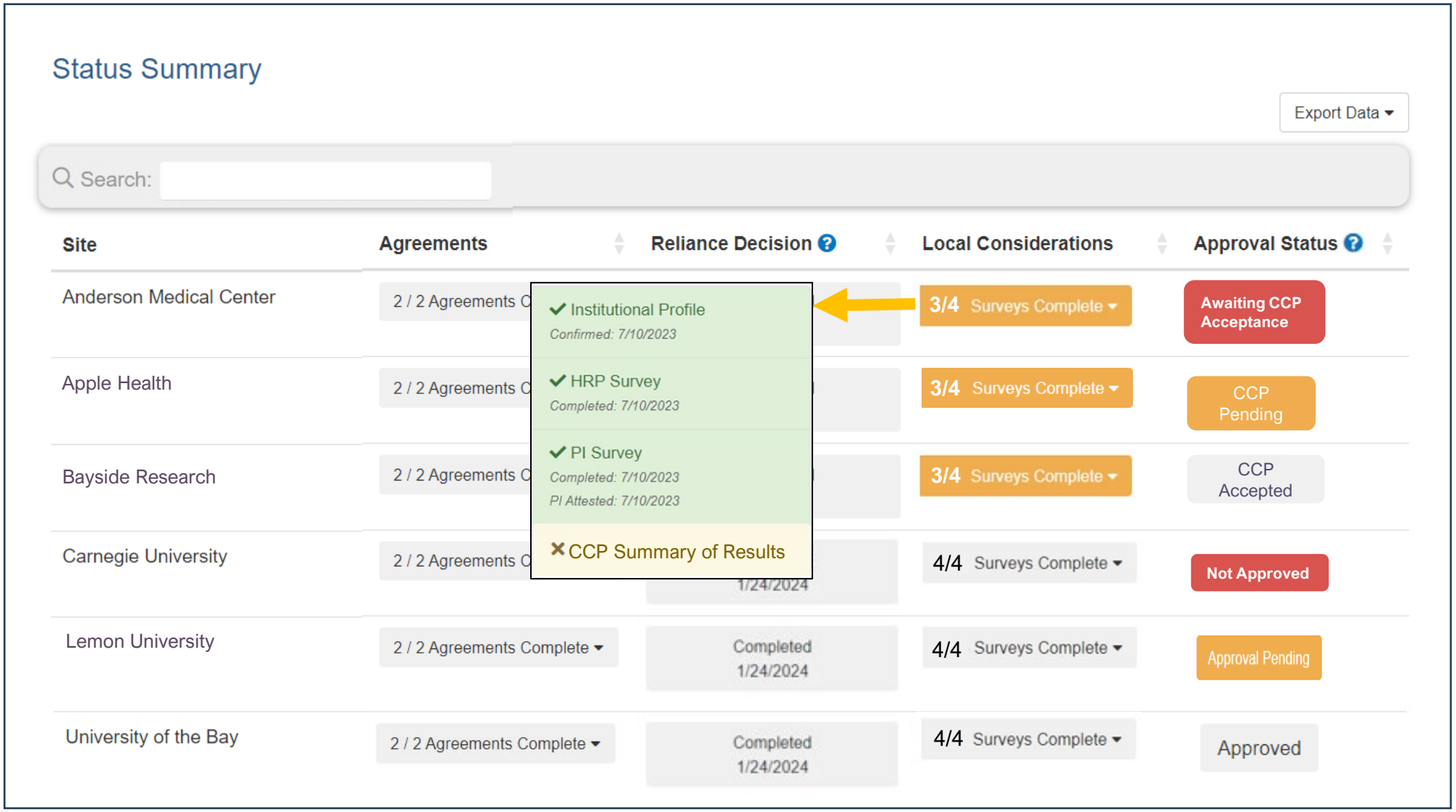


Status Summary:
CCP Summary of Results Uploaded



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

EFIC Status Summary Tab Approval Status



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

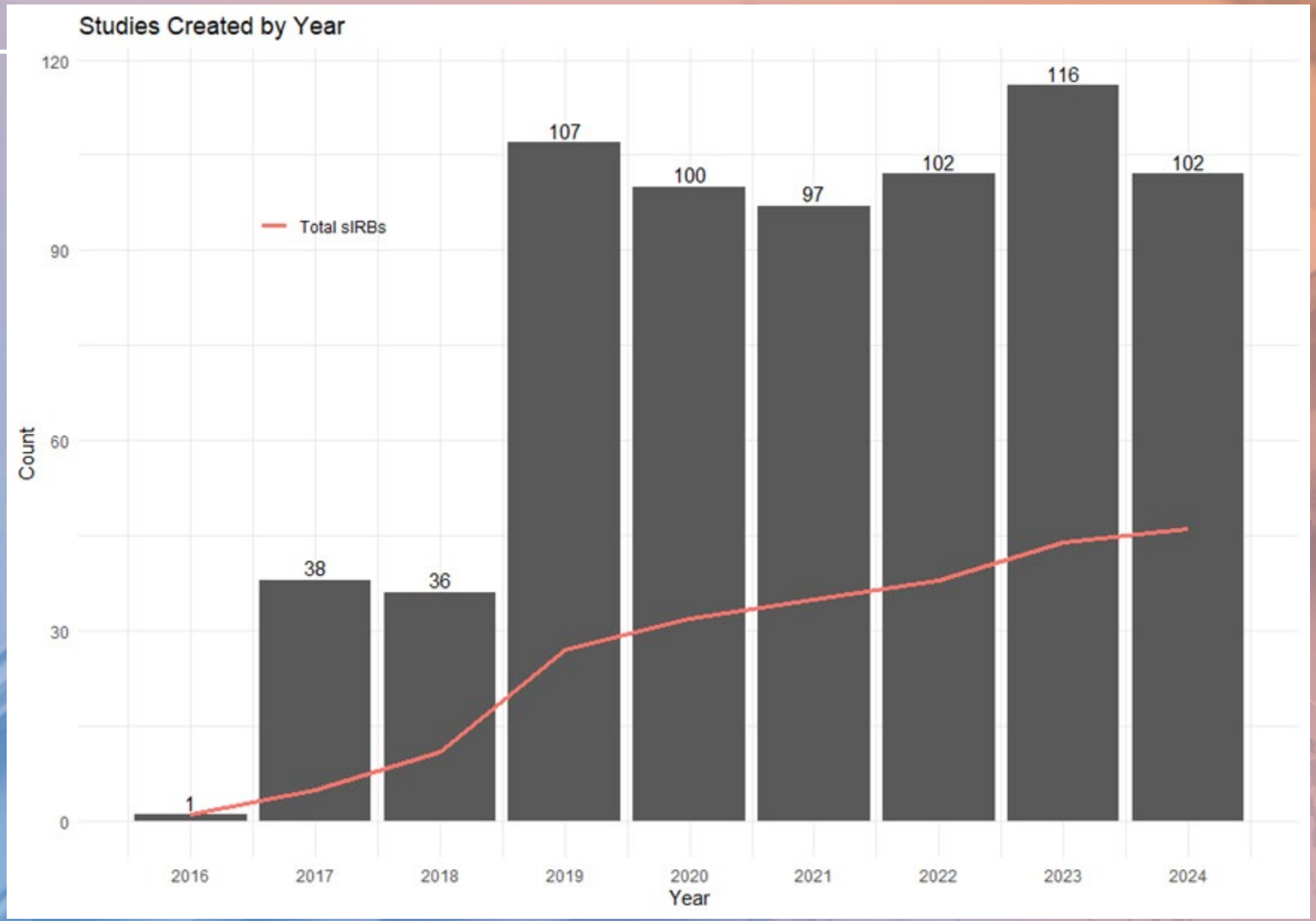
October 2024

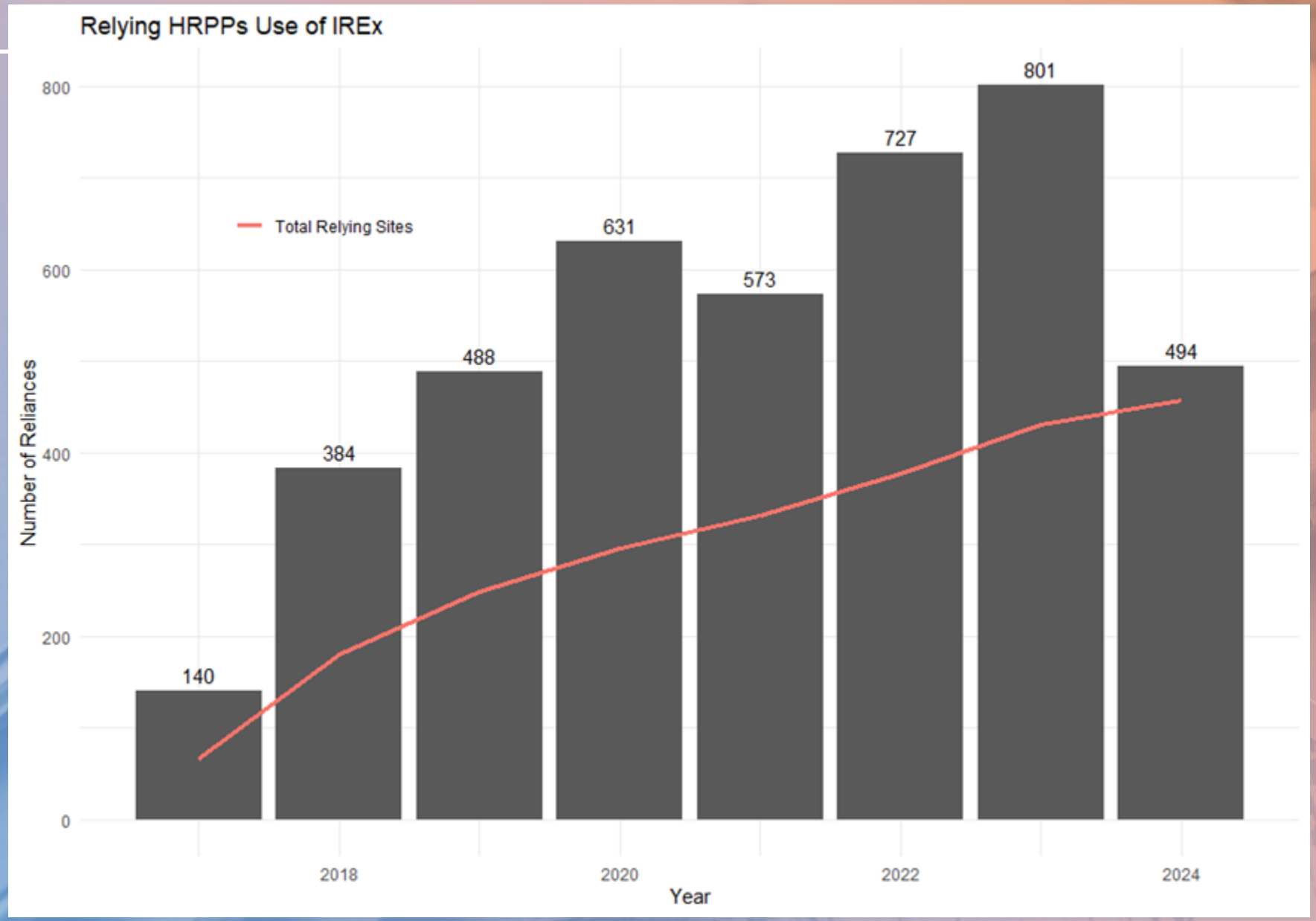
2024 Q3 Metrics Update

- **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
120
90
60
30
0
Count
Total sIRBs
1
38
36
107
100
97
102
116
102
2016
2017
2018
2019
2020
2021
2022
2023
2024
Year


Relying HRPPs Use of IREx
Total Relying Sites
Number of Reliances
Year
0
200
400
600
800
2018
2020
2022
2024
140
384
488
631
573
727
801
494

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

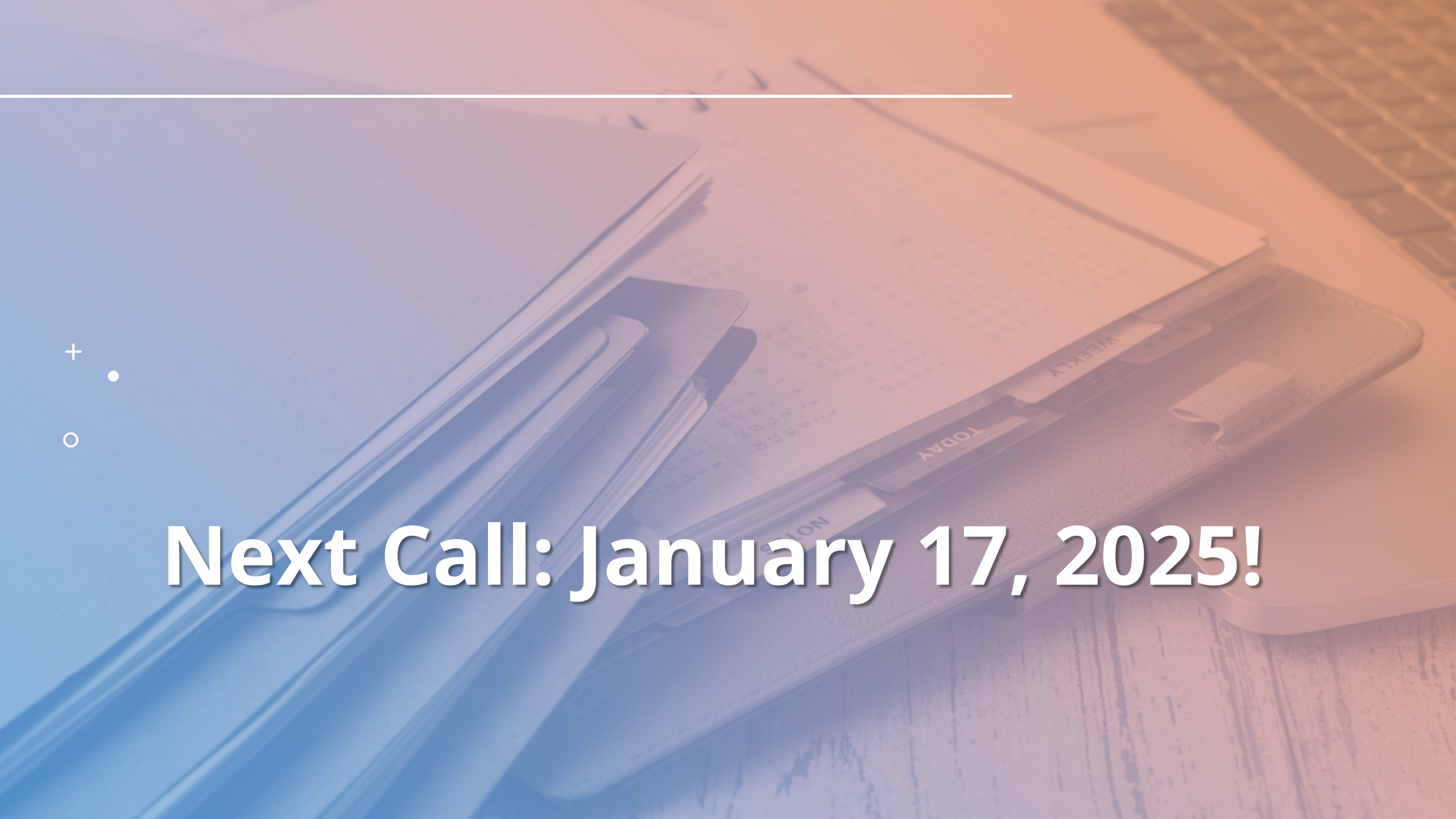
Unique Protocol Elements
❑Standard of care with description from protocol
❑Pregnancy testing
❑Genetic testing

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!