



# • 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**



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# 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](#)

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**January 19, 2024**

**April 19, 2024**

**July 19, 2024**

**October 18, 2024**



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# Announcements

# IREx Website Makeover



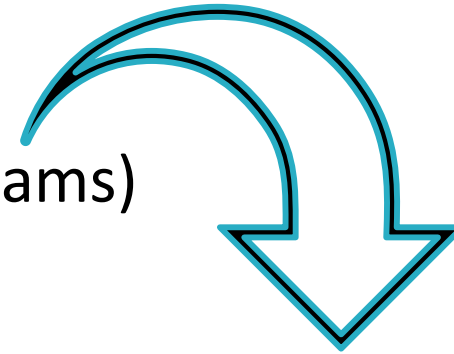
- New homepage: <https://www.irbexchange.org/p/>
- New testimonials added:  
<https://www.irbexchange.org/p/what-our-users-say/>
- New Presentations & Publications page:  
<https://www.irbexchange.org/p/publications/>
- View/sort Institutions by the # of studies where they're relying on a single IRB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

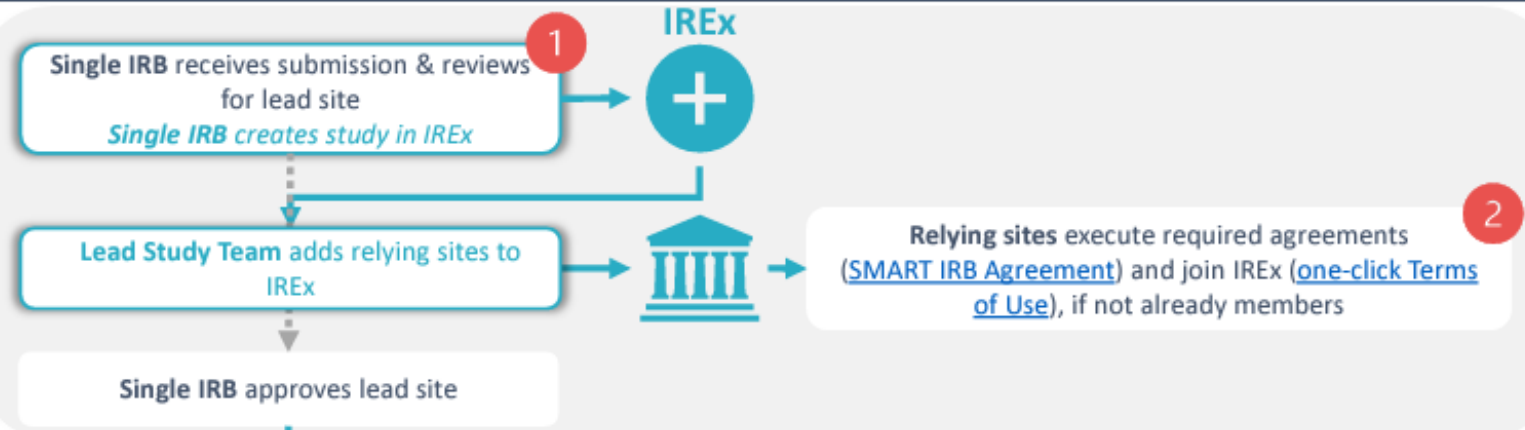
- **\*NEW\*** [IREx Workflow + Lessons Learned](#)

**RESOURCES**

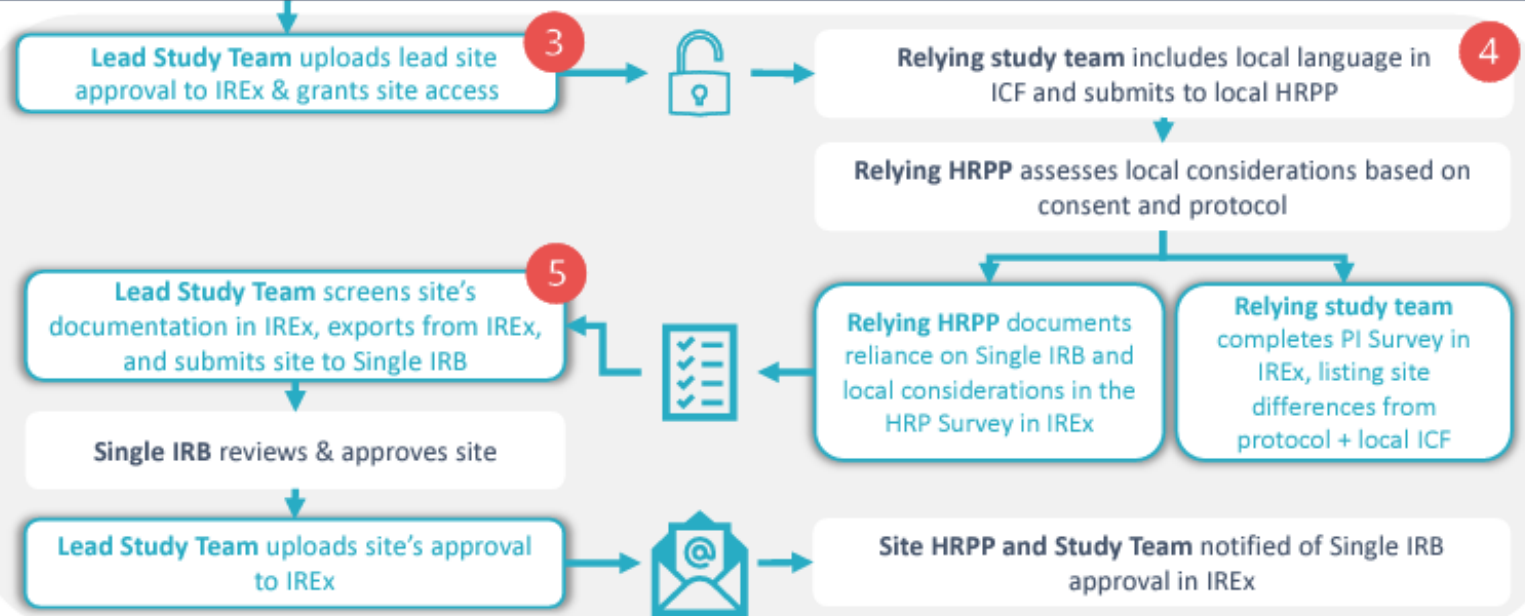
We have resources for each role within IREx. Click the link to access each resource page:

 Reviewing IRB Resources	 Participating Site HRPP Resources
 Study Manager Resources	 Study Team Resources

## Prior to Lead Site Approval



## After Lead Site Approval



Key: [Actions taken in IREx](#); IRB Reliance Exchange (IREx); Informed Consent Form (ICF); Human Research Protections Program (HRPP)

## Lessons Learned

- 1 To avoid requesting revisions and delay site onboarding,** approve the lead site first, before asking sites for local HRPP documentation.
- 2 To minimize onboarding time,** use the SMART IRB Agreement and ask sites to execute any incomplete agreements while the lead site is being reviewed.
- 3 To standardize the process and centralize documentation,** use IREx and identify a lead study team member to communicate and coordinate the Single IRB process to sites.
- 4 To streamline Single IRB review of sites,** allow limited editing of the informed consent to only designated sections.
- 5 To avoid bottlenecks in Single IRB review,** encourage the lead study team to pre-screen the HRP & PI Surveys before submitting the site to the Single IRB for review.



# 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?](#)



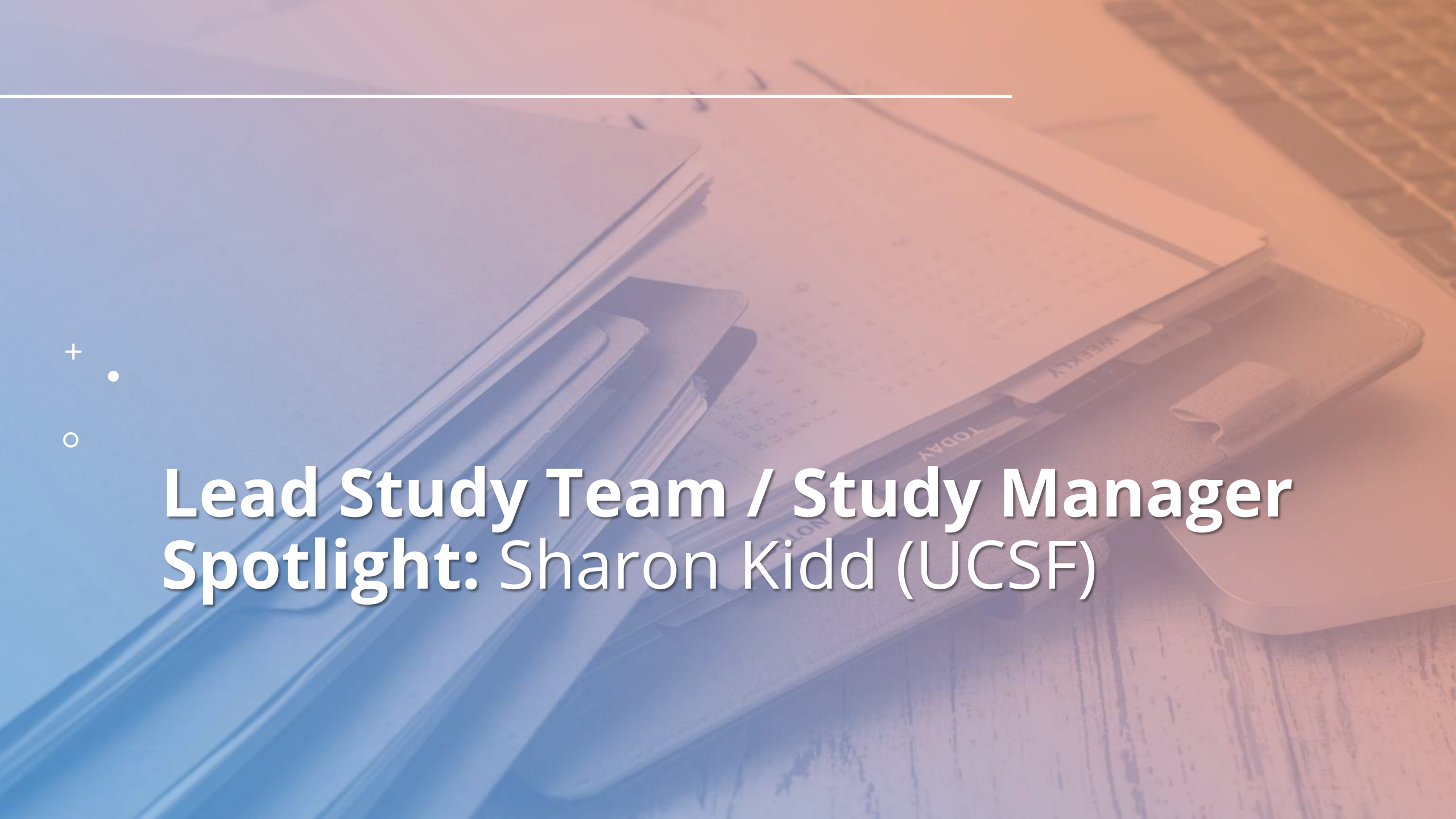
## FOR sIRBs

- [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](#)

The screenshot displays the YouTube channel for IRB Reliance Exchange 'IREx'. The channel name is IRB Reliance Exchange 'IREx' with the handle @IRBRelianceExchange, 34 subscribers, and 30 videos. The bio states: "IRB Reliance Exchange (IREx) is a freely available, web-based portal support...". The website irbexchange.org is listed. The navigation menu includes HOME, VIDEOS, PLAYLISTS, COMMUNITY, CHANNELS, and ABOUT. The video list is sorted by 'Latest' and shows four video thumbnails with their titles and durations: 'Getting Approved & Accessing Approval Documents' (1:22), 'Removing Access for an Existing User in IREx' (0:43), 'How do Relying HRPPs register for a study in IREx?' (1:56), and 'How to Create a Study in IREx' (7:06). The last video has 8 views and was posted 6 days ago.



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# 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 20<sup>th</sup>, 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

Site	Agreements	Reliance Decision ?	Local Considerations	Approval Status
Ann & Robert H. Lurie Children's Hospital of Chicago	2 / 2 Agreements Complete	Completed 7/21/2023	1 / 3 Surveys Complete	Not Approved
Baylor College of Medicine	2 / 2 Agreements Complete	Completed 12/1/2022	3 / 3 Surveys Complete	Not Approved
Boston Children's Hospital Dana-Farber	2 / 2 Agreements Complete	Contacted 6/30/2023		
Children's Healthcare of Atlanta, Inc. Emory University	2 / 2 Agreements Complete	Completed 9/19/2022	1 / 3 Surveys Complete	Not Approved

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

Institution	Granted Access	PI (required)	Coordinator	
Ann & Robert H. Lurie Children's Hospital of Chicago #00001011	✓	Sonali Chaudhury	Eric Brown Marianne Moreno	Contacts  Email
Baylor College of Medicine #00000286	✓	Lisa Forbes-Satter	Renee Ali Betty Hernandez Supriya Parikh Mariam Imam	Contacts  Email
Children's Hospital of Alabama #00005810	✗	Hilary Haines	+ Add Coordinator	Contacts  Email

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



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# What's New?

*Feature Updates & Releases Since July 2023*

# Single IRBs Confirm New Site Instructions

sIRBs

### IREx Project Settings

Confirm Site Instructions for Executing Required Agreements

An optional IREx notification can be sent to sites requesting they execute any incomplete agreements for the study. This email is triggered from the Status Summary tab.

The following document(s) will be attached to the email for sites missing the agreement(s):

Who can use IREx to send instructions for executing the required agreements?  
 Lead study team and/or sIRB  sIRB only

Preview the site instructions below. Do you want to include additional instructions as an attachment?  
 Use default IREx instructions only  Attach additional instructions

PREVIEW: Site instructions for executing required agreements

Dear HRPP(s) and Site Investigator,

This email contains instructions for executing incomplete agreements for the study below where [Investigator Name], an investigator at [Site Name] (FWA: #####), has been listed on the following study in IREx.

Study Title	[Study Title Name]
Reviewing IRB	[SIRB Link]
Reviewing IRB Contact	[Primary SIRB Contact]

SHOW MORE

Continue →

### 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.

The following documents are included as an attachment, if applicable:

- Zip file of current sIRB approval documents

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

PREVIEW: Site instructions for completing the single IRB process

Dear HRPP(s) and Study Team,

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

[Investigator Name] has been listed as an investigator at [Site Name] (FWA: #####). All study team members included on this email now have access to the study in IREx.

Study Title	[Study Title Name]
Study Link	[Study Link]
Reviewing IRB	[SIRB Link]

SHOW MORE

Continue →

# Sites Page – Adding Sites

Approvals Status Summary **Sites** Contacts

## Sites

[Return to participating sites list](#)

### Add a participating site

Site 1

-- Select site --

- Goodall component - Goodall College of Education - FWA#430207030
- Goodall University Medical Center - FWA#78899657**
- GUMC component - Goodall Children's Hospital - FWA#78899657
- GUMC component - Goodall Psychiatry Hospital - FWA#78899657
- Grady Memorial - FWA#43412341
- Green Medical Center - FWA#123456777
- Hampshire University - FWA#

Approvals Status Summary **Sites** Contacts

## Sites

[Return to participating sites list](#)

### Add a participating site

Site

Goodall University Medical Center - FWA#78899657

List study team contacts that will need access to IREx. Go to Status Summary to grant study access.

This Study Team engages additional sites

#### Personnel

Role	Email	First name	Last name
PI <span>2</span>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Coordinator	<input type="text"/>	<input type="text"/>	<input type="text"/>

3

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

The screenshot shows the 'Sites' page in the IREx Study Manager & sIRBs interface. The page has a navigation bar with 'Approvals', 'Status Summary', 'Sites', and 'Contacts'. The 'Sites' section is active. A table lists sites with columns for 'Institution', 'Granted Access', 'PI (required)', and 'Coordinator'. Callouts 1-5 highlight specific features: 1. '+ Add Site' button; 2. 'Contacts' and 'Email' buttons for a site; 3. 'Granted Access' column with a red 'x' and green checkmark; 4. Multiple PIs and coordinators for a site; 5. 'Email' button for a site. A tooltip says 'To remove an approved site create a Site Closure'.

Institution	Granted Access	PI (required)	Coordinator	Actions
Anderson Medical Center #54687921	×	Anderson PI	+ Add Coordinator	Contacts, Email, [trash]
Bridge University #0120103	✓	PI Bridge, PI Pete Bridge	Coordinator Bridge U, Coordy Bridge U, New Coord Bridge, Coord 2 Bridge	Contacts, Email, [trash]
Carnegie University #3232282999	×	Carnegie PI	+ Add Coordinator	Contacts, Email, [trash]
Peabody Institute of Medicine #897645665	✓	Peabody Pi	Peabody Coordinator, Cory Coordinator	Contacts, Email, [lock]
University of the Bay #00012553	×	Lead PI	UBay Coordinator, Bay Uni Coordinator	Contacts, Email, [trash]

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

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.

IREx Study Manager & sIRBs

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The screenshot shows the 'Status Summary' page in the IREx Study Manager. The table lists sites and their agreement status. For 'University of the Bay', a dropdown menu is open, showing options: 'Request Agreement(s)' (highlighted with a circled '1'), 'Notify & Grant Access', 'Reliance Agreement SMART 2', 'Indemnification Mellon LOI' (with an 'Update' button), and 'IREx Access'.

Site	Agreements	Reliance Decision	Local Consideration
Anderson Medical Center	2 / 3 Agreements Complete	Notify & Grant Access	
Bridge University	✓ Reliance Agreement SMART 2	Contacted 8/15/2023	
Carnegie University	✗ Indemnification Mellon LOI (Update)	Notify & Grant Access	
Peabody Institute of Medicine	✓ IREx Access	Started 6/13/2023	0 / 3 Surveys Complete
University of the Bay	✗ Request Agreement(s) (1)	Notify & Grant Access	

The email is titled 'Action Required: Please Complete Agreement(s) for sIRB study'. It is from Lindsey Smith to IRBExchangeAdministrator. The email body contains instructions for executing incomplete agreements for a study at Anderson Medical Center. It includes a table with study details and a table listing required agreements and their status.

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.

Field	Value
Study Title	Demo Study Title Here
Reviewing IRB	Mellon University Medical Center
Reviewing IRB Contact	Mellon Liaison ( <a href="mailto:liaison@mellon.cdu">liaison@mellon.cdu</a> )
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.	Complete
OR	
Mellon Letter of Indemnification	Incomplete — The indemnification agreement is attached. Send questions and executed agreements to Mellon Liaison ( <a href="mailto:liaison@mellon.cdu">liaison@mellon.cdu</a> ).
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](mailto:sm@mellon.cdu)

# New Feature: Notify & Grant Access to Study Teams

IREx Study Manager & sIRBs

(Preview notification before sending)

Site	Agreements	Reliance Decision	Local Considerations	Approval Status
Anderson Medical Center	2 / 3 Agreements Complete	Notify & Grant Access		
Bridge University	3 / 3 Agreements Complete	Contacted 6/15/2023		
Carnegie University	3 / 3 Agreements Complete	Notify & Grant Access		
Peabody Institute of Medicine	3 / 3 Agreements Complete	Started 6/13/2023	0 / 3 Surveys Complete	Not Approved
University of the Bay	2 / 3 Agreements Complete	Notify & Grant Access		

Notify & Grant Site Access

Notification Preview — Carnegie 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.

Carnegie PI has been listed as an investigator at Carnegie University (FWA: 3232282999). All study team members included on this email now have access to the study in IREx.

Study Title	Demo IREx Study Title
Study Link	<a href="https://test.irex.com">https://test.irex.com</a>
Reviewing IRB	Mellon University
Reviewing IRB Contact	Mellon Liaison (Mellon)
Study Manager	Study Manager

**Next Steps:**

The overall/lead site approval is available in IREx. If a file is attached, please contact the study manager and initiate the reliance process.

- LOCAL HRPP facilitates agreement. The study requires the following items:
  - Agreement/Resource
    - SMART IRB Agreement: A national agreement supporting single IRB review.
    - Mellon Letter of Indemnification.
    - IRB Reliance Exchange (IREx): A documentation and communication platform.
- STUDY TEAM prepares local consent form and submits to local HRPP for review.
  - If applicable for the study, review the approved informed consent template(s) in IREx and insert your site-specific information.
  - 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.
- STUDY TEAM & HRPP provide documentation in IREx.

**STUDY TEAM:** You will receive an email when the PI Survey can be completed in IREx.

  - The coordinator can complete the PI Survey on behalf of the PI, but the PI must attest to the PI Survey after completion and if edits are made.
  - If the study involves consent forms, they are uploaded to the PI Survey after the local HRPP has reviewed them.

**HRPP:** If you have not received a local submission for this study, consider educating your local investigator about initiating reliance at your institution. When ready login to IREx and complete the following steps:

  - Register to confirm your site's engagement on this study. *This is not an indication of reliance.*
  - Confirm the Institutional Profile
  - Indicate Reliance by accepting the Study-Specific Reliance Plan (SSRP), the sIRB's plan for handling HIPAA, auditing, reporting, and other flexible parts of the SMART IRB Agreement.
  - Complete the Human Research Protections (HRP) Survey, which captures study-specific considerations for your site (e.g., applicable state or local laws, regulations, study team qualifications, etc.) that might affect the conduct or approval of the research at your site.
  - Review PI Survey (optional), which captures your local consent and specific processes regarding the study conduct at your site.

After all steps are completed, your site will be submitted to the Reviewing IRB for review. HRPPs and study teams will receive an email notification from IREx when your site's approval is available in IREx.

**Need Help?**

Access the user quick guides and other materials from the IREx Participating Site HRPP Resources and IREx Participating Study Teams Resources.

Thank you,  
Mellon Liaison  
[liaison@mellon.edu](mailto:liaison@mellon.edu)

Cancel Send now

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

Review - Mellon University Medical Center

Upload Documents

Drag file into document type or click a document type to upload.

**IRB Approval Documentation** **Amendment Application** **Consents & Assents** **Grant Application**

**Required**

Meeting Notes Investigators Brochure Device Manual Package Insert

Measures Recruitment & Advertisements Additional IRB Approved Documents Others

Uploaded Documents

Type	Document	Date Approved	
Protocol [1]	PROTOCOL_v1.1.pdf	10/5/2021	
Consents & Assents	CONSENT FORM - Adult - CR.docx	10/2/2022	Delete
Consents & Assents	CONSENT FORM - Assent - CR.docx	10/2/2022	Delete

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

Institution	Granted Access	PI (required)	Coordinator	
Anderson Medical Center #54687921	✓	Mellon PI		<a href="#">Contacts</a> <a href="#">Email</a>
<b>Carnegie U Med Ctr component - Carnegie Children's Hospital #12345678</b> Site Closed	✓	Carn Child	Carnegie Coordinator	<a href="#">Email</a>
Faraday Institute of Research, Science and Technology #01569874	✗	<a href="#">+ Add PI</a>	<a href="#">+ Add Coordinator</a>	<a href="#">Contacts</a> <a href="#">Email</a>
Middle-earth College of Agriculture #456431546 Baystate Health, Inc #00004355	✓	Baystate PI	Middle earth Coordinator New Coordinator Mellon Calista Coordinator	<a href="#">Contacts</a> <a href="#">Email</a>
Peabody Institute of Medicine #89764566	✗	Study PI	<a href="#">+ Add Coordinator</a>	<a href="#">Contacts</a> <a href="#">Email</a>

# 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.

Approvals | Status Summary | Sites | Contacts | My Site Info | Edit Study Info

Approvals

Study-wide IRB Approvals | Approval History

View As: Carnegie U Med Ctr component - Carnegie Children's Hospital

View All | Amendments | Continuing Reviews

Carnegie Children's Hospital

Protocol Version: 1, 8/24/2023

Initial Study: Full Board (approved 9/8/2023)

Study Info | Key Dates

- IRB Number:
- Type of Study: Greater than Minimal Risk
- Reviewing IRB Decision: approved
- Review Cycle: 12 mo
- Submitted for Local Review:
- Local Review Conducted:
- Local Review Completed:
- Reviewing IRB Submitted: 9/8/2023
- Reviewing IRB Reviewed: 9/8/2023
- Reviewing IRB Approved: 9/8/2023

+ Add Site Amendment  
+ Add Site Closure  
+ Add Study Team Access

Site Contacts

These study team contacts have IREx access.  
Add new study team contacts to grant access.

Email	Name	Role	
studypi@carnegie.edu	Study Investigator	PI	✖

Add A Contact

Type of contact ...  
Type of contact ...  
PI  
Coordinator

first name  
last name

+ Add Contact

Cancel Save

# 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

Faraday Inst  
GETTING STARTED

- Start PI Survey for Faraday Inst
- Awaiting PI Attestation for Faraday Inst
- Add / Edit Study Team Access**
- ⌚ Awaiting Reviewing IRB Approval

### Investigator/PI

Faraday Inst  
GETTING STARTED


- Complete/Attest to PI Survey
- Add / Edit Study Team Access
- ⌚ Awaiting Reviewing IRB Approval






This step will be available once the local HRPP registers for the study. You will receive an email from IREx when the PI Survey becomes available.

# 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](mailto:dexterpi@peabody.cdu) | CC: [coordinator@peabody.cdu](mailto:coordinator@peabody.cdu); [coord2@peabody.cdu](mailto:coord2@peabody.cdu); [coord3@peabody.cdu](mailto:coord3@peabody.cdu); [coord@anderson.cdu](mailto:coord@anderson.cdu) | BCC: [admin@irbexchange.org](mailto: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.

<b>Study Title:</b>	Turnip_Tuesday_Sept.12.2023
<b>Reviewing IRB:</b>	Mellon University Medical Center
<b>Sites You Engage:</b>	<ul style="list-style-type: none"><li>• Peabody Institute of Medicine - FWA#89764566</li><li>• Anderson Medical Center - FWA#54687921</li></ul>
<b>Study Link:</b>	<a href="https://test.irbexchange.org/main-branch/public/s/project/6849984">https://test.irbexchange.org/main-branch/public/s/project/6849984</a>

## Need Help?

Send any questions or requests for assistance to [admin@irbexchange.org](mailto: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.

The image shows a screenshot of a study team checklist on the left and a notification modal on the right. The checklist is titled "Faraday Inst GETTING STARTED" and contains three items: "Complete/Attest to PI Survey" (checked), "Add / Edit Study Team Access", and "Awaiting Reviewing IRB Approval" (highlighted with a yellow box). A red arrow points from the highlighted item to the notification modal. The modal is titled "Awaiting Reviewing IRB Approval" and contains the text "The Reviewing IRB has not yet uploaded approval for your site." with "Close" and "Ok" buttons.

Faraday Inst  
GETTING STARTED

- ✓ Complete/Attest to PI Survey
- Add / Edit Study Team Access
- Awaiting Reviewing IRB Approval**

Awaiting Reviewing IRB Approval

The Reviewing IRB has not yet uploaded approval for your site.

Close Ok

# 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 <b>AAHRPP</b>	74	<a href="#">updated 10/9/2023</a>	Philadelphia, PA	Christine DeLussey Joyce Hartley Meghan Riley Amy Schwarzhoff Sarah Shade
Stanford University <b>AAHRPP</b> <b>CTSA</b>	64	<a href="#">updated 9/25/2023</a>	Palo Alto, CA	Michelle LeManager Ellen O'Connor
University of Michigan <b>AAHRPP</b> <b>CTSA</b>	63	<a href="#">updated 8/29/2023</a>	Ann Arbor, MI	Judy Birk Mary Donnelly Joshua Fedewa Nicole Robson Corey Zolondek
University of California, San Francisco <b>CTSA</b>	60	<a href="#">updated 10/16/2023</a>	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

Approvals Status Summary Sites **Contacts**

### Contacts

The individuals on this list have access to the study in IREx and can also give access to other members at their site.

[Download CSV](#)

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

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	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

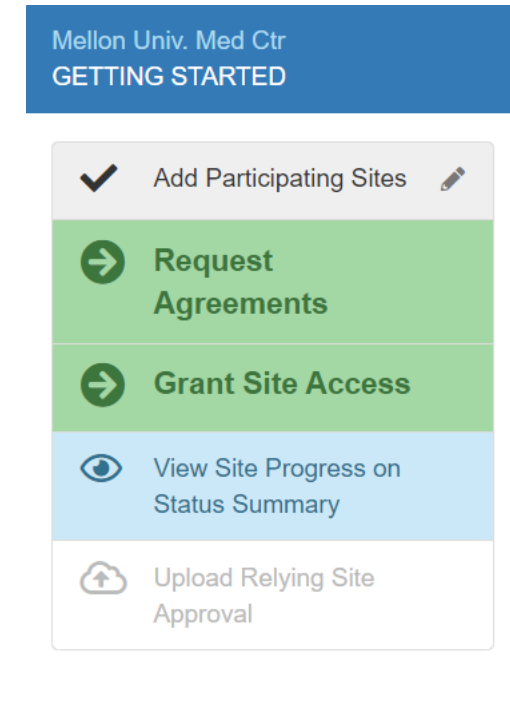


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# What's Next for IREx?

# 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](#)