



IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR COORDINATING CENTERS/LEAD STUDY TEAMS

April 26, 2019

- User Training
- Study Support

Natalie Dilts



- System Development
- Data analysis

Adoma Manful



- Project Manager

Emily Serdoz



- Site Onboarding
- Study Support

Bridget Swindell

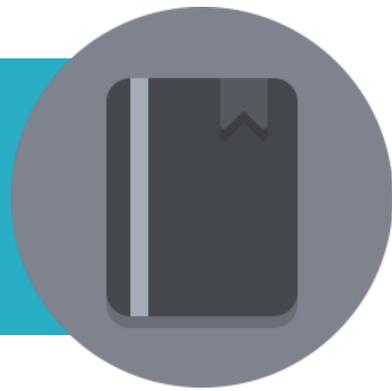


- User Support
- Study Support

Linda Tan



QUARTERLY CALL AGENDA – HRPPs



- Welcome & Reminders
- New Study Manager Dashboard
- Exporting the Status Summary Tab
- Tracking Letters of Indemnification (LOIs)
- Managing FWAs Sites Engaged on a Study
- Updated Resources

Reminders from the Last Call

IN CASE YOU MISSED IT...



- Catch IREx improvements as they are released
 - Check out the [IREx Feature Release Log](#)
 - Read our monthly [IREx Newsletter](#)

members 255 studies 117 LOGIN

About Resources FAQs Newsletters **Feature Release Log** Contact

What is IREx? [Learn more](#)

IRB Reliance Exchange (IREx) is a freely available, web-based portal that supports single IRB (sIRB) review documentation and communication for multi-center clinical trials.

*Any reliance agreement.
Any institution.
Any study.
One portal.*

WHAT IS IREX? JOIN IREX! SIGN UP FOR TRAINING

- New to IREx or need a refresher? Join a training!
 - [Lead Study Teams/Coordination Centers](#) – using IREx to support your sIRB study
 - [Capturing Local Considerations Using IREx](#) – in-depth review of the local considerations
 - [Using IREx as the Participating Site Study Team](#) – 4 min video, no training required
 - Can't make the monthly trainings? [Request a demo](#) for your team/ psites

New Study Manager Dashboard

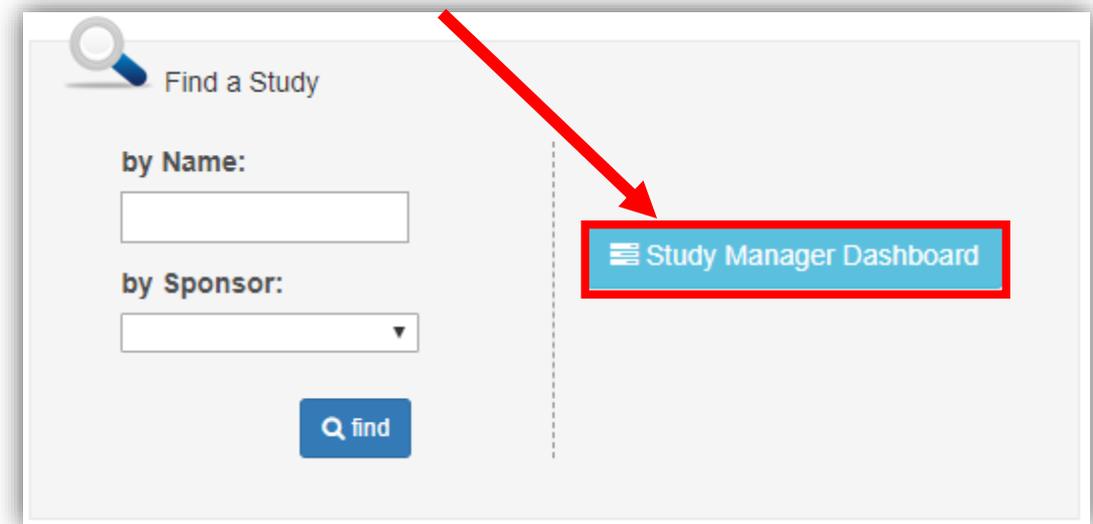
AVAILABLE IN IREX NOW!

NEW STUDY MANAGER DASHBOARD



IREx Study Managers have a **new dashboard** to manage studies in IREx

- Goal: Provide a quick overview of all your studies



Note: Studies will not be shown on the dashboard if you are listed as a coordinator

AVAILABLE IN IREX NOW!

NEW STUDY MANAGER DASHBOARD



*Note: Each counter will turn green when **all** the participating sites listed on the study have completed the step.*

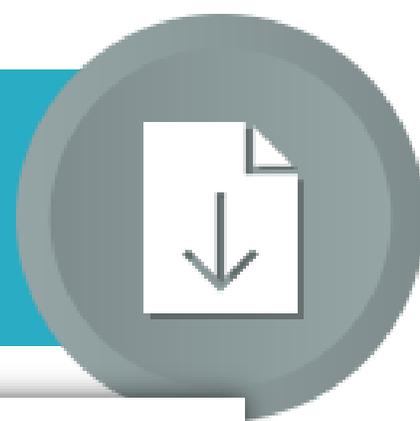
Study Manager Dashboard

Search:

Study Title	Registered?	Completed Agreements?	Indicated Reliance?	Completed Local Context?	Approved?
	Sites	Signed Agreements	Reliance	Local Context	Current Version Approved
A Cluster Randomized Multi-center Baseline Assessment of Carbon Dioxide Emission (ACE)	1 / 4 Registered	SMART IRB: 4 LOI: 1 IREx: 4	1	1	1
Evidence for the Association between Reduced Sleep and Noise Pollution (EARN)	Add Participating Sites				
Assessing the Influenza-A Checklist for Health Outcome Optimization (ACHOO)	21 / 21 Registered	SMART IRB: 19 IREx: 21	21	21	20
A Randomized, Double- Blind, Placebo-Controlled Trial to Assess the Primary Outcomes of Tramadol to treat acute post-surgical pain (PRIMARY)	6 / 14 Registered	SMART IRB: 4 LOI: 0 IREx: 13	3	n/a	2

Export the Status Summary Tab

EXPORT THE STATUS SUMMARY TAB



Reviewing IRBs and IREx Study Managers can generate a CSV download of the status summary tab

Reviewing IRB Approvals | Relying Site Approvals | **Status Summary**

Participant Status Summary

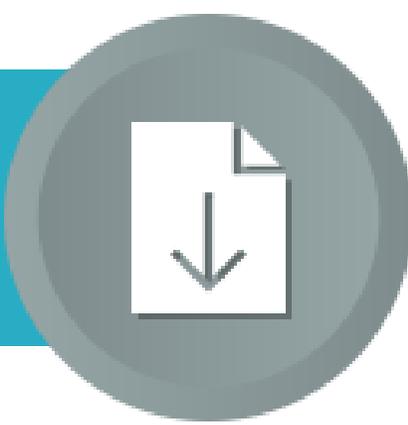
Search:

Export Data ▼

- Export Local Considerations
- Export Status Summary Tab**

Site	SMART IRB	LOI	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Carnegie University Medical Center	✓	✓	✓	Completed 12/04/2018	3 / 3 Surveys Complete	Approved
Central Ohio Medical Center	✓	✗	✓	Contacted 12/04/2018	0 / 3 Surveys Complete	Approval Not Ready
Columbus University	✗	✓	✓	Add PI Info	0 / 3 Surveys Complete	Approval Not Ready
Eastman Medical Center of Ohio	✗	✓	✓	Add PI Info	0 / 3 Surveys Complete	Approval Not Ready
Midwest University Medical Center	✓	✓	✓	Completed 12/07/2018	3 / 3 Surveys Complete	Not Approved
Peabody Institute of Medicine	✓	✓	✓	Started 12/07/2018	0 / 3 Surveys Complete	Not Approved
University of the Bay	✓	✗	✓	Notify HRPP	0 / 3 Surveys Complete	Approval Not Ready

EXPORT THE STATUS SUMMARY TAB

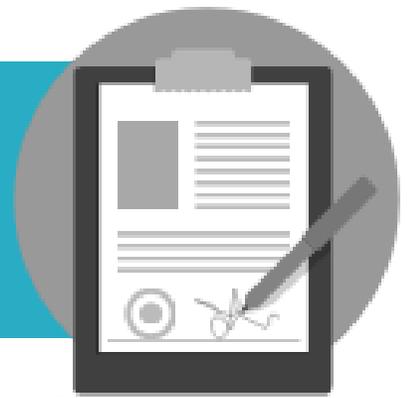


- The Status Summary Tab download includes:
 - Site name
 - FWA holder name
 - FWA number
 - Agreement status
 - SMART IRB, LOI, IREx Access
 - Reliance Decision Status
 - Dates Contacted, Started, and Completed
 - Local Considerations Completion (if applicable)
 - Date IP Confirmed
 - Date HRP Survey Completed
 - Date PI survey Completed and Validated by HRPP
 - Approval Status for the current version



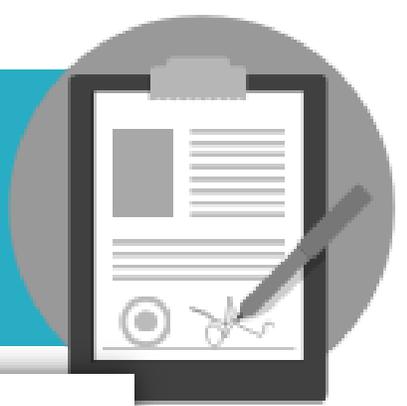
Tracking Letters of Indemnification (LOIs)

TRACKING LETTERS OF INDEMNIFICATION (LOIs)



- **Some institutions require an LOI given that SMART IRB is silent on indemnification**
- **IREx will allow for tracking of institutional-level LOIs**
 - Cannot have different LOIs for different studies
- **Internal and External LOI tracking**
 - Sites who have signed your LOI
 - External LOIs you signed

TRACKING LETTERS OF INDEMNIFICATION (LOIs)



- The **Reviewing IRB** will turn LOI tracking on for your study
- Use the **Status Summary Tab** to track LOI completion

Note: Please check the LOI status with your IRB before you follow up with sites.

Site	SMART IRB	LOI	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Baystate component - Western Mass Med Ctr	✓	✓	✓	Contacted 02/07/2019		
Carnegie University Medical Center	✗	✓	✓	Started 02/05/2019	0 / 3 Surveys Complete	Not Approved
Eastman Medical Center of Ohio	✗	✗	✓	Started 02/13/2019	0 / 3 Surveys Complete	Not Approved
Hartford College of Medicine	✓	✓	✓	Started 02/01/2019	3 / 3 Surveys Complete	Not Approved
Mellon University Medical Center	✗	✓	✓	Notify HRPP		
Midwest University Medical Center	✓	✓	✓	Started 02/11/2019	0 / 3 Surveys Complete	Not Approved
MUMC component - Peabody Institute of Medicine	✓	✓	✓	Add PI Info		
Peabody Institute of Medicine	✓	✓	✓	Completed 02/01/2019	1 / 3 Surveys Complete	Not Approved

TRACKING LETTERS OF INDEMNIFICATION (LOIs)



Participating Sites **must complete agreements** in order to indicate reliance for a study

GETTING STARTED

- ✓ Register
- ✓ Add Study Team
- ➔ Complete Agreements**
- ➔ Confirm Institutional Profile
- ➔ Indicate Reliance
- ➔ Complete HRP Survey
- ➔ Remind PI To Complete PI Survey
- ➔ Awaiting Reviewing IRB Approval

Required Agreements

SMART	Your site has signed the SMART IRB agreement.	✓
LOI	Your site must sign the LOI from Vanderbilt University Medical Center before you can indicate reliance. LOI Template from the Reviewing IRB LOI Template.docx Reviewing IRB Liaison Please send any questions and return the executed LOI to Taylor Jansen	✗

Note: HRPPs can begin documenting local considerations before completing agreements

Available now in IREx!

TRACKING LETTERS OF INDEMNIFICATION (LOIs)



Note: The Notification of Reliance Letter will include the LOI name



IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Official Documentation of Reliance

April 22, 2019

Dear all,

This letter serves as documentation that **University of the Bay** has agreed to rely on the **Vanderbilt University Medical Center** IRB using the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement and **Letter of Indemnification pursuant to section 4.11 "Indemnification" of the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement.**

NOTE: This is not a notice of IRB approval. A separate email will be sent when the study is approved by the reviewing IRB.

Study Title: Measuring Levels of Baseline Radiation Exposure in Routine Care Visits (RADIATE)

Relying Site PI: Emilio Shawn

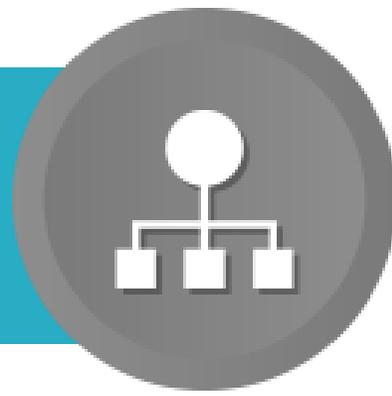
Information about this study is available online at:
<https://www.irbexchange.org/study/index?proj=50573>

Sincerely,

The IREx Team

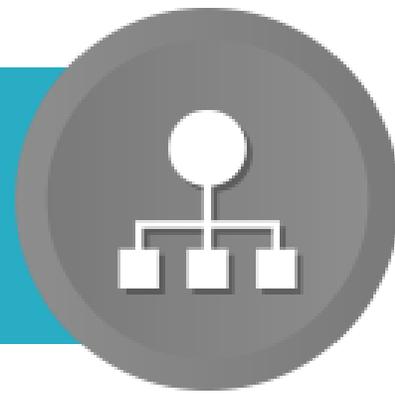
Managing FWA Sites Engaged

MANAGING FWA SITES ENGAGED FOR A STUDY



- Correctly identifying **which sites are engaged for a study** can be difficult
 - Eg:
 - Component sites under the same FWA
 - Separate FWA institutions that share an IRB
 - Study teams that engage multiple FWAs institutions
 - PIs with dual appointments
- Currently no easy way to do this in IREx
 - **Coming soon:** *Relying Institutions will have the ability to indicate FWA engagement*

MANAGING FWA SITES ENGAGED FOR A STUDY



What can I do now?

1) Ensure the correct **FWA number** is listed on your study

You can search for sites by FWA#

Add A Site

Site Name:

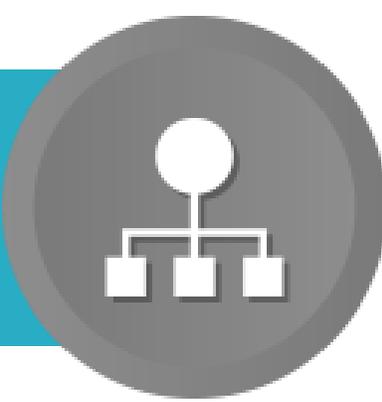
Participating Sites

Show All Personnel

<input checked="" type="checkbox"/> Carnegie University Medical Center #12345678	▼
<input checked="" type="checkbox"/> Central Ohio Medical Center #123456	▼
<input checked="" type="checkbox"/> Faraday Institute of Research, Science and Technology #01569874	▼
<input checked="" type="checkbox"/> Hartford College of Medicine #00003216	▼
<input checked="" type="checkbox"/> Mellon University Medical Center #00001111	▼
<input checked="" type="checkbox"/> Midwest University Medical Center #00951753	▼
<input checked="" type="checkbox"/> University of the Bay #00012553	▼

Check FWA# listed in IREx

MANAGING FWA SITES ENGAGED FOR A STUDY



What can I do now?

2) Ensure the correct **component sites** are listed on your study

Resources

- Find other users
- Find other sites
- Request Help
- Join A Training
- Resources

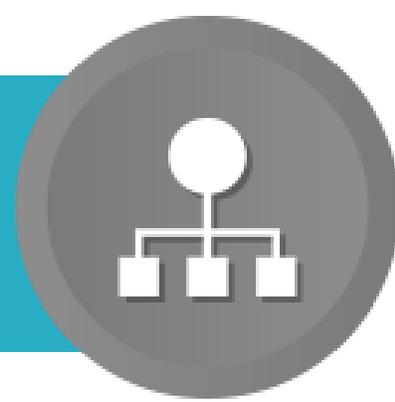


Sites Legend ▾

Search:

Name	SMART IRB	IREx Access	Profile	Download
Augusta University aahrpp smart-irb	✓	✓	view profile	download profile
Ball State University smart-irb	✓	✓	view profile	download profile
Brown University smart-irb	✓	✓	view profile	download profile
Columbia University aahrpp ctsa smart-irb <ul style="list-style-type: none"> Earth Institute Lamont-Doherty Earth Observatory Trustees of Columbia University in the City of New York (The) 	✓	✓	view profile	download profile
Columbia University Medical Center smart-irb <ul style="list-style-type: none"> Children's Hospital of New York College of Physicians and Surgeons Columbia University College of Dental Medicine Mailman School of Public Health New York State Psychiatric Institute School of Nursing 	✓	✓	view profile	download profile
Drexel University aahrpp smart-irb	✓	✓	view profile	download profile

MANAGING FWA SITES ENGAGED FOR A STUDY



Why should I list component sites?

- + Delineate where research is happening
- + Allows for multiple, separate study teams to be engaged on the same study
- + *Coming soon: allows relying sites to indicate which sites are engaged in research for a study*

Reviewing IRB Approvals		Relying Site Approvals		Status Summary	
Participant Status Summary Export Data					
Search: <input type="text"/>					
Site	SMART IRB	LOI	IREx Access	Reliance Decision	Approval Status (current version)
University of the Bay	✓	✓	✓	Completed 04/22/2019	Not Approved
Univ of the Bay component - University of the Bay School of Nursing and Family Health	✓	✓	✓	Completed 04/22/2019	Not Approved

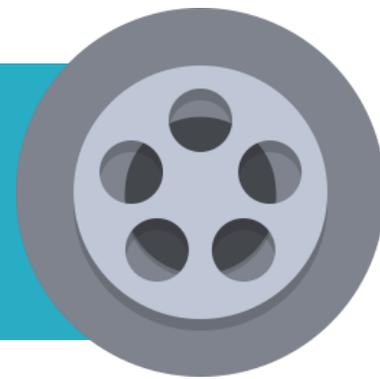
FWA Holder

FWA Component

IREx Resources Update

IREX QUICK GUIDES

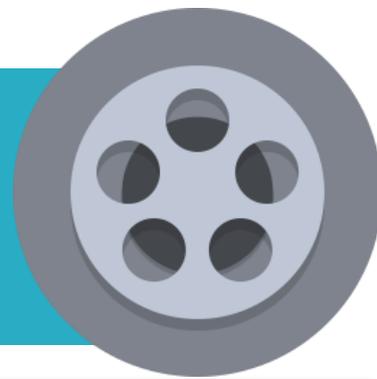
<https://www.irbexchange.org/p/resources/>



Title	Target Audience
IREx Study Manager Step-by-Step Guide	Coordinating Center Staff or Lead Study Teams
Using IREx as the Participating Site Study Team	Participating Site Study Teams
Adding & Removing Study Team Members from a Study in IREx	<ul style="list-style-type: none">• Coordinating Center Staff or Lead Study Teams• Participating site study teams• Participating site HRPPs
Adding & Removing Participating Site Access to Studies in IREx	<ul style="list-style-type: none">• Reviewing IRBs• Coordinating Center Staff or Lead Study Teams
NEW How to Add Study-wide and Site-specific Amendments	<ul style="list-style-type: none">• Reviewing IRBs• Coordinating Center Staff or Lead Study Teams
NEW How to Add Continuing Review Approvals	<ul style="list-style-type: none">• Reviewing IRBs• Coordinating Center Staff or Lead Study Teams
NEW How to Add Initial Study Approvals for Relying Sites	<ul style="list-style-type: none">• Reviewing IRBs• Coordinating Center Staff or Lead Study Teams

IREX VIDEOS ON YOUTUBE

<https://www.youtube.com/channel/UCVXKpNczhIPcsQRwF7oWcwA/videos>



Video Title	Target Audience	Length	Link
How to: Register and Cede Review	Participating Site HRPPs	4 mins	https://www.youtube.com/watch?v=yW-TS-z6So
What is the Study Specific Reliance Plan (SSRP)?	<ul style="list-style-type: none">Participating Site HRPPsReviewing IRBs	1.5 mins	https://www.youtube.com/watch?v=T9FbOV6oN7U
How HRPP/ IRB Liaisons use the IRB Dashboards	<ul style="list-style-type: none">Participating site HRPPsReviewing IRBs	1.5 mins	https://www.youtube.com/watch?v=TKy0Z9_yhf4
How to: Add/Remove Study Team Members from a study in IREx	<ul style="list-style-type: none">Coordinating Center Staff or Lead Study TeamsParticipating site study teams	2 mins	https://www.youtube.com/watch?v=f_hKS8nqbb8
Using IREx as a Participating Site Study Team	Participating site study teams	4 mins	https://www.youtube.com/watch?v=iKjO47Qslws
What is IREx?	All Users	2.5 mins	https://www.youtube.com/watch?v=Nv94eUBylMg
How to: Manage Participating Sites in IREx	<ul style="list-style-type: none">Reviewing IRBsCoordinating Center Staff or Lead Study Teams	4 mins	https://www.youtube.com/watch?v=1sxprbGZn5M
IREx Features for HRPPs/ IRBs	<ul style="list-style-type: none">Participating Site HRPPsReviewing IRBs	4 mins	https://www.youtube.com/watch?v=Xv6xLNAxKBA
IREx Features for Lead Study Teams and Coordinating Centers	<ul style="list-style-type: none">Coordinating Center Staff or Lead Study TeamsParticipating site study teams	4.5 mins	https://www.youtube.com/watch?v=KoBAytIY5Cw
How to: Create a Study	Reviewing IRBs	6 mins	https://www.youtube.com/watch?v=xli8YXgDIN4
How to: Add Study-wide and Site-specific Amendments	<ul style="list-style-type: none">Reviewing IRBsCoordinating Center Staff or Lead Study Teams	9 mins	https://www.youtube.com/watch?v=vlrEUIV-BMY&t=2s

Next Call

- July 19, 2019 @ 2 PM ET/11 AM PT