



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



04.21.2023 QUARTERLY CALL AGENDA

- Welcome & Announcements
- Brief updates
- **PREVIEW: New System Features**

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

Upcoming Quarterly Calls



July 21st, 2023

October 20th, 2023

January 19, 2024

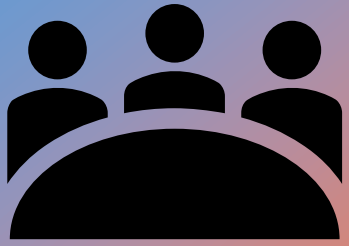


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IREx Satisfaction Survey Efforts

- April – June 2023
- sIRB Liaisons
- Relying HRPP Liaisons
- Study Managers
- \$20 e gift card for responding



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IREx Study Manager Focus Group

- June 2023
- Feedback on IREx
- Feedback on new materials
- Feedback on outreach efforts
- Up to \$150 for participating



Features Coming Soon!

IREx Division of Labor: 2018*

* IREx began capturing local considerations

	Single IRB	Lead Study Team
Create study	X	
Complete IREx Setup	X	
Confirm Study-specific Reliance Plan (SSRP)	X	
Upload overall study approval	X	
Indicate executed IAAs and/or indemnification	NA	NA
Add PSites		X
Track PSites progress		X
Export PSite documentation		X
Upload PSite Approval		X
Upload Continuing Reviews	X	
Upload Study-wide Amendments	X	
Upload Site Modifications	X	
Total Tasks	7	4

IREx Division of Labor: 2022



	Single IRB	Lead Study Team
Create study	X	
Complete IREx Setup	X	
Confirm Study-specific Reliance Plan (SSRP)	X	
Upload overall study approval		X
Indicate executed IAAs and/or indemnification	X	
Add PSites		X
Track PSites progress		X
Export PSite documentation		X
Upload PSite Approval		X
Upload Continuing Reviews		X
Upload Study-wide Amendments		X
Upload Site Modifications		X
Total Tasks	4	8

Some Early Communications Occur **Outside** of IREx



	Single IRB	Lead Study Team
Create study	X	
Complete IREx Setup	X	
Confirm Study-specific Reliance Plan (SSRP)	X	
Upload overall study approval		X
Indicate executed IAAs and/or indemnification	X	
Add PSites		X
Track PSites progress		X
Export PSite documentation		X
Upload PSite Approval		X
Upload Continuing Reviews		X
Upload Study-wide Amendments		X
Upload Site Modifications		X
Total Tasks	4	8

PRIOR TO OVERALL APPROVAL

1. Request sites complete required agreements

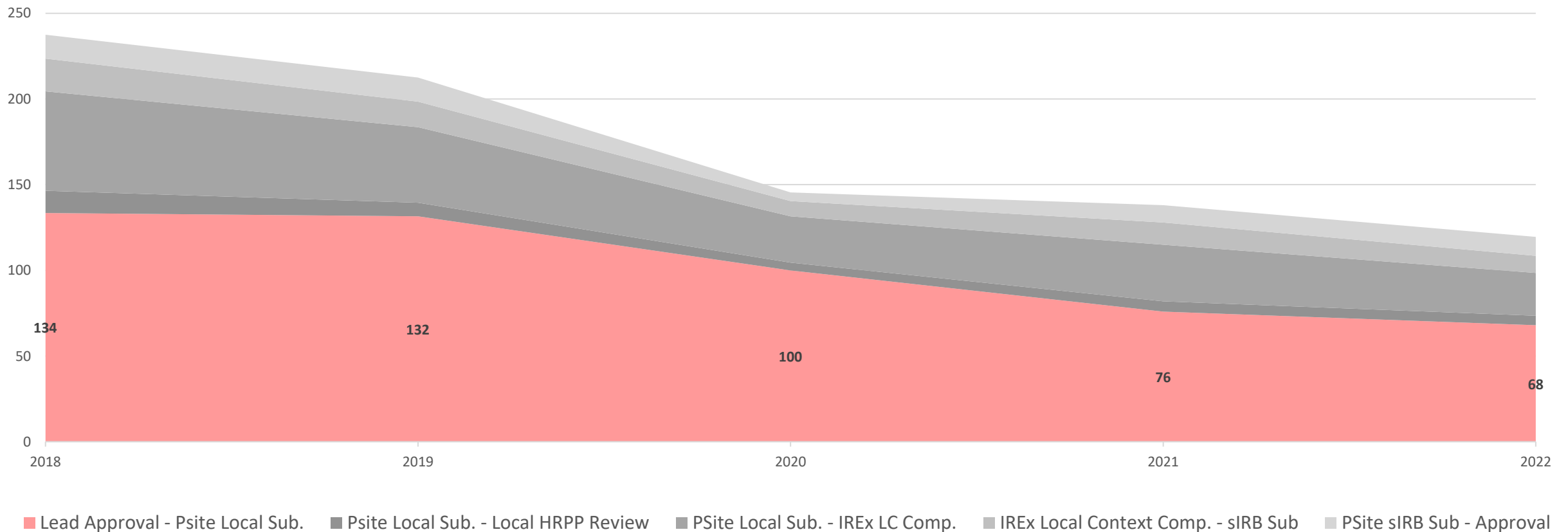
AFTER OVERALL APPROVAL

1. Disseminate overall approval to sites
2. Include instructions for relying on the single IRB

These early communications are critical!



Time to PSite Approval by the sIRB –
Time from Lead Site Approval to PSite Submission



Upcoming IREx Enhancements



Prior to overall study approval

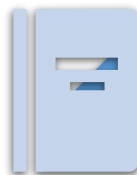


Request required agreements from IREx

After overall study approval



Provide single IRB / reliance instructions to sites from IREx



Grant Study Teams access to the overall approval in IREx *without requiring HRPP to register*

NEW for Single IRBs: Include Instruction Templates for PSites



Mellon Univ. Med Ctr
GETTING STARTED

- Complete IREx Setup
- Confirm Primary Study Contacts
- Upload Overall Study Approval
- Publish Approval

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]
Study Manager	[Study Manager]

SHOW MORE

Continue →

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]
Study Manager	[Study Manager]

Agreement/Resource	Status
SMART IRB Agreement: A national, master reliance agreement supporting single IRB review.	[Status/Next Steps]
IRB Reliance Exchange (IREx): A single IRB documentation and communication portal. <i>This is a web-based platform, not a reliance agreement.</i>	[Status/Next Steps]

Thank you,

- sIRB Options:**
1. Use the default IREx instructions
 2. Upload your own instructions
 3. Control whether the Study Manager can request agreements

NEW for Single IRBs: Include Instruction Templates for PSites

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Mellon Univ. Med Ctr
GETTING STARTED

➔ Complete IREx
Setup

➔ Confirm Primary Study
Contacts

➔ Upload Overall Study
Approval

➔ Publish Approval

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]
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Reviewing IRB	[sIRB Link]
---------------	-------------

SHOW MORE

Continue ➔

sIRB Options:

1. Use the default IREx instructions
2. Upload your own instructions

NEW for Single IRBs: Include Instruction Templates for PSites



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]
Reviewing IRB Contact	[Primary SIRB Contact]
Study Manager	[Study Manager]

Next Steps:

The overall/lead site approval is available in IREx and the approval documents are attached as a zip file. If no file is attached, please contact the study manager listed above. Use these documents to prepare your local submission and initiate the reliance process at your site.

1. LOCAL HRPP facilitates agreement execution:

The study requires the following items to be completed, which can be facilitated by the local HRPP, as needed:

Agreement/Resource	Status
SMART IRB Agreement: A national, master reliance agreement supporting single IRB review.	[Status/Next Steps]
ACTS LOI	[Status/Next Steps]
IRB Reliance Exchange (IREx): A single IRB documentation and communication portal. <i>This is a web-based platform, not a reliance agreement.</i>	[Status/Next Steps]

2. 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.**

3. 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,

Aalanya Sanders (HRPP)

NEW: Redesigned Status Summary



CURRENT

Study-wide IRB Approvals

Approval History

Status Summary

Participant Status Summary

Manage Agreements

Export Data

Q Search:

Site	Reliance Agreement ?	Indemnification	IREx Access ?	Reliance Decision ?	Local Considerations	Approval Status (current version)
Anderson Medical Center	SMART 2	ACTS LOI Update	✗	Incomplete		
Central Ohio Medical Center	SMART 1	ACTS LOI	✓	Notify HRPP		
Faraday Institute of Research, Science and Technology	SMART 2	ACTS LOI	✓	Contacted 4/13/2023		

NEW: Redesigned Status Summary



UPDATED

Q Search:

Site	Agreements	Reliance Decision ?	Local Considerations	Approval Status
Anderson Medical Center	1 / 3 Agreements Complete			Notify & Grant Access
Central Ohio Medical Center	3 / 3 Agreements Complete			Notify & Grant Access
Faraday Institute of Research, Science and Technology	3 / 3 Agreements Complete			Contacted 4/13/2023

NEW: Redesigned Status Summary



UPDATED

Study-wide IRB Approvals

Approval History

Status Summary

Participant Status Summary

Search:

Site	Agreements	Reliance Decision
Anderson Medical Center	1 / 3 Agreements Complete	Notify & Grant A
Central Ohio Medical Center	Reliance Agreement SMART 2	Notify & Grant A
Faraday Institute of Research, Science and Technology	Indemnification ACTS LOI IREx Access	Contacted 4/13/2025

- ✓ Reliance Agreement SMART 2
- ✗ Indemnification ACTS LOI [Update](#)
- ✗ IREx Access [?](#)
- [Request Agreement\(s\)](#)

ACTS 2023 - Action Required: Please Complete Agreement(s) for sIRB study

Reply Reply All Forward

IndemnificationAgreement_forCUMC.docx 19 KB

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

Study Title	Association for Clinical and Translational Research: A panel presentation 2023
Reviewing IRB	Carnegie University Medical Center
Reviewing IRB Contact	Bianca Fisher (bianca@fisher.cdu)
Study Manager	IREx SM

As a first step towards relying on Carnegie 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
Carnegie University Medical Center (CUMC) Indemnification Agreement	Incomplete — The indemnification agreement is attached. Send questions and executed agreements to Bianca Fisher (bianca@fisher.cdu).
IRB Reliance Exchange (IREx): A single IRB documentation and communication portal. This is a web-based platform, not a reliance agreement.	Incomplete — A HRPP administrator, director, or manager can initiate access here .

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,

NEW for Study Managers: Disseminate Overall / Lead Site Approval Docs via IREx



Q Search:

Site	Agreements	Reliance Decision ?	Local Considerations	Approval Status
Anderson Medical Center	1 / 3 Agreements Complete	Notify & Grant Access		
Central Ohio Medical Center	3 / 3 Agreements Complete	Notify & Grant Access		
Faraday Institute of Research, Science and Technology	3 / 3 Agreements Complete	Contacted 4/13/2023		

NEW!

1. **Include instructions**
instead of creating your own
2. **Include approval documents**
instead of emailing them separately
3. **Grant immediate IREx Access to study teams**
instead of waiting for HRPP to register

ACTS 2023 - IREx Access and Single IRB Instructions

General

SiteVersionExport-3269874.zip 317 KB

Dear HRPP(s) and Study Team,

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

ana First has been listed as an investigator at Faraday Institute of Research, Science and Technology (FWA: 01569874). All study team members included on this email now have access to the study in IREx.

Study Title	Association for Clinical and Translational Research: A panel presentation 2023
Study Link	https://best-irexchange.org/feature-branch/public/project/5943022
Reviewing IRB	Carnegie University Medical Center
Reviewing IRB Contact	Bianca Fisher (bianca@fisher.edu)
Study Manager	IREx SM

Next Steps:

The overall/lead site approval is available in IREx and the approval documents are attached as a zip file. If no file is attached, please contact the study manager listed above. Use these documents to prepare your local submission and initiate the reliance process at your site.

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

Agreement/Resource	Status
SMART IRB Agreement: A national, master reliance agreement supporting single IRB review.	Complete
ACTS LOI	Complete
IRB Reliance Exchange (IREx): A single IRB documentation and communication portal. This is a web-based platform, not a reliance agreement.	Complete
2. **STUDY TEAM prepares local consent form and submits to local HRPP for review.**
 - a. If applicable for the study, review the approved informed consent template(s) in IREx and insert your site-specific information.
 - b. Seek guidance from your HRPP/Research Office/IRB regarding what needs to be submitted to your local HRPP to rely on the Reviewing IRB. Most HRPPs require a local submission to complete their documentation in IREx.
3. **STUDY TEAM & HRPP provide documentation in IREx.**

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

 - o 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.
 - o 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:

- a. Register to confirm your site's engagement on this study. This is not an indication of reliance.
- b. Confirm the Institutional Profile
- c. 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.
- d. 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.
- e. Review PI Survey (optional), which captures your local consent and specific processes regarding the study conduct at your site.

NEW: Study Navigation Bar



DEMO **IRB Reliance Exchange**
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Carnegie University Medical Center Aalanya Sanders (HRPP)

Home Your Profile Resources Admin Admin Dash API Logout

Study search... Search

Association for Clinical and Translational Research: A panel presentation 2023

Approvals Status Summary Sites Contacts

Approvals

Study-wide IRB Approvals Approval History

SIRB: Carnegie University Medical Center [View All](#) [Amendments](#) [Continuing Reviews](#)

Lead Site: Carnegie University Medical Center

Protocol Version: 1 [Manage Version](#)

Initial Study: Expedited (approved 4/6/2023) **Current**

[Edit review](#) [Site approvals](#)

Study Info		Key Dates	
Role:	Reviewing IRB	Submitted:	4/1/2023
IRB Number:	34123	Pre-Reviewed:	4/3/2023
Reviewing IRB Decision:	approved	Reviewed:	4/5/2023
Submission Type:	Initial Study: Expedited	Approved:	4/6/2023
Review Cycle:	No Further Review Required	Expires:	

NEW: Participating Sites Page – “Sites”



Association for Clinical and Translational Research: A panel presentation 2023

Institution	Granted Access	PI (required)	Coordinator	
Anderson Medical Center #54687921 Let this site know their HRPP/IRB needs to initiate IREx access for their site here: https://redcap.link/JoinIREx	✗	Andrea Medi Anders Serno	Andrew Idem	Manage Contacts Email [trash]
Central Ohio Medical Center #12345622	✗	Johanna Jones	Johan Jenkins Noah Noles Haylee Lee	Manage Contacts Email [trash]
Faraday Institute of Research, Science and Technology #01569874	✓	Lana First	Lawrence First	Manage Contacts Email [trash]

1. Include multiple PIs and/or Contacts
2. Edit contacts any time
3. Contacts never disappear from view

NEW for Study Managers: Include Additional Site Contacts



Approvals | Status Summary | **Sites** | Contacts

Sites

[← Return to participating sites list](#) [How to add participating sites](#)

Add a participating site

Site
Peabody Institute of Medicine - FWA#897645665

This Study Team engages additional sites

Personnel

Role	Email	First name	Last name
PI	<input type="text" value="pi@peabody.cdu"/>	<input type="text" value="PI"/>	<input type="text" value="Peabody"/>
Coordinator	<input type="text" value="coordinator@peabody.cdu"/>	<input type="text" value="Coordinator"/>	<input type="text" value="Peabody"/>
<input type="text" value="Coordinator"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

NEW Streamlined Status Summary



Study-wide IRB Approvals | Approval History | **Status Summary**

Participant Status Summary

Manage Agreements | Exp

Q Search:

Site	Reliance Agreement	Indemnification	IREx Access	Reliance Decision	Local Considerations
Anderson Medical Center	SMART 2	ACTS LOI Update	✗	Incomplete	
Central Ohio Medical Center	SMART 1	ACTS LOI	✓	Notify HRPP	
Faraday Institute of Research, Science and Technology	SMART 2	ACTS LOI	✓	Contacted 4/13/2023	
Mellon University Medical Center	SMART 2	ACTS LOI	✓	Completed 4/21/2023	3 / 3 Surveys Complete
Middle-earth College of Agriculture	SMART 2	ACTS LOI	✓	Started 4/21/2023	1 / 3 Surveys Complete

Association for Clinical and Translational Research: A panel presentation 2023

Approvals | **Status Summary** | Sites | Contacts

Status Summary

Manage Agreements | Export Data

Q Search:

Site	Agreements	Reliance Decision	Local Considerations	Approval Status
Anderson Medical Center	1 / 3 Agreements Complete	Notify & Grant Access		
Central Ohio Medical Center	3 / 3 Agreements Complete	Notify & Grant Access		
Faraday Institute of Research, Science and Technology	3 / 3 Agreements Complete	Contacted 4/13/2023		
Mellon University Medical Center	3 / 3 Agreements Complete	Completed 4/21/2023	3 / 3 Surveys Complete	Not Approved
Middle-earth College of Agriculture	3 / 3 Agreements Complete	Started 4/21/2023	1 / 3 Surveys Complete	

Considerations for Single IRBs

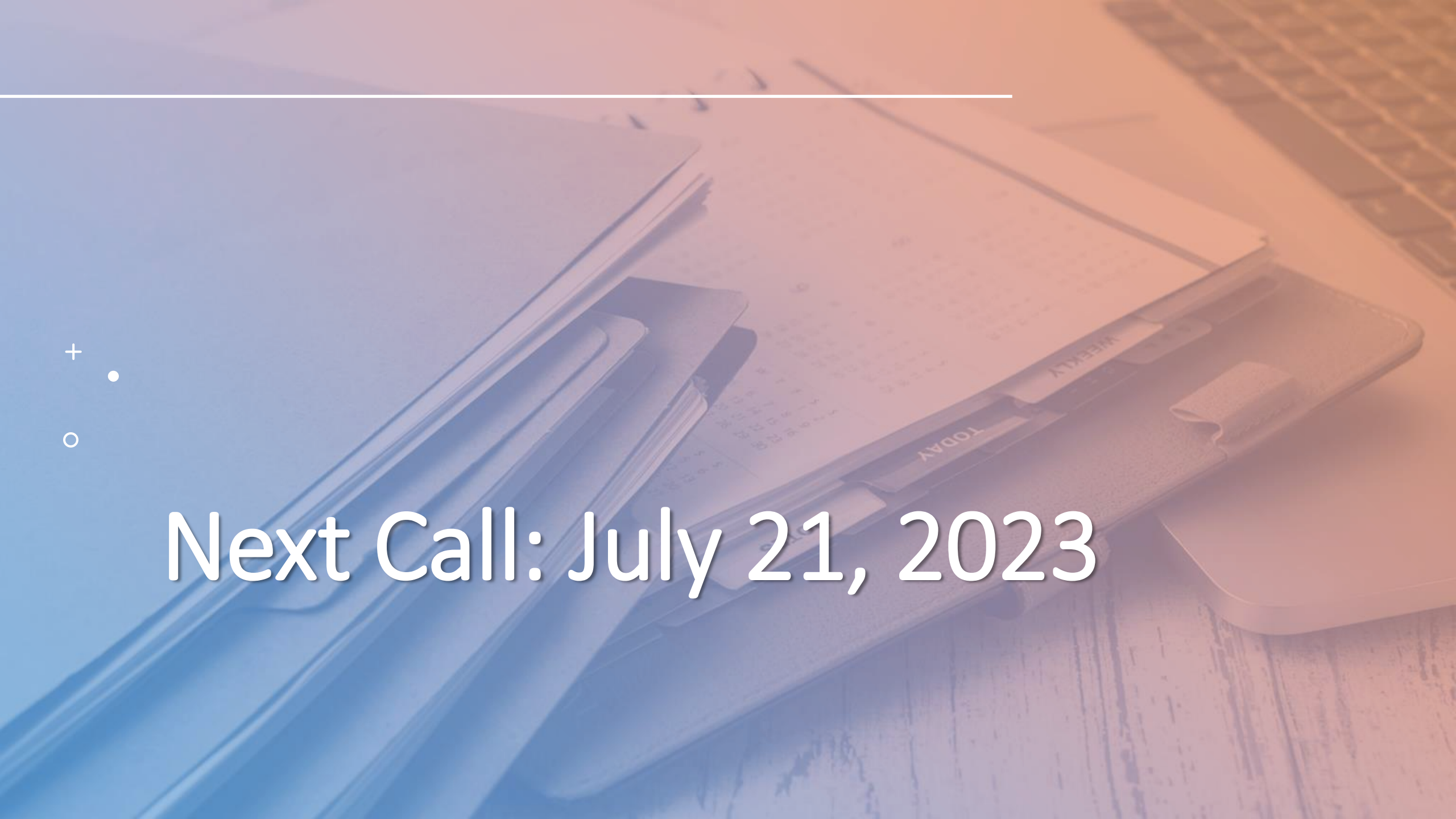


- 1. IREx is your friend**
 - It's easy
 - Steps are front-loaded
 - It empowers your lead study team
- 2. Just get it over with** – *create the study in IREx after the study has been through pre-review*
 - Don't wait until the overall study / lead site is approved.
 - The Lead Study Team / Study Manager can begin requesting sites complete agreements
- 3. Set your preferences** – *use IREx's default instructions or upload your own!*
 - Instructions for completing agreements
 - Instructions for completing the single IRB process

New Feature Release

- Week of May 15th
- Newsletter announcement a few days before the release
- Tips for Study Managers of existing studies
- Updated quick guides, videos, and trainings





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Next Call: July 21, 2023