



• IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

IREx Quarterly Call

- Training
- Special projects

Natalie Dilts



- Manager, Application Development

Joshua Milford



- 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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1.19.2023 QUARTERLY CALL AGENDA



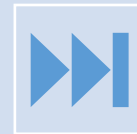
Welcome & Announcements



**Lead Study Team / Study Manager
Spotlight – Tyler Caven (U
Rochester)**



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



January 19, 2024

April 19, 2024

July 19, 2024

October 18, 2024



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Announcements

New / Revised IREx Materials



FOR STUDY MANAGERS

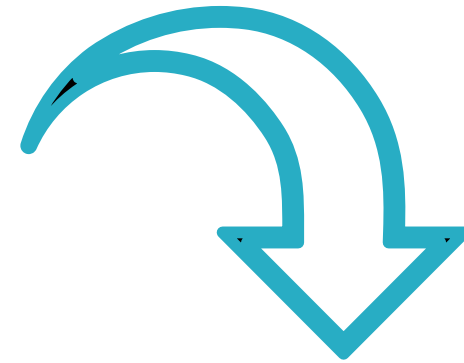
- [How to Add Relying Site Study Team Member Access](#)
- [How Relying Site Study Teams Use a Single IRB and IREx](#) (for your study teams)
- [How Study Teams Add/Remove Access](#) (for your study teams)
- [Study Manager Step-by-Step Guide](#)
- [How to Upload Study-Wide Amendment Approvals in IREx](#)
- [How to Upload Continuing Review Approvals in IREx](#)

FOR REVIEWING/SINGLE IRBS

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





FOR ANY & EVERYBODY!

- [IREx Workflow](#)
- [Getting Started Checklists](#)



RESOURCES

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

-  [Reviewing IRB Resources](#)
-  [Participating Site HRPP Resources](#)
-  [Study Manager Resources](#)
-  [Study Team Resources](#)

Updated Videos Available via [IREx YouTube Channel](#)



FOR STUDY MANAGERS

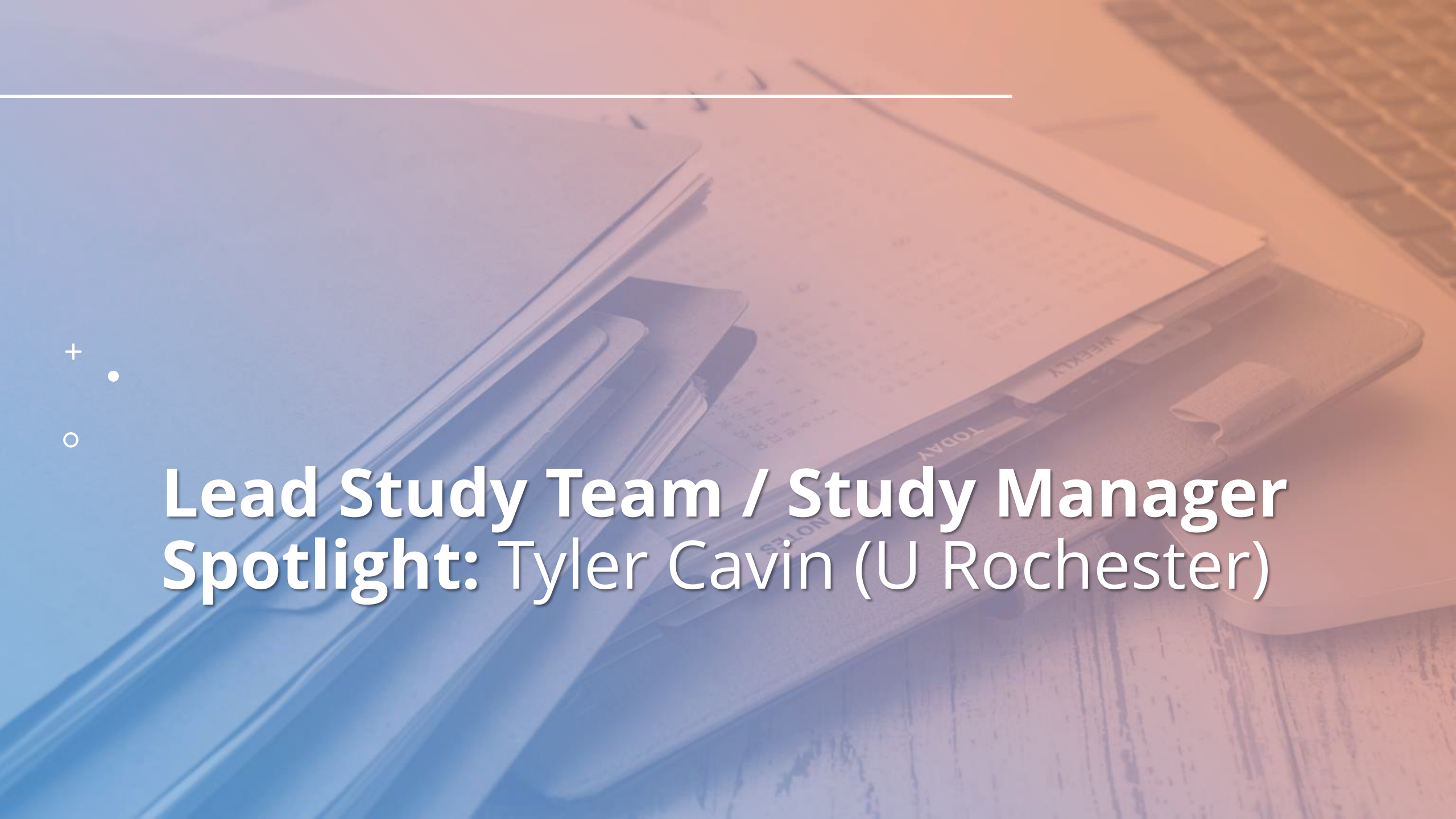
- [How Study Managers Grant Study Access to New Relying Site Study Team Members](#)
- [How do I add/remove study team members in IREx? \(for your study teams\)](#)
- [Introduction to Single IRB Review and IREx for Relying Site Study Teams \(for your study teams\)](#)

FOR REVIEWING/SINGLE IRBs

- [How to Create a Study 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. Navigation tabs include HOME, VIDEOS, PLAYLISTS, COMMUNITY, CHANNELS, and ABOUT. A search icon is also present. Below the navigation, there are filter buttons for 'Latest', 'Popular', and 'Oldest'. The video grid shows four thumbnails: 1. 'Getting Approved & Accessing Approvals in IREx' (1:22), 2. 'Removing Access for an Existing User in IREx' (0:43), 3. 'How do Relying HRPPs register for a study in IREx?' (1:56), and 4. 'How to Create a Study in IREx' (7:06). The fourth video has 8 views and was posted 6 days ago.



Lead Study Team / Study Manager
Spotlight: Tyler Cavin (U Rochester)



USING IRE_x FOR MULTI-SITE STUDY MANAGEMENT

URMC: TYLER CAVIN

INTRODUCTION

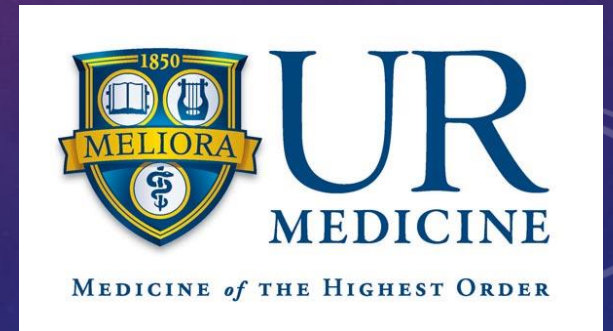


TYLER CAVIN, MPH
CLINICAL RESEARCH MANAGER

UNIVERSITY OF ROCHESTER MEDICAL CENTER
ROCHESTER, NY

PROJECT COORDINATOR:

- AMP AIM-FOR-RA
- AMP AIM ELLIPSS





AMP AIM Network Strategic Plan Framework



Trans-Disease Network Project

Sjogren's	Lupus	PSD	RA
Salivary Gland	Kidney/Skin	Skin/Synovium	Synovium

Cross Disease – Skin
Lupus - PSD

Cross-Disease –Synovium
PSD - RA

Sjogren's
Disease
Project

Lupus Disease
Project

Psoriatic
Spectrum
Disease Project

RA Disease
Project



Psoriatic Spectrum Disease Team

MY PROJECTS



AMP AIM-FOR-RA

Site
Brigham and Women's Hospital
Columbia University Medical Center
Hospital for Special Surgery
Univ Colorado Denver component - University of Colorado, Denver Anschutz Medical Campus
University of Alabama Birmingham
University of California, San Diego



AMP AIM ELLIPSS

Site
Columbia University Medical Center
New York University Grossman School of Medicine
Northwestern University
University of Alabama Birmingham
University of California, San Diego
University of California, San Francisco
University of Michigan
University of Pennsylvania

MY EXPERIENCE USING IRE_x

Approval Status
Approved
Approved
Approved
Approved
Approved
Approved
Approved

Approval Status
Not Approved
Approved
Approved
Not Approved
Approved
Approved
Approved
Approved

TRACKING PROJECT STATUSES:

- AMENDMENTS
- CONTINUING REVIEWS
- IRB APPROVALS
- RELIANCE DOCUMENTATION

DOCUMENT PORTAL

- APPROVAL LETTERS
- INFORMED CONSENT FORMS
- PROTOCOL VERSIONS
- LOCAL CONTEXT SUREVEYS

MY EXPERIENCE USING IRE_x

Approvals

Study-wide IRB Approvals

Approval History

SIRB: [University of Rochester](#)

Lead Site: University of Rochester

View All

Amendments

Continuing Reviews

Protocol Version: 09-OCT-2023

Manage Version ▾

▼ Continuing Review: Full Board (approved 12/12/2023)

Current

▼ Study-Wide Amendment: Full Board #1 [change summary](#) (approved 12/4/2023)

Archived

Protocol Version: 30-DEC-2022

▼ Initial Study: Full Board (approved 1/3/2023)

Archived



THANK YOU!



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What's New?

Features Released Since October 2023

New Feature: Reviewing IRBs can now upload additional documents to share with sites

Confirm Site Instructions for completing the Single IRB Process

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

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

- Use default IREx instructions
 Attach custom instructions

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

- Yes
 No

Upload Additional Document(s)



Choose a file or drag it here (Required)

Additional Documents



Part II Consent.docx



sIRB SOP.docx



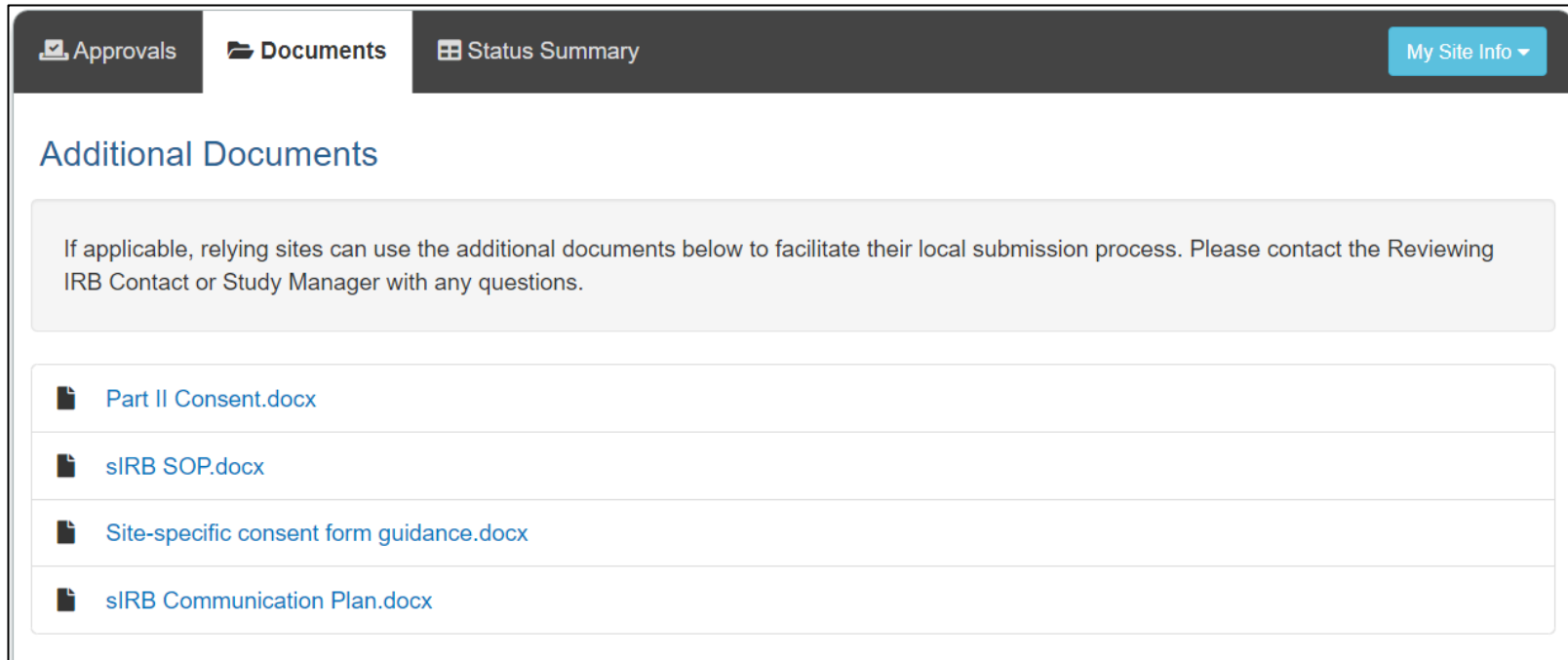
Site-specific consent form guidance.docx



sIRB Communication Plan.docx



New Feature: Reviewing IRBs can now upload additional documents to share with sites



The screenshot displays a web interface for IRB review. At the top, there is a dark navigation bar with three tabs: 'Approvals' (with a checkmark icon), 'Documents' (with a folder icon), and 'Status Summary' (with a grid icon). On the right side of this bar is a blue button labeled 'My Site Info' with a downward arrow. Below the navigation bar, the main content area is titled 'Additional Documents'. A light gray informational box contains the text: 'If applicable, relying sites can use the additional documents below to facilitate their local submission process. Please contact the Reviewing IRB Contact or Study Manager with any questions.' Below this box is a list of four document files, each with a document icon and a blue text label: 'Part II Consent.docx', 'sIRB SOP.docx', 'Site-specific consent form guidance.docx', and 'sIRB Communication Plan.docx'.

Approvals Documents Status Summary My Site Info

Additional Documents

If applicable, relying sites can use the additional documents below to facilitate their local submission process. Please contact the Reviewing IRB Contact or Study Manager with any questions.

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

Annual reminder to update Institutional Profile (IP) sent to HRPPs

517 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)
Adnab Research	1	updated 6/2/2022	Torrance, CA	Erika Carrillo
Advanced Neurology Specialists	1	updated 4/3/2018	Great Falls, MT	Laura Armstrong
Advarra, Inc.	0	<i>incomplete</i>	Columbia, MD	Lauri Carlile Kathleen Rankin
Adventist Health System, Sunbelt Healthcare Corporation d/b/a AdventHealth AAHRPP	7	updated 8/18/2023	Orlando, FL	Michelle McKinney Janice Turchin
Adventist Healthcare, Inc.	1	updated 7/12/2023	Gaithersburg, MD	Elizabeth Carroll
Advocate Health Care Network (Downers Grove)	7	updated 1/15/2024	Downers Grove, IL	Patti Allard Michelle Maternowski Jasmine Taylor

Capture Multiple Sponsors when Creating a Study

Create a Study ✕

Study Description

Title

Short Title
This will be added to email subjects to help easily identify studies.

Study Summary

NCT#
[+ Add NCT#](#)

Sponsor

Name of other sponsor(s)
⚠ Please specify the sponsor name
[+ Add other sponsor](#)

[Continue →](#)

Coordinator renamed to "Study Team Member"

Site Contacts

[These study team contacts have IREx access.](#)
Add new study team contacts to grant access.

Email	Name	Role	
coordinator@faraday.cdu	Faraday Coordinator	Study Team Member	✖
pi@faraday.cdu	Faraday PI	PI	✖

Add A Contact

Type of contact ...

Type of contact ...

PI

Study Team Member

first name

last name

+ Add Contact

Cancel Save

Updated Feature: Reviewing IRB Checklist

Mellon Univ. Med Ctr
GETTING STARTED

- ✓ Create Study
- ✓ Complete IREx Setup
- ✓ Confirm Primary Study Contacts
- ✓ Confirm SSRP
- ✓ Upload Overall Study Approval
- ✓ Publish Approval
- ➔ Request Agreements**
- ➔ Manage Agreements

Approvals | **Status Summary** | Sites | Contacts | Edit Study Info

Status Summary

Manage Agreements | Export Data

Search:

Site	Agreements	Reliance Decision	Local Considerations	Approval Status
Blueberry University	2 / 3 Agreements Complete	?		

Notify & Grant Access

Updated Feature: Request Agreements, again!

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

Status Summary

Manage Agreements | Export Data

Search:

Site	Agreements	Reliance Decision	Local Consideration	Approval
Bridge University	2 / 3 Agreements Complete	Notify & Grant Access		
Carnegie University	<ul style="list-style-type: none">Reliance Agreement SMART 2Indemnification Mellon LOIIREx AccessRequested 10/24/2023	Contacted 11/1/2023		

Please Confirm

Bridge University was sent an email requesting completion of agreements on **10/24/2023 at 4:30pm CDT**

Do you want to re-notify the site?

Cancel | Resend

Updated Feature: Study Manager Checklist

Mellon Univ. Med Ctr
GETTING STARTED

- ✓ Add Participating Sites
- ➔ Request Agreements
- ➔ Grant Site Access
- 👁 View Site Progress on Status Summary
- 📁 Upload Relying Site Approval

Request Agreements

From the Status Summary's Agreement column, use the drop down to **Request Agreement(s)** for sites with incomplete agreements.

OK

Grant Site Access

The following sites can be granted access to this study in IREx:

- Anderson Medical Center - FWA#54687921
- Peabody Institute of Medicine - FWA#89764566

To grant site access to the lead site's approval, on the Status Summary Tab, press **Notify & Grant Site Access** in the Reliance Decision column.

OK



What's Next?

Features In / Slated for Development

What's Next:

Major Enhancement Jan – March 2024



- **Enhancing the Capture of Local Considerations:**
 1. Updating local considerations for the life of the study (e.g., for study modifications)
 2. Facilitating EFIC studies
 3. SMART IRB local recommendations
- **Accounting for SMART IRB Agreement v3**
 - New studies will only offer SMART v3 or a one-off reliance agreement
 - TBD – Existing studies can continue
 - TBD – Changes to the Institutional Profile (IP) & Study Specific Reliance Plan

Interested in informing development? Join our IREx User Feedback Group: <https://redcap.vanderbilt.edu/surveys/?s=ECMXA8FE9N>

Updating local considerations for the life of the study

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Relying HRPP or Study Team:

Update PI Survey when there is a PI change, when needed.



Relying HRPP or Study Team:

Update HRP and/or PI Survey to report new/changes to local or state laws or institutional policies



sIRBs and Lead Study Teams can PROMPT sites to update their local considerations after approval of a study modification is posted to IREx





Next Call: April 19, 2024!