IRBx

IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

IREx Quarterly Call

- Training
- Special projects

Natalie Dilts

- Manager, Application Development

Bryce Embry

- Study Support
- User Training

David Crenshaw

- Materials Development
- Study support

Kaysi Quarles

- Site onboarding
- Study Support

Tiffany Chen

- Platform direction
- Evaluation

Emily Serdoz

- Study Support
- User Training

Bridget Swindell

- System Development

Linda Tan

- Application Developer

Jason Tan

- Application Developer

Evan Wimberly

- Materials Development

Katelyn Benhoff

10.20.2023 QUARTERLY CALL AGENDA

- Welcome
- Announcement: Website makeover
- Lead Study Team / Study Manager Spotlight – Sharon Kidd (UCSF)
- Recent Feature Releases
- What's Next

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

2024 Quarterly Calls

New registration link coming after this call

Register HERE for IREx 2024 Quarterly Calls

- **January 19, 2024**
- **April 19, 2024**
- **July 19, 2024**
- **October 18, 2024**

Announcements

IREx Website Makeover

- New homepage: https://www.irbexchange.org/p/
- New testimonials added: https://www.irbexchange.org/p/what-our-users-say/
- New Presentations & Publications page: https://www.irbexchange.org/p/publications/
- View/sort Institutions by the # of studies where they're relying on a single IRB (# total relying studies): https://www.irbexchange.org/p/participants/

New / Revised IREx Materials

FOR STUDY MANAGERS

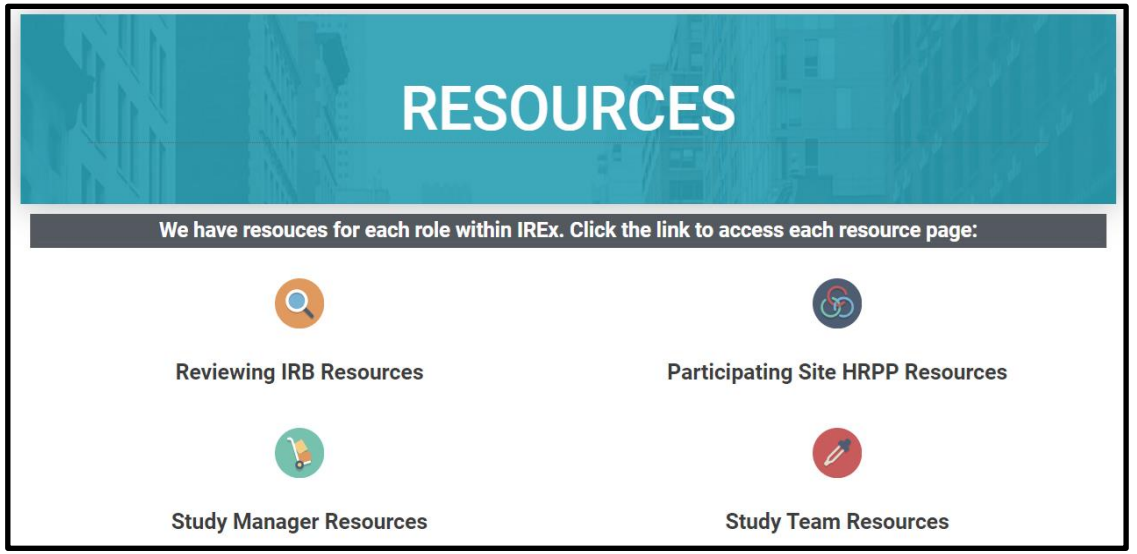
- IREx Study Manager Step-by-Step Guide
- How to Upload Continuing Review Quick Guide
- Accessing Approvals Quick Guide (for your study teams)

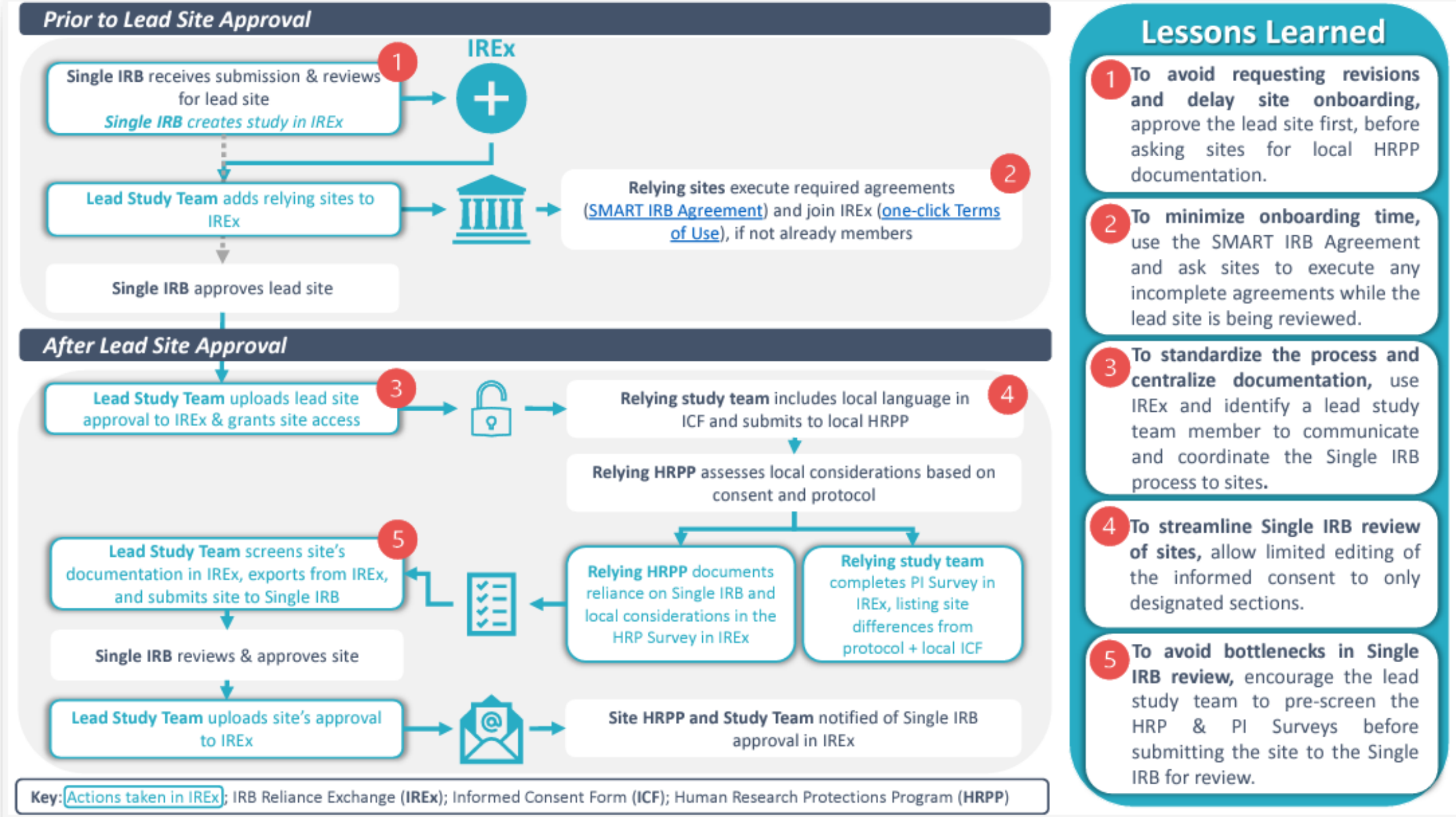
FOR RELYING HRPPs

- Relying Site HRPP Quick Guide

FOR ANY & EVERYBODY!

- *NEW* IREx Workflow + Lessons Learned





Moore, J. Brian; Smith, S. Carrie; Russell, Laurie P.; Serdoz, Emily S.; Dilts, Natalie A.; Alexander, Amir A.; Reboussin, David M.; Bagwell, Benjamin M.; Spainhour, Mitzie H.; Reeves-Daniel, Amber M.; Wesley-Farrington, Deborah J.; Ma, Lijun; Freedman, Barry I.; for the APOLLO Consortium. Creation of a Single Institutional Review Board for Collaborative Research in Nephrology: The APOLLO Experience. Clinical Journal of the American Society of Nephrology 18(10):p 1362-1365, October 2023. | DOI: 10.2215/CJN.0000000000000197

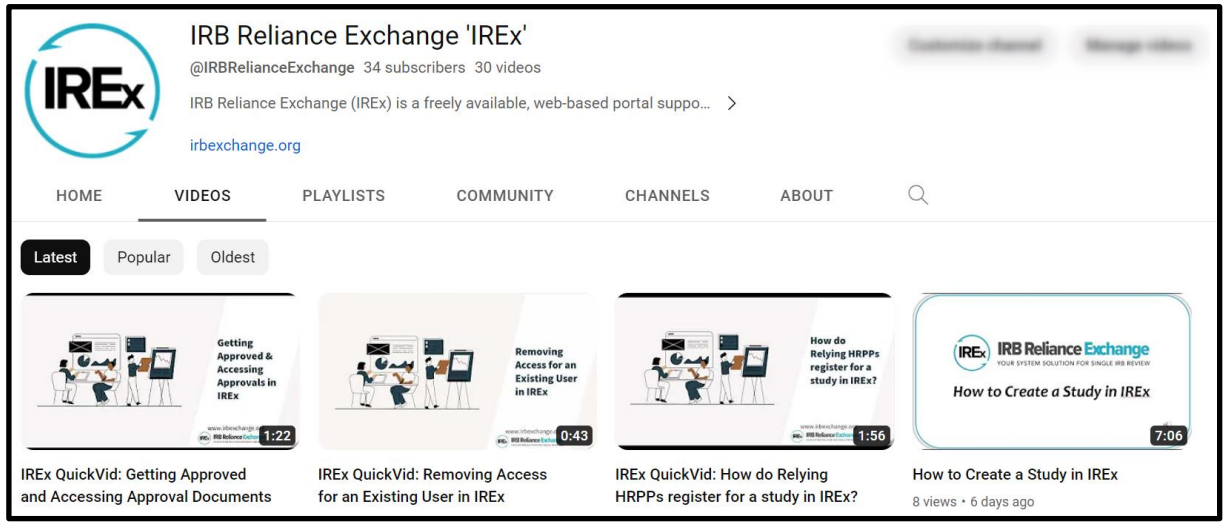
Updated Videos Available via IREx YouTube Channel

FOR STUDY MANAGERS
- Using IREx as the Study Manager
- Getting Approved and Accessing Approval Documents (for your study teams)
- How do I add/remove study team members in IREx? (for your study teams)

FOR RELYING HRPPs
- How do Relying HRPPs register for a study in IREx?

FOR sIRBs
- How to Create a Study in IREx

FOR ALL HRPPS (sIRBs & RELYING SITES)
- How to add HRPP / IRB Contacts in IREx
- Removing Access for an Existing User in IREx



Lead Study Team / Study Manager Spotlight: Sharon Kidd (UCSF)

IREx – The PIDTC Experience

Sharon Kidd, Senior Program Manager

The Primary Immune Deficiency Treatment Consortium (PIDTC)

October 20th, 2023

A little about our Consortium…

- The Primary Immune Deficiency Treatment Consortium (PIDTC) is a network of 47+/- immunology and hematopoietic stem cell transplant (HCT) centers throughout the USA and Canada that was established in 2009
- We have 3 natural history or observational studies that collect data on patients with Primary Immune Deficiencies (PID) from the clinical visits related to their ongoing care and treatment
- This involves collection of current and historical medical history from electronic - and sometimes paper (!) – medical records, laboratory tests that capitalize on clinical blood draws, stool sample collections, and self-report quality of life and socioeconomic status questionnaires

Use of IRBs for our protocols…

- Currently, there is a mandate for NIH-funded studies that ALL sites have to rely on a single IRB
- Previously, we had a mix of local HRPPs and single IRB for our previous protocols with almost as many sites
  - On the one hand, you could let the sites using their local HRPP fend for themselves, but on the other hand, you didn't have as much control over the content of consents and assuring that all sites were including all pertinent content
  - e.g. data sharing with other entities - we didn't really have a final say in the language of consents

Our use of IREx…

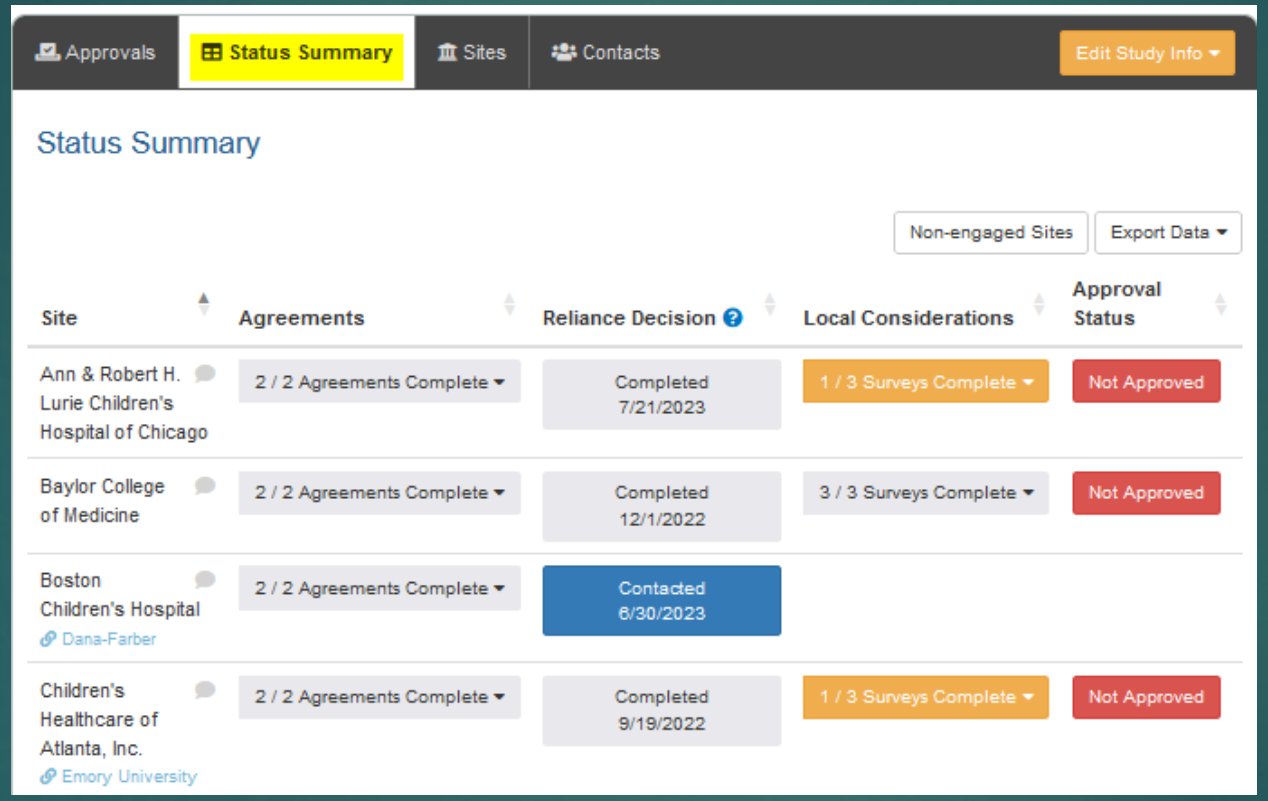
- 3 large protocols at 47 sites:
  - Severe Combined Immune Deficiency (SCID) – 6 consents
  - Chronic Granulomatous Disease (CGD) – 3 consents;
  - Primary Immune Regulatory Disorders (PIRD) – 5 consents
- SCID as an example of workload…6 consents x 47 = 282 consents to review; 3 IREx Surveys x 47 = 141 local considerations surveys to take into account; and 47 reliance agreements to get completed
- Our single IRB contact said that it would be hard at the beginning, but that we would thank ourselves for using IREx as we continued along…

Advantages so far…

- One-stop shopping
  - All sites doing the same thing, so a great advantage for our 3 protocols that all methods are the same for each protocol
    - Identify the key personnel, complete the Surveys, upload consents for local review
  - Each site has their own local “platform” to access their own consents and other local materials
  - Study-Wide platform so that our standardized forms, such as questionnaires, recruitment materials, etc. are loaded once and available to all the other sites
- No more emailing out local consents to all sites!
- User-friendly with good resource documents for step-by-step instruction as needed

Fave features…

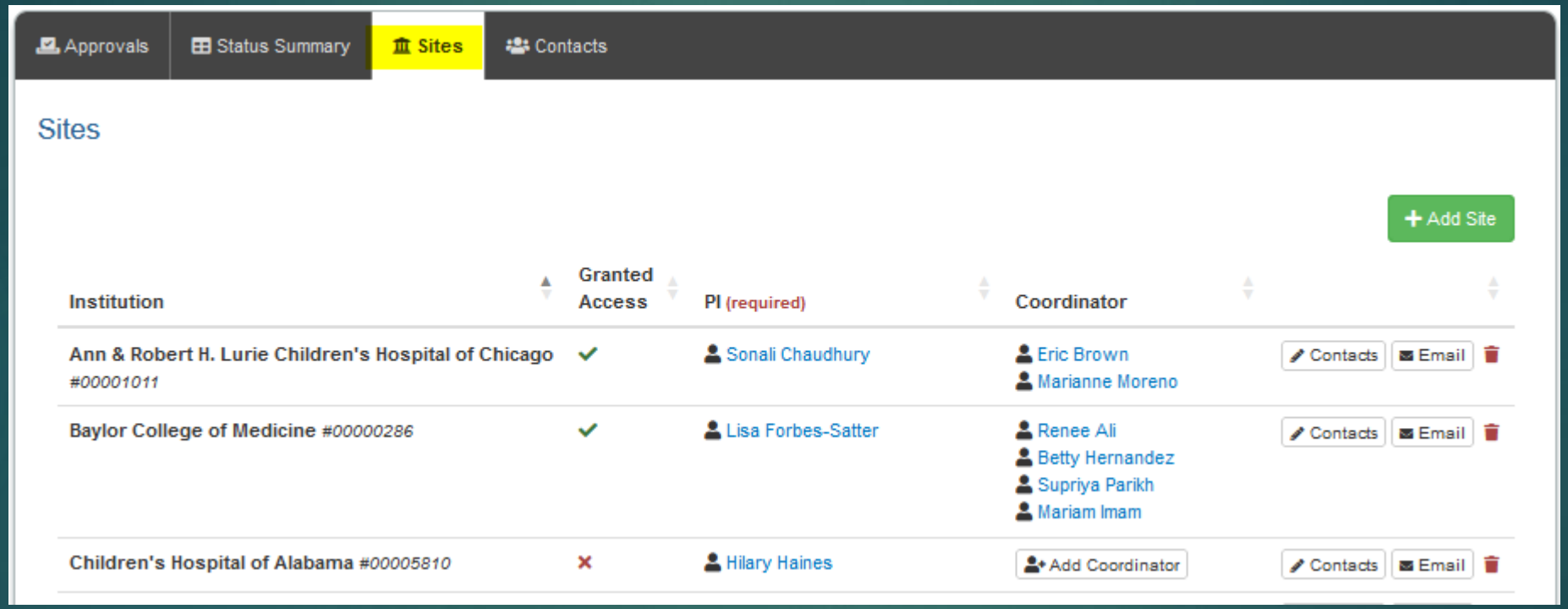
The Status Summary – at-a-glance nature



The new color scheme is an improvement over the previous all-color scheme

Fave features…

The Sites tab – ability for the coordinating team to add/delete local team



Although I wish the local staff would do this themselves, there are pluses to having both teams with the capability to edit

In conclusion…

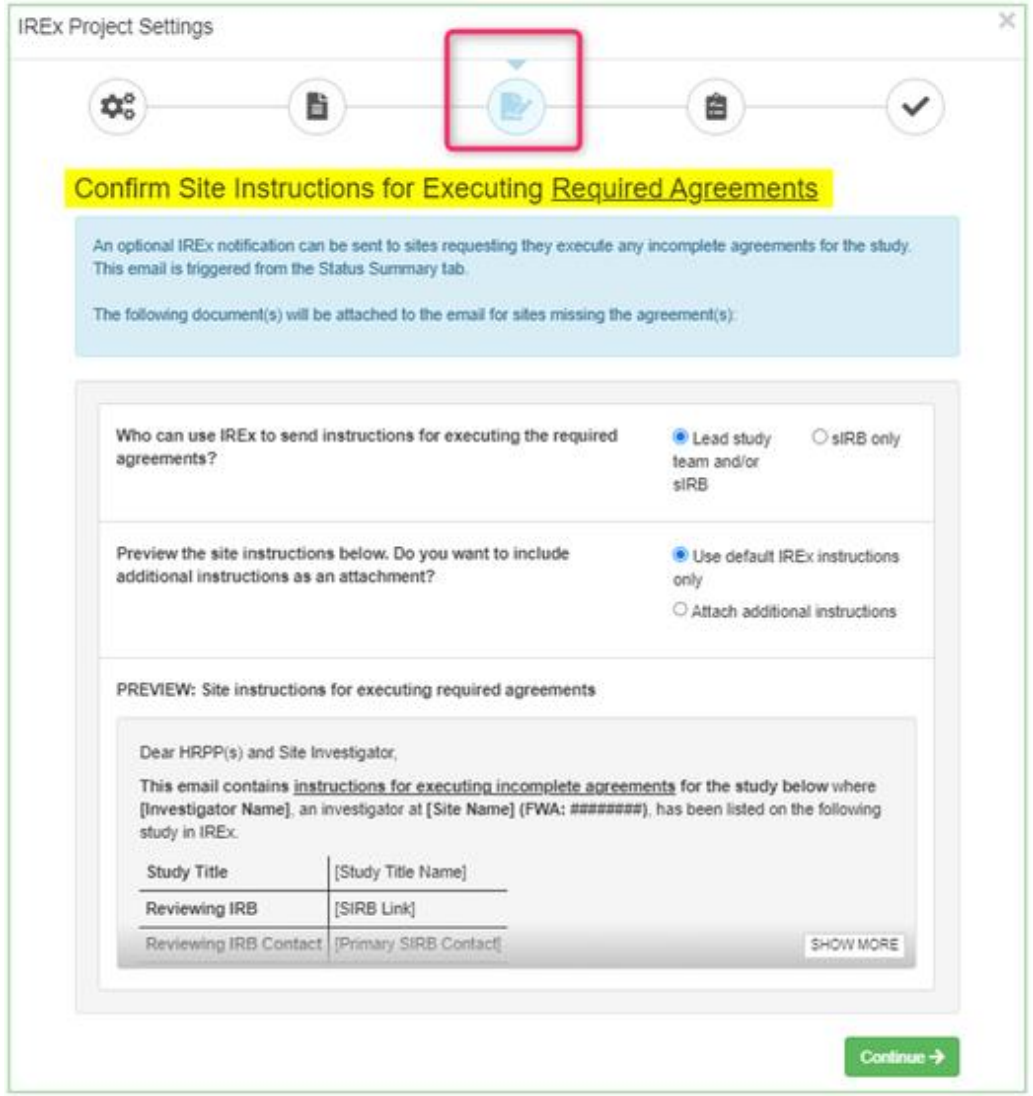
- High quality customer service nature of IREx staff is fast disappearing in our society
  - Prompt responses reducing delay in progress is HUGE
  - Shout-outs to David, Bridget, and other IRBExchangeAdministrators for their amiable interactions and for really trying to help resolve an issue

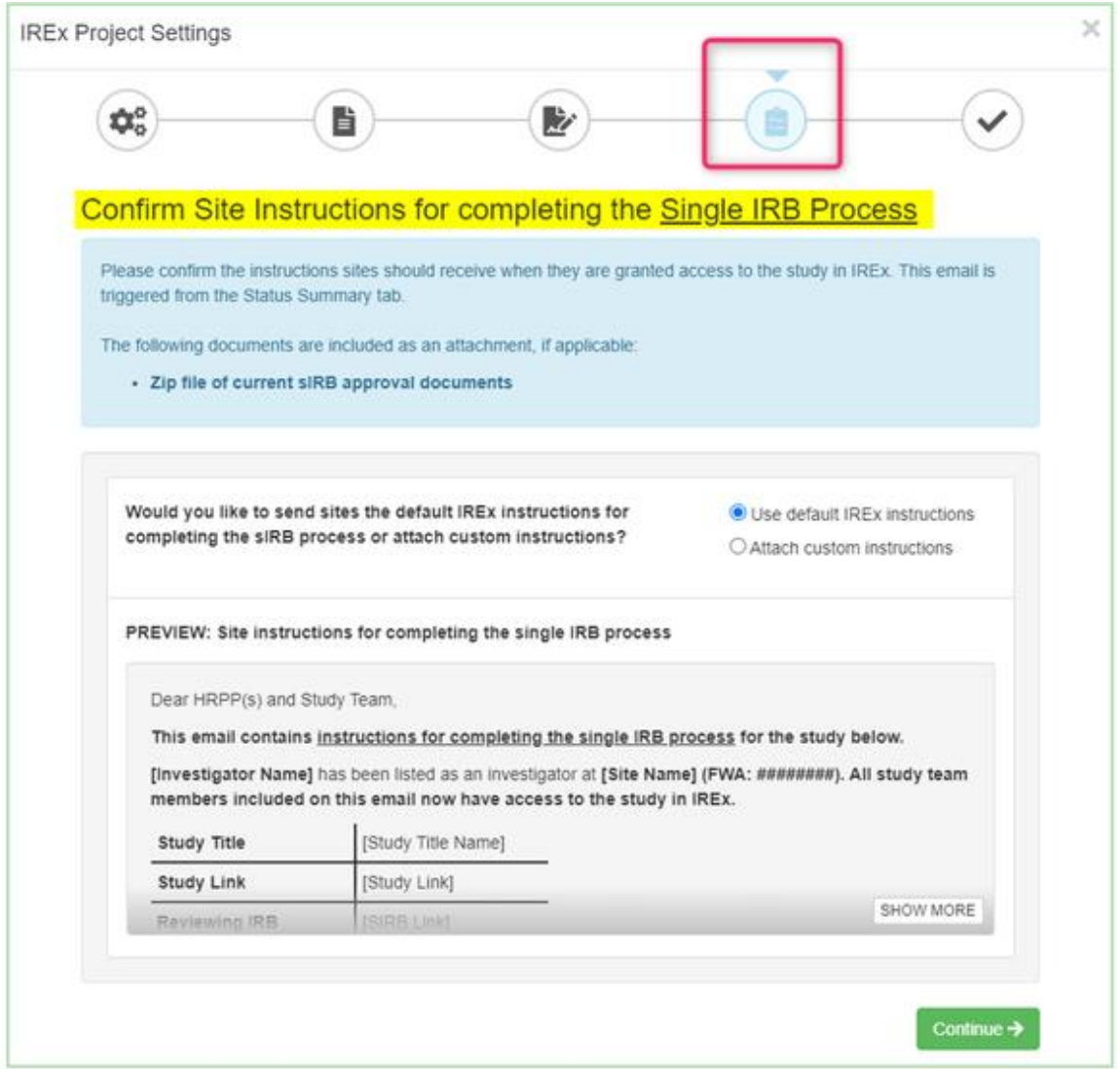
- And yes, we are thanking ourselves for using IREx

What's New?

Feature Updates & Releases Since July 2023

Single IRBs Confirm New Site Instructions

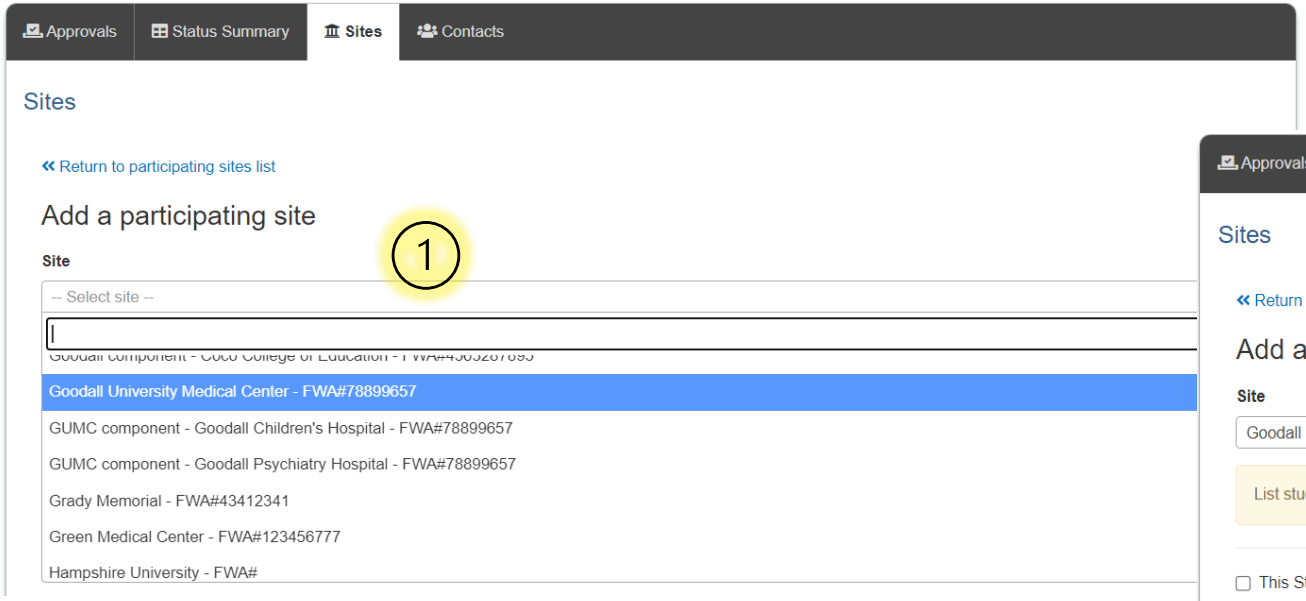


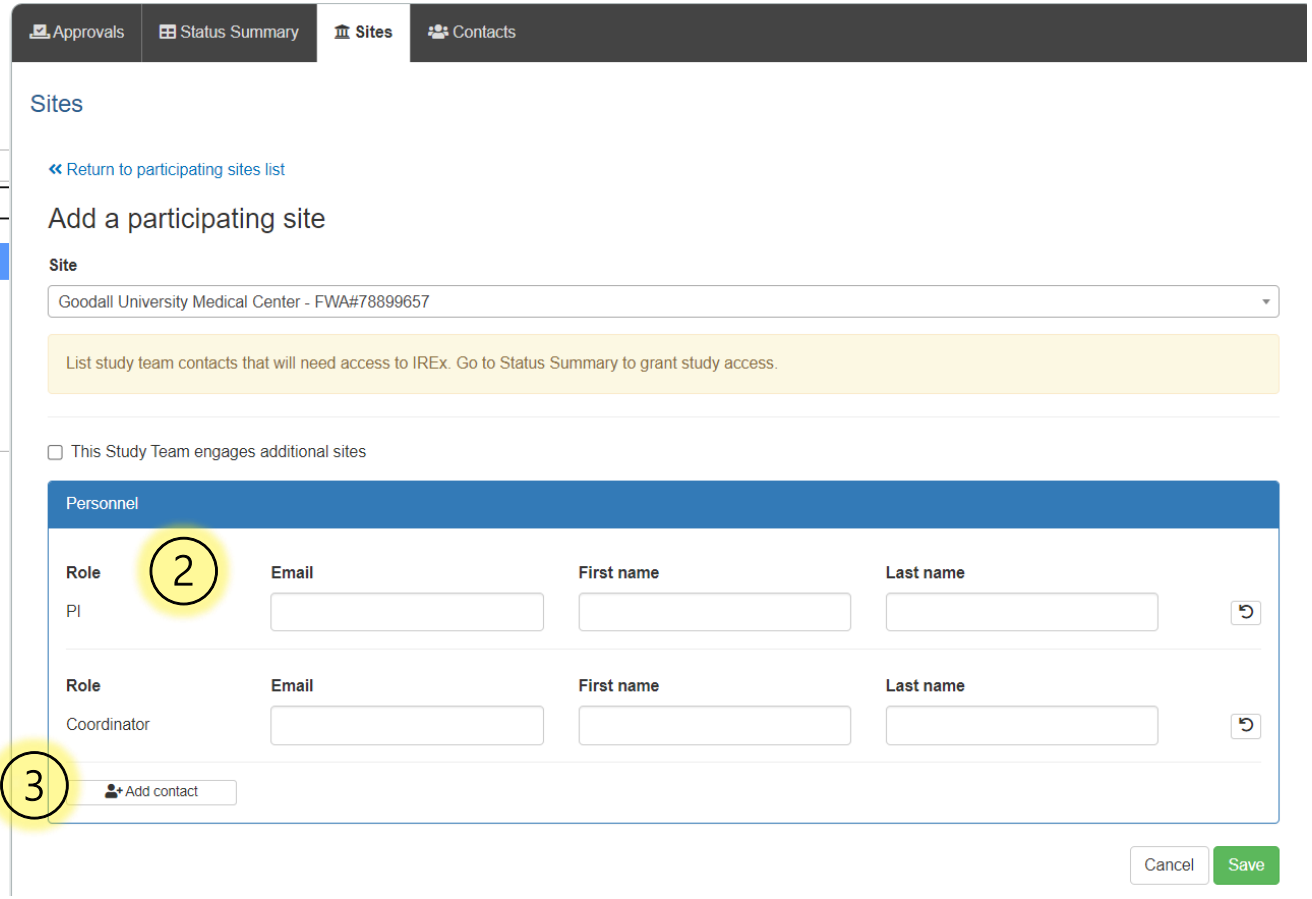


sIRBs

Sites Page – Adding Sites

IREx Study Manager

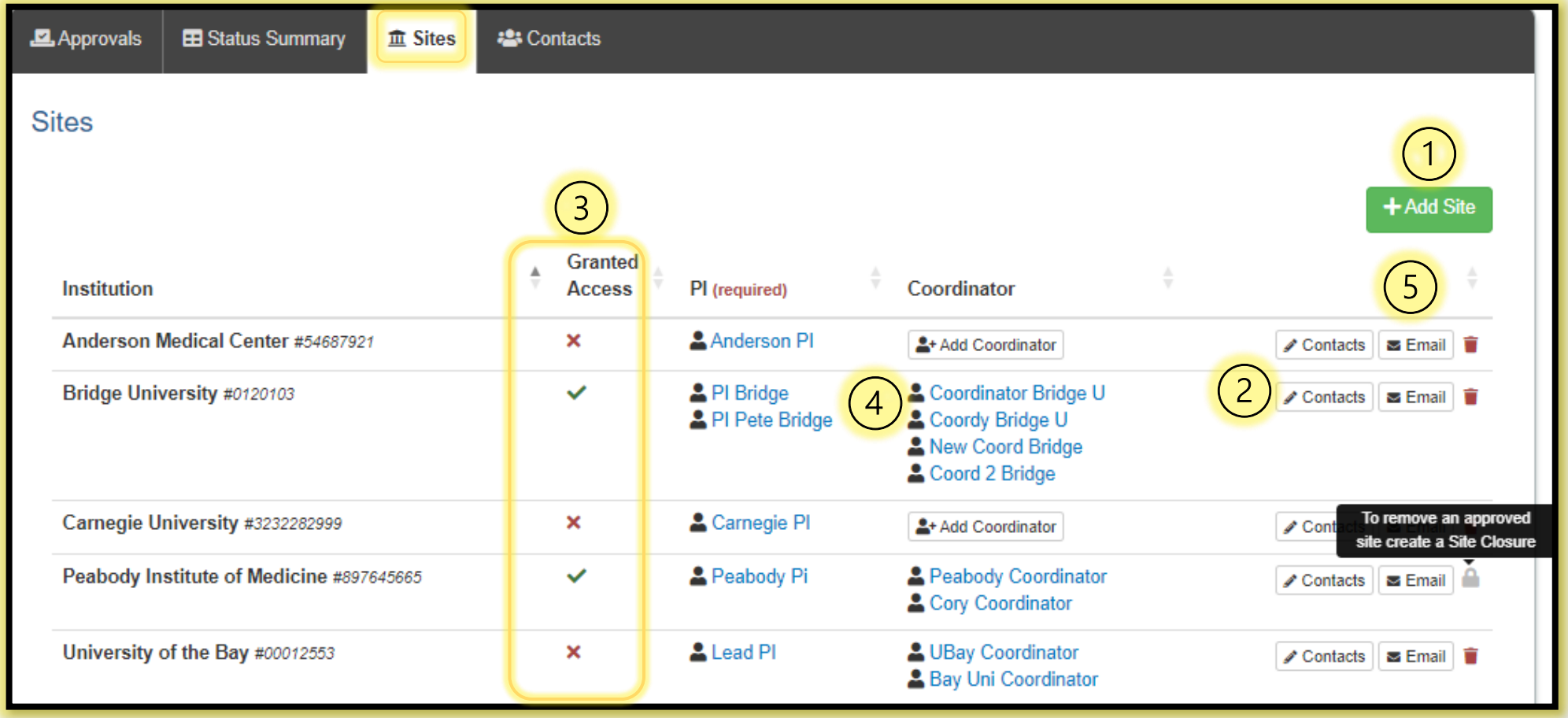




1. **Enter site name and select from dropdown**
2. **Enter PI and Coordinator information**
3. **Add additional contacts**

Sites Page Enhancements

IREx Study Manager & sIRBs

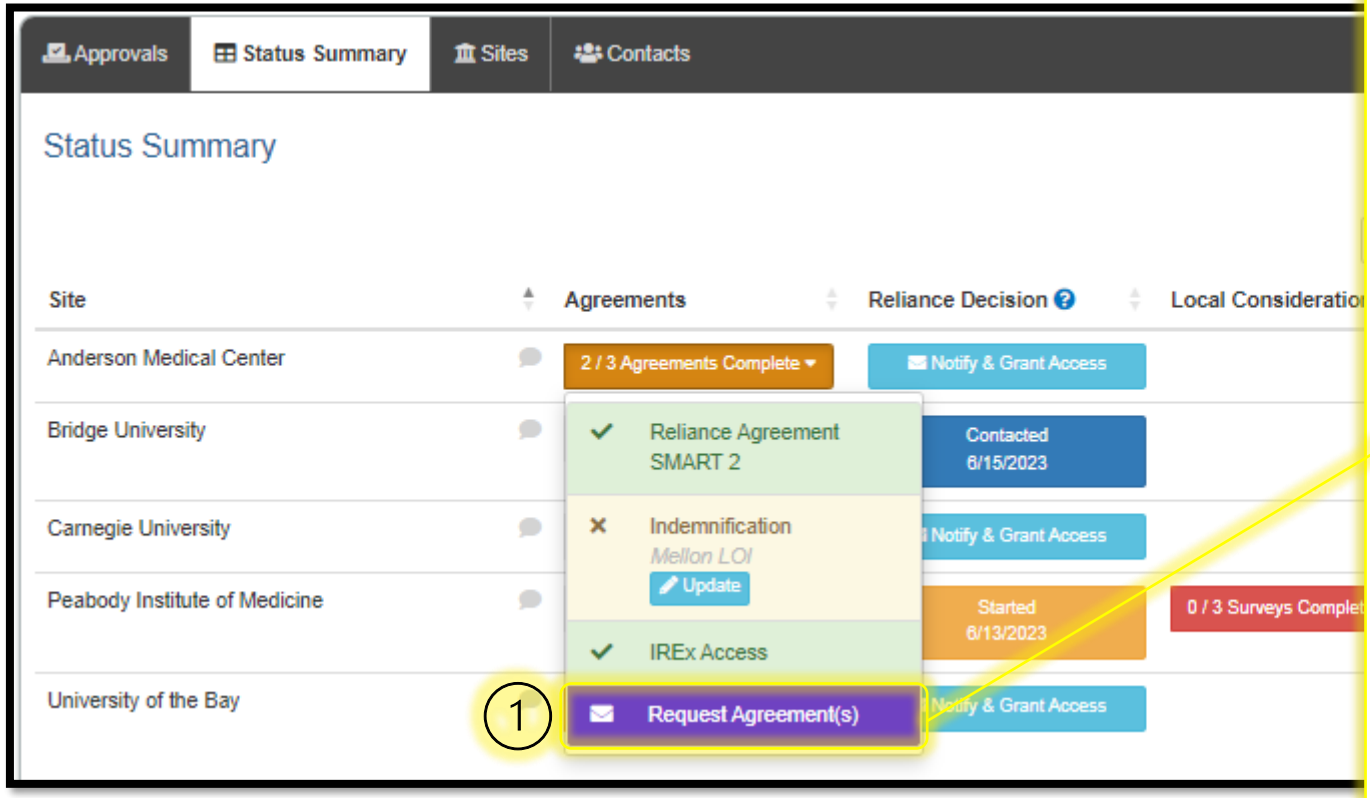


1. **Add new sites**
2. **Edit contacts for an existing site**
3. **View whether sites have been granted access to the study**
4. **View multiple PIs and/or coordinators for each site**
5. **Email all site contacts with the click of a button**

New Feature: Request Agreements from Sites

IREx Study Manager & sIRBs

1. sIRBs or Study Managers can **Request Agreements** from any site(s) missing the required agreements.
2. Instructions include links to complete agreements (SMART IRB) or an attachment of the sIRB's required agreement template.



2

Action Required: Please Complete Agreement(s) for sIRB study

Reply | Reply All | Forward

Lindsey Smith <donotreply@irbexchange.org>
To IRBExchangeAdministrator

LOI Template.docx
19 KB

Dear HRPP(s) and Site Investigator,

This email contains instructions for executing incomplete agreements for the study below where **Anderson PI**, an investigator at **Anderson Medical Center (FWA: 54687921)**, has been listed on the following study in IREx.

Study Title	Demo Study Title Here
Reviewing IRB	Mellon University Medical Center
Reviewing IRB Contact	Mellon Liaison (liaison@mellon.cdu)
Study Manager	Study Manager Mellon

As a first step towards relying on Mellon University Medical Center, please execute the incomplete items below.

Agreement/Resource	Status
SMART IRB Agreement: A national, master reliance agreement supporting single IRB review. OR	**Complete**
Mellon Letter of Indemnification	**Incomplete** — The indemnification agreement is attached. Send questions and executed agreements to Mellon Liaison (liaison@mellon.cdu).
IRB Reliance Exchange (IREx): A single IRB documentation and communication portal. *This is a web-based platform, not a reliance agreement.*	**Complete**

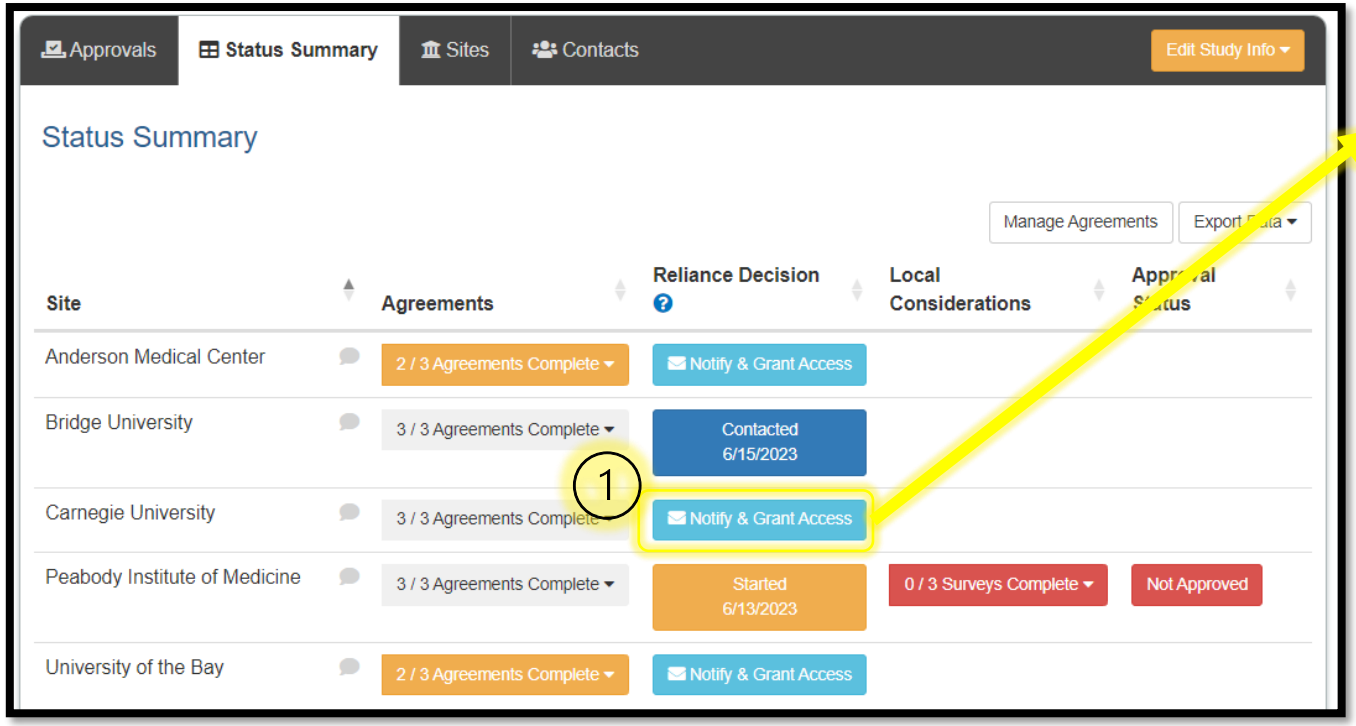
After your site has completed all the items above and the initial protocol has been approved by the Reviewing IRB, additional instructions will be sent regarding next steps.

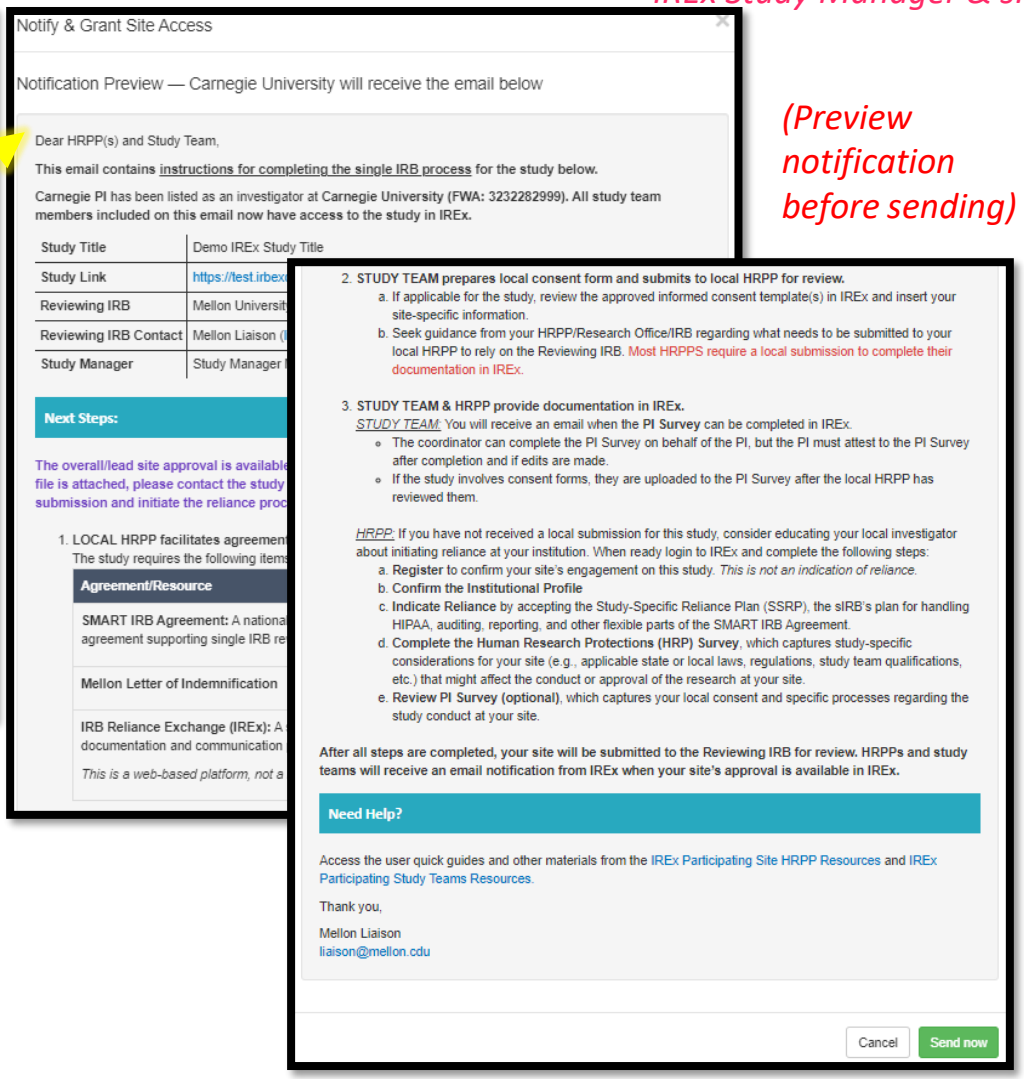
Thank you,

Mellon Study Manager
sm@mellon.cdu

New Feature:
Notify & Grant Access to Study Teams

IREx Study Manager & sIRBs

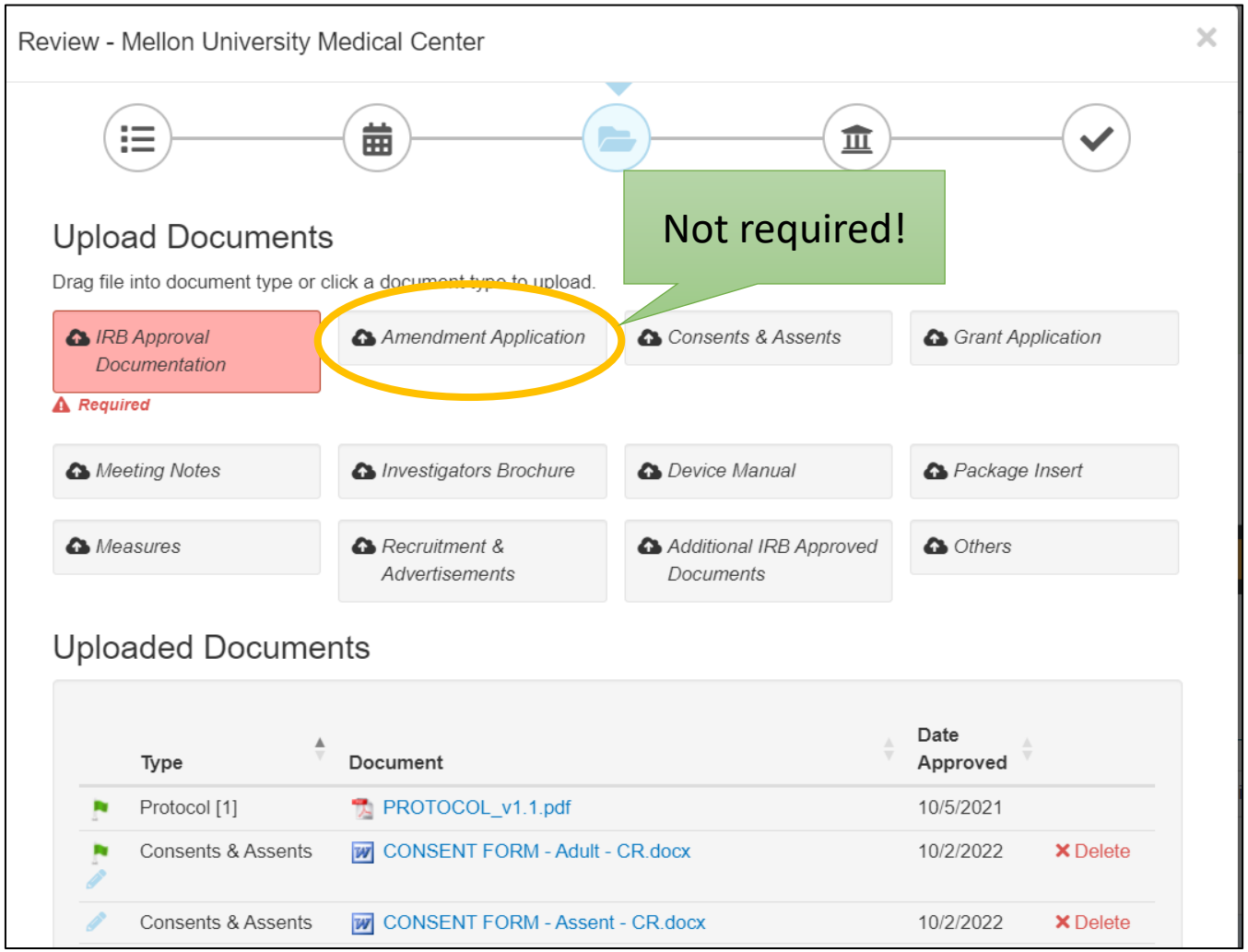




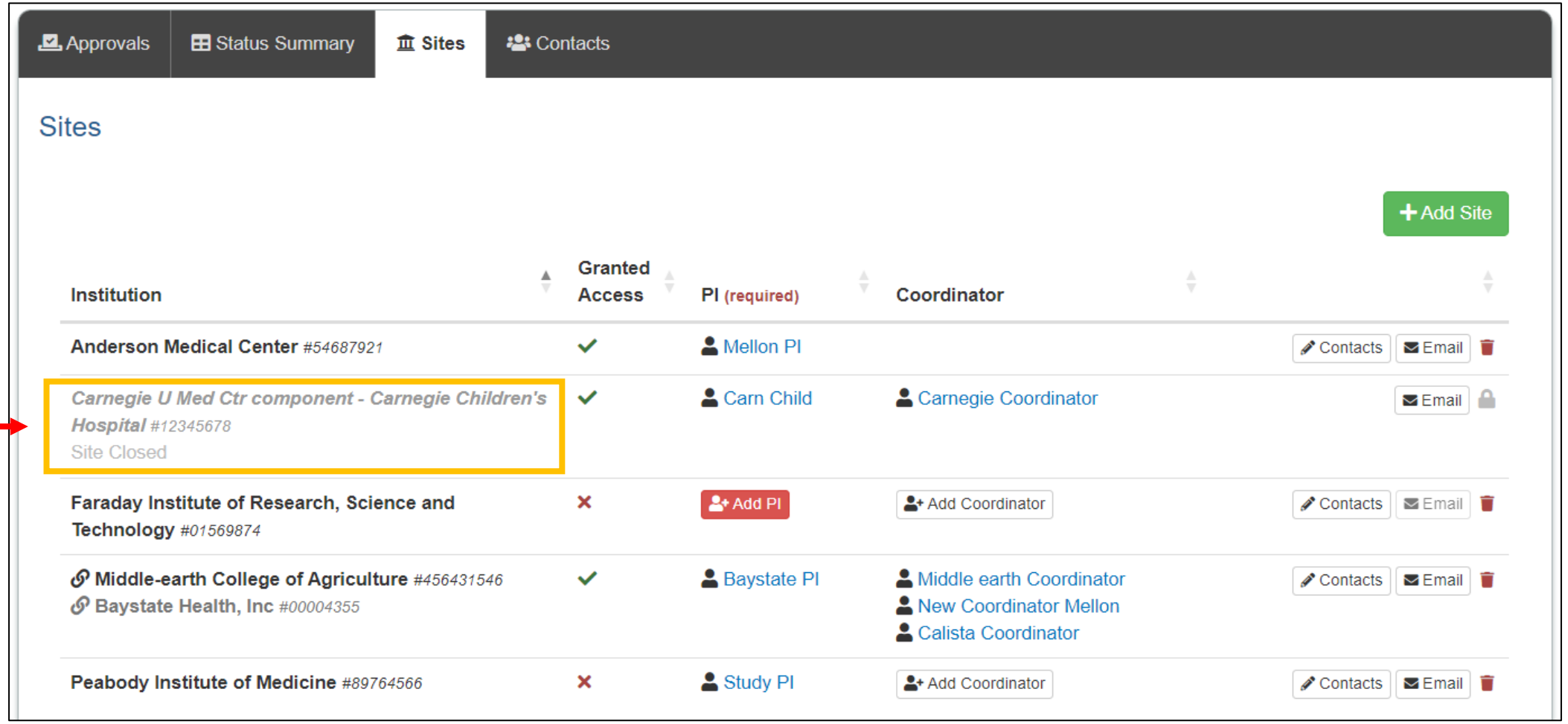
(Preview notification before sending)

1. **Notify & Grant Access** grants the study team immediate access to the study & approved study materials to prepare for local submission.

Updated Feature:
Amendment application no longer required



Updated Feature:
Closed sites will be indicted on the Sites page



Updated Feature:
All users with study access can grant access to Site PIs

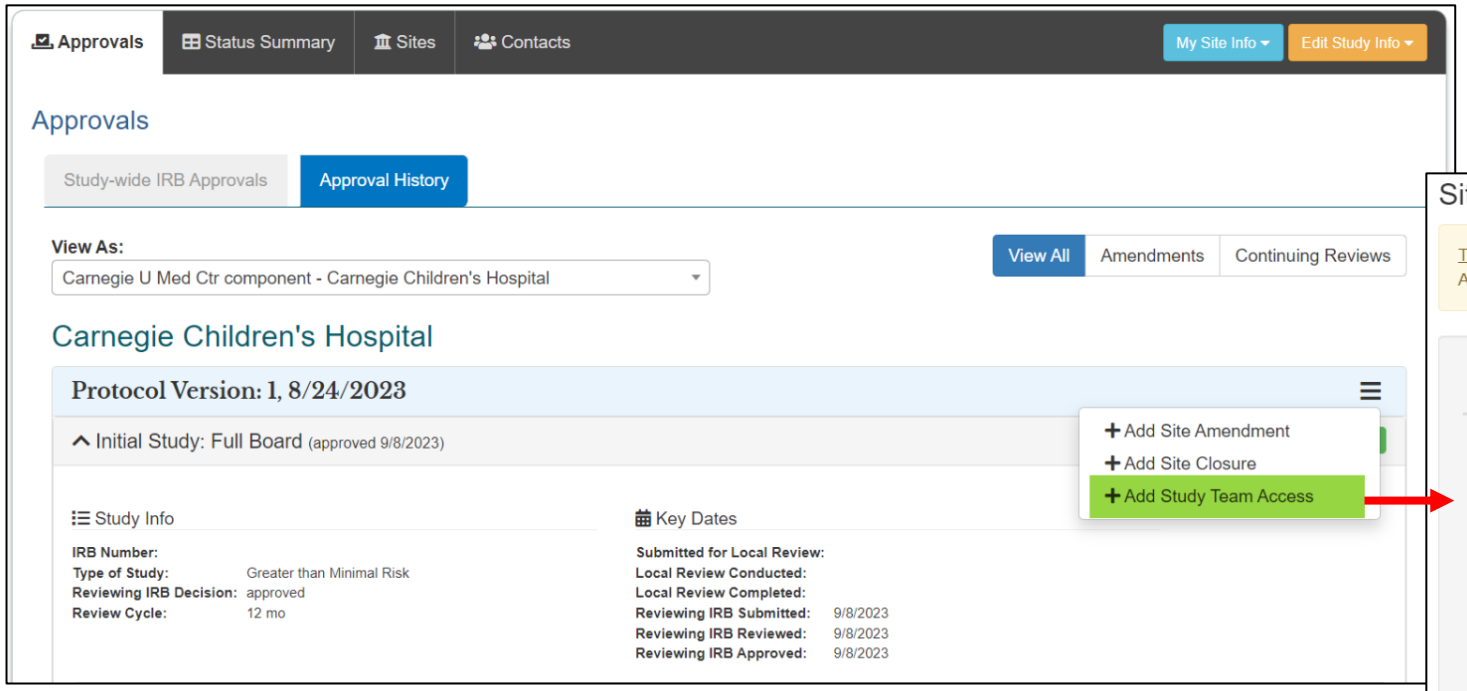
Grant PI access to a site that has approval site amendment not required

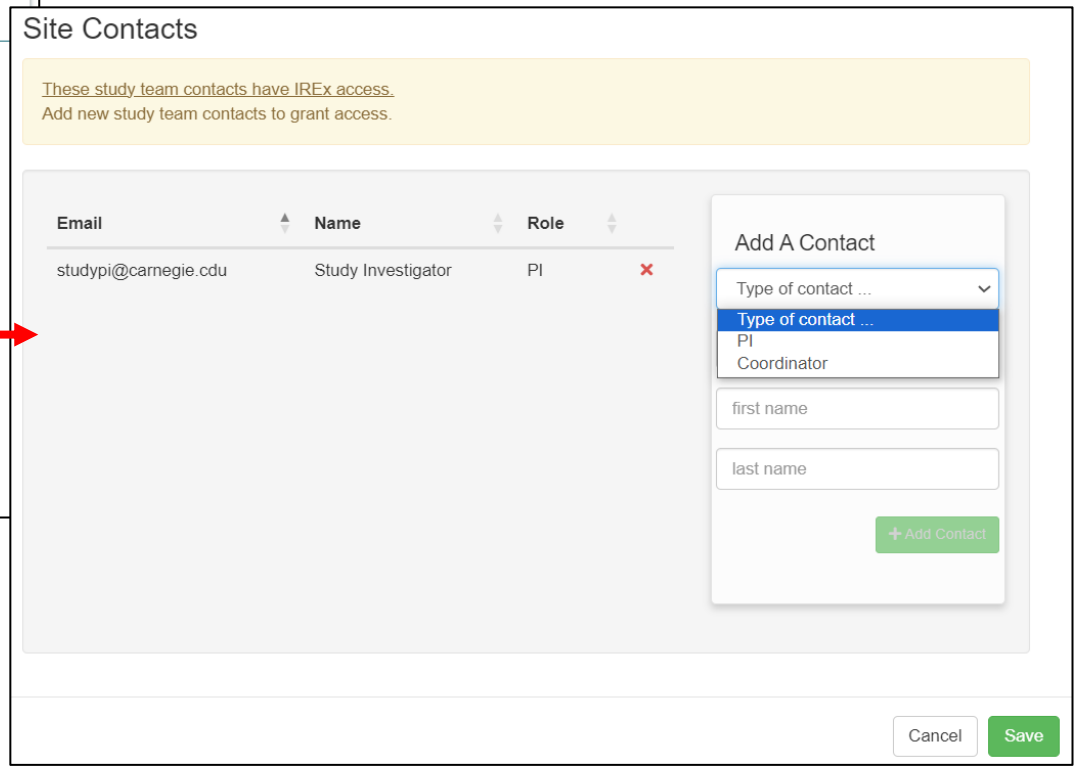
- Relying site HRPPs and study teams
- Lead Study Teams/ IREx Study Managers
- Single IRB Liaison

IREx Access

Updated Feature:
Renamed ‘Add Site Coordinator Access’ dialog

The ‘Add Site Coordinator Access’ from the Approval History tab has been renamed ‘Add Study Team Access’ and updated to allow adding a PI at anytime.

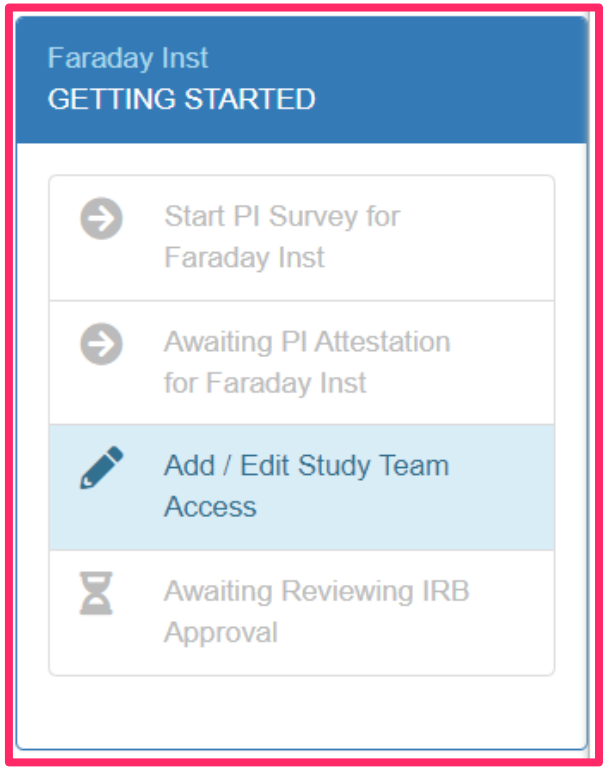




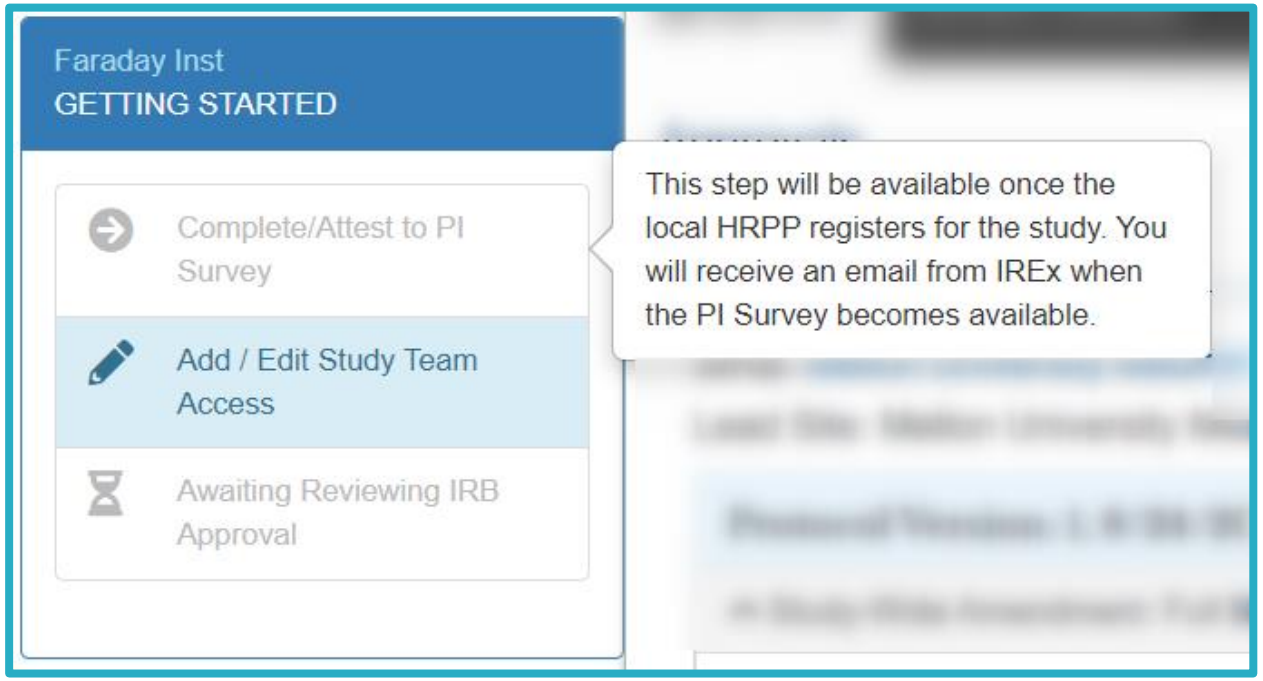
Updated Feature:
Study teams see Getting Started Checklist when granted study access

1. PIs and Coordinators see their Getting Started Checklists when granted study access
2. ‘Start/Complete PI Survey’ is unavailable until the HRPP registers for the study.

Coordinator

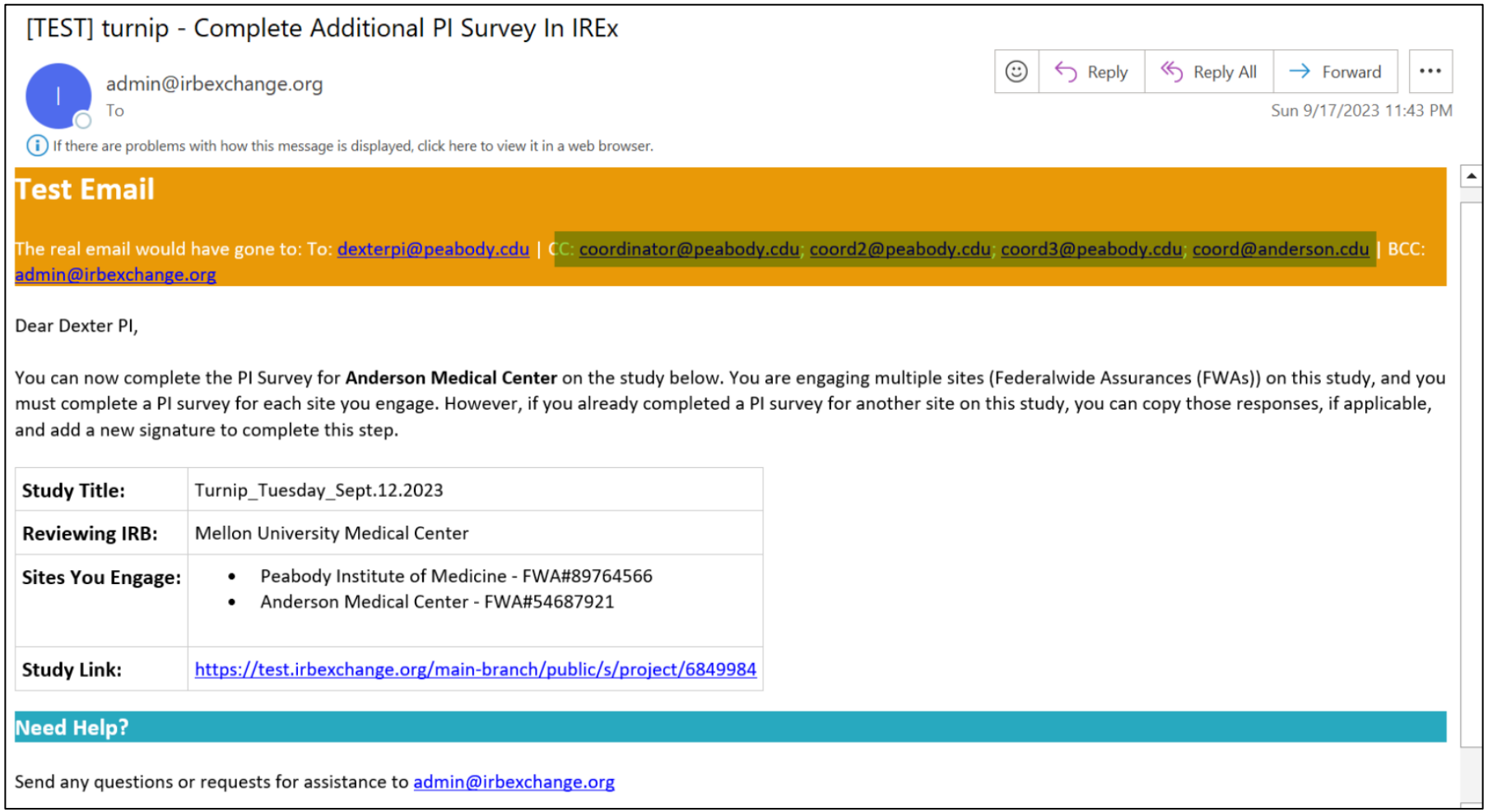


Investigator/PI



Updated Feature:
Site Coordinators are cc'd on all emails to a PI

Exception: PI's access and login email.



[TEST] turnip - Complete Additional PI Survey In IREx

admin@irbexchange.org
To

Reply | Reply All | Forward | ...
Sun 9/17/2023 11:43 PM

If there are problems with how this message is displayed, click here to view it in a web browser.

Test Email

The real email would have gone to: To: dexterpi@peabody.cdu | CC: coordinator@peabody.cdu; coord2@peabody.cdu; coord3@peabody.cdu; coord@anderson.cdu | BCC: admin@irbexchange.org

Dear Dexter PI,

You can now complete the PI Survey for **Anderson Medical Center** on the study below. You are engaging multiple sites (Federalwide Assurances (FWAs)) on this study, and you must complete a PI survey for each site you engage. However, if you already completed a PI survey for another site on this study, you can copy those responses, if applicable, and add a new signature to complete this step.

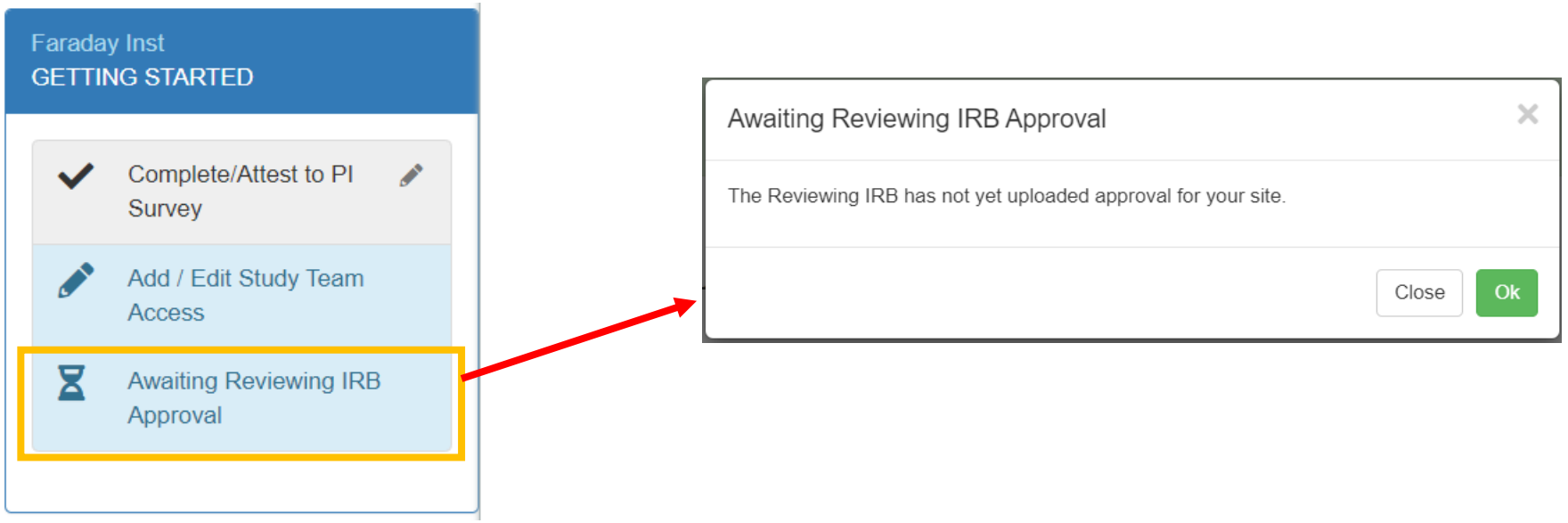
Study Title:	Turnip_Tuesday_Sept.12.2023
Reviewing IRB:	Mellon University Medical Center
Sites You Engage:	• Peabody Institute of Medicine - FWA#89764566 • Anderson Medical Center - FWA#54687921
Study Link:	https://test.irbexchange.org/main-branch/public/s/project/6849984

Need Help?

Send any questions or requests for assistance to admin@irbexchange.org

Updated Features: *'Awaiting Reviewing IRB Approval' now on study team checklist*

Study teams will now see the 'Awaiting Reviewing IRB Approval' step on their checklist to let know them what's next/upcoming.



Updated Feature:
View total # of relying studies / site on website

https://www.irbexchange.org/p/participants/

513 IREx Participating Institutions

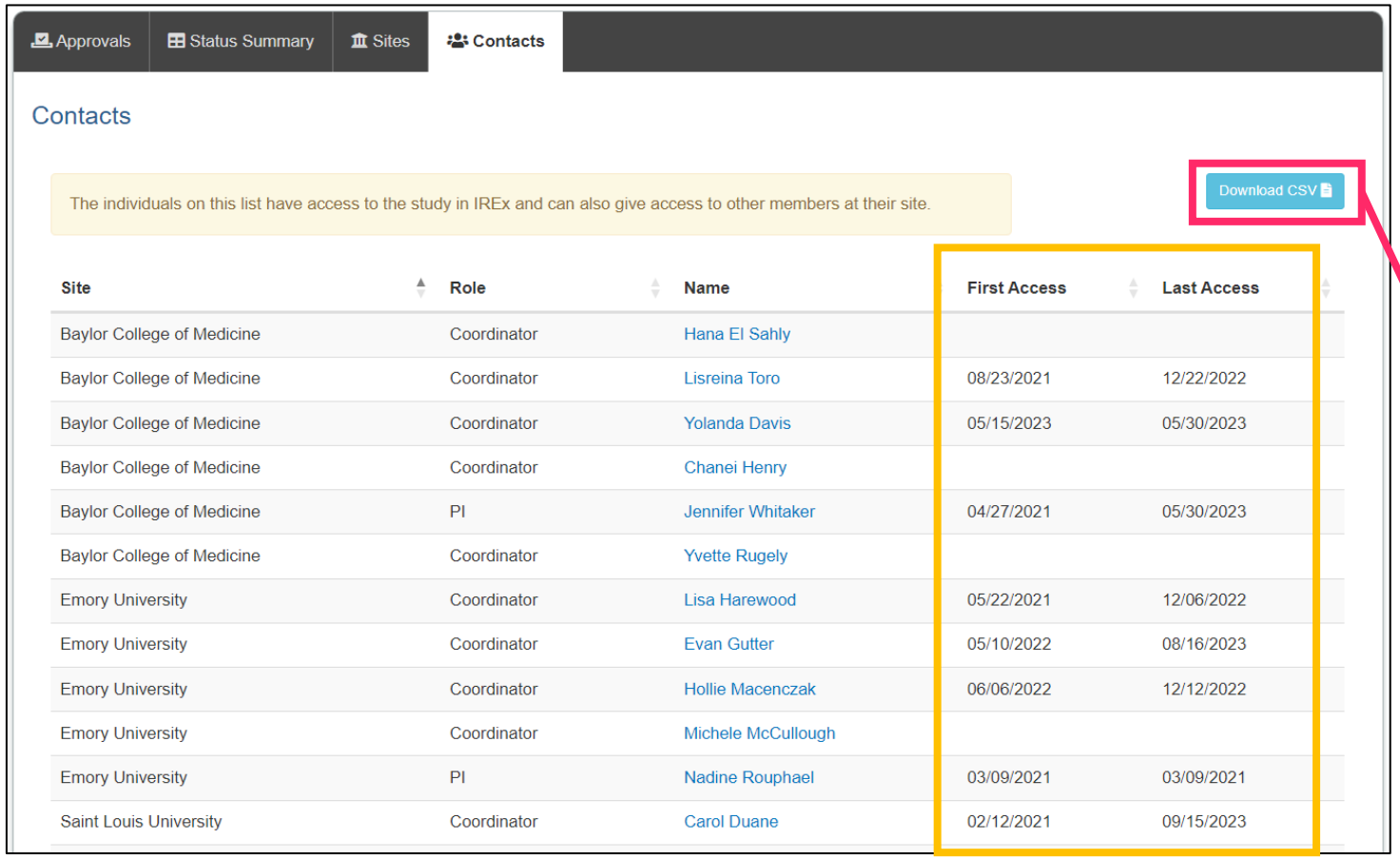
Not in IREx yet? Visit our Join IREx page to see how.

View a list of institutions using IREx as the Single IRB here.

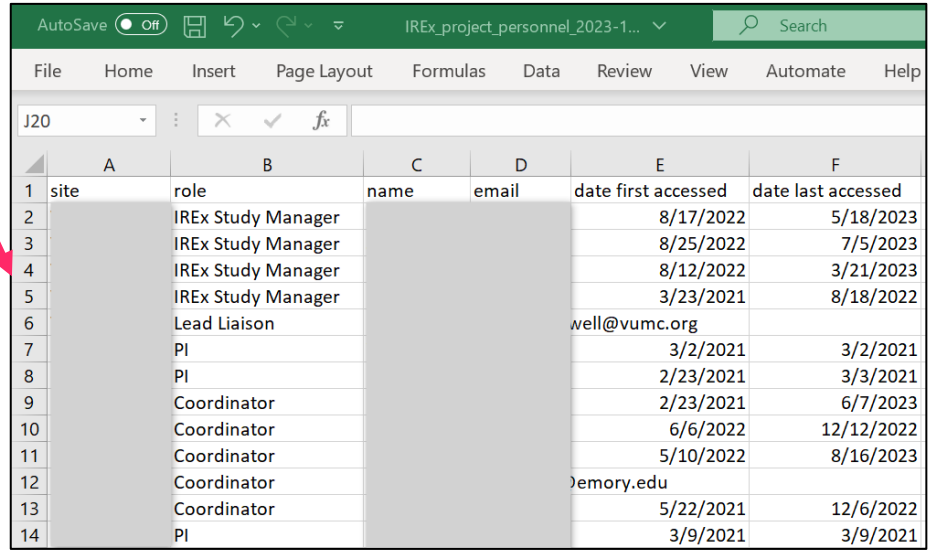
Download the IREx Quick Guide to the Institutional Profile.

NAME	# TOTAL RELYING STUDIES	INSTITUTIONAL PROFILE	LOCATION	LIAISON(S)
Children's Hospital of Philadelphia AAHRPP	74	updated 10/9/2023	Philadelphia, PA	Christine DeLussey Joyce Hartley Meghan Riley Amy Schwarzhoff Sarah Shade
Stanford University AAHRPP CTSA	64	updated 9/25/2023	Palo Alto, CA	Michelle LeManager Ellen O'Conor
University of Michigan AAHRPP CTSA	63	updated 8/29/2023	Ann Arbor, MI	Judy Birk Mary Donnelly Joshua Fedewa Nicole Robson Corey Zolondek
University of California, San Francisco CTSA	60	updated 10/16/2023	San Francisco, CA	Erin Coons Lana Hancer Alejandro Heredia Junie Hildebrandt Edward Kuczynski Jessica Phillips

New Feature:
IREx captures study teams' first and last access dates



Site	Role	Name	First Access	Last Access
Baylor College of Medicine	Coordinator	Hana El Sahly		
Baylor College of Medicine	Coordinator	Lisreina Toro	08/23/2021	12/22/2022
Baylor College of Medicine	Coordinator	Yolanda Davis	05/15/2023	05/30/2023
Baylor College of Medicine	Coordinator	Chanei Henry		
Baylor College of Medicine	PI	Jennifer Whitaker	04/27/2021	05/30/2023
Baylor College of Medicine	Coordinator	Yvette Rugely		
Emory University	Coordinator	Lisa Harewood	05/22/2021	12/06/2022
Emory University	Coordinator	Evan Gutter	05/10/2022	08/16/2023
Emory University	Coordinator	Hollie Macenczak	06/06/2022	12/12/2022
Emory University	Coordinator	Michele McCullough		
Emory University	PI	Nadine Rouphael	03/09/2021	03/09/2021
Saint Louis University	Coordinator	Carol Duane	02/12/2021	09/15/2023



	A	B	C	D	E	F
1	site	role	name	email	date first accessed	date last accessed
2		IREx Study Manager			8/17/2022	5/18/2023
3		IREx Study Manager			8/25/2022	7/5/2023
4		IREx Study Manager			8/12/2022	3/21/2023
5		IREx Study Manager			3/23/2021	8/18/2022
6		Lead Liaison			well@vumc.org	
7		PI			3/2/2021	3/2/2021
8		PI			2/23/2021	3/3/2021
9		Coordinator			2/23/2021	6/7/2023
10		Coordinator			6/6/2022	12/12/2022
11		Coordinator			5/10/2022	8/16/2023
12		Coordinator			emory.edu	
13		Coordinator			5/22/2021	12/6/2022
14		PI			3/9/2021	3/9/2021

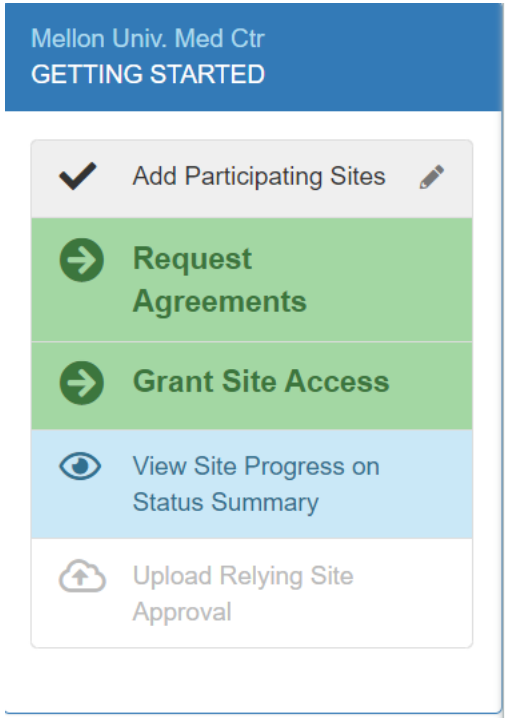
What's Next for IREx?

What's Next:
Minor Enhancements through mid-November

- **Lead Study Teams/IREx Study Managers**
  - Ability to edit site contacts from Contacts page (currently view only)
  - Adding 'request agreements' to Getting Started Checklist
  - Request

- **Reviewing IRB** – new steps on Getting Started Checklist
  - Manage Agreements, if using non-SMART agreement or indemnification

- **All**: renaming 'Coordinator' to 'Study Team Member' to be more inclusive



What's Next:
Major Enhancement Nov – March 2024

- **Enhancing the Capture of Local Considerations in IREx to account for:**
  - SMART IRB recommendations
  - When sIRBs need to request sites confirm or update their local considerations based on study changes
  - Studies that require the addition of study-specific questions (routine care)
  - Documentation requirements & workflow for EFIC studies
- **Interested in informing development:** https://redcap.vanderbilt.edu/surveys/?s=ECMXA8FE9N

Next Call: January 19, 2024!

Register HERE for IREx 2024 Quarterly Calls