



IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR HRPPS

October 19, 2018

- User Training
- Study Support

Natalie Dilts



- System Development
- Data analysis

Adoma Manful



- Project Manager

Emily Serdoz



- Site Onboarding
- Study Support

Bridget Swindell

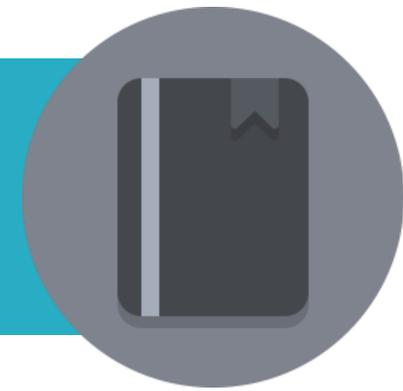


- User Support
- Study Support

Linda Tan



QUARTERLY CALL AGENDA – HRPPs



- Introductions
- New Features for Reviewing IRBs
- IREx switches to Terms of Use
- IREx Resources Update
- Next Call Info

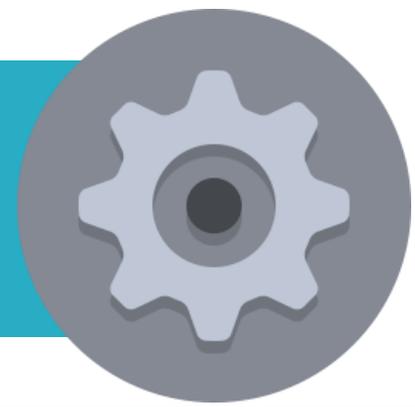
New Features for Reviewing IRBs

Streamlined Study Creation

Empower the IREx Study Manager (Lead Study Team or Coordinating Center)

Using IREx to Capture Local Considerations/Context

STREAMLINED STUDY CREATION



- Streamlined study set up
- Identify the Primary IRB Liaison for the sIRB to better streamline communications
- IREx Study Manager is now required (i.e., Lead Study Team coordinator or Coordinating Center contacts)

A screenshot of a web interface for finding studies. The interface is light grey and contains a search section on the left and a 'Create a Study' button on the right. The search section has a magnifying glass icon and the text 'Find a Study'. Below this are two search criteria: 'by Name:' with a text input field, and 'by Sponsor:' with a dropdown menu. A green 'find' button with a magnifying glass icon is at the bottom of the search section. The right section has the text 'Don't see your study listed?' and a blue 'Create a Study' button with a folder icon.

Find a Study

by Name:

by Sponsor:

Don't see your study listed?

IREX STUDY MANAGER NOTIFICATION



Dear Taylor Jansen,

You have been given access, as an IREx Study Manager, to the study below in IREx. If this is your first study on this platform, a separate email was also sent with your login information.

Study Title A Cluster Randomized Multi-Center Baseline Assessments of Carbon Dioxide Emission (ACE)

Reviewing IRB Vanderbilt University Medical Center

Study Link <https://victptest.irbchoice.org/embryb/irex/public/study/index/?proj=50349>

Your Next Steps

Visit the [resources page](#) for detailed instructions on these steps:

1. Designate the Participating Sites and site PIs in IREx.

Please login and enter the participating sites and their corresponding study PIs to help the Human Research Protection Program (HRPP)/IRB Liaisons check on the status of the study at their sites.

2. IREx notifies the participating site HRPPs of the study.

After you send the study start up packet (protocol, consent templates, regulatory documents, etc) to your participating site study teams, click the “Notify HRPP” button in IREx to notify the participating site HRPPs/IRBs about the study. The HRPP/IRB will confirm their institution’s engagement in research, begin the cede review process, and provide the study team with access to IREx when appropriate. Generally, a local submission is required before the HRPP/IRB will begin completing their steps in IREx.

IMPORTANT: Participating site study teams should receive the study start-up packets BEFORE IREx notifies their HRPP/IRB about the study. Study teams need these materials to begin preparing their local IRB submission. IREx is not used to disseminate the study start up materials as study teams can not get access until their local HRPP/IRB receives a local submission.

3. Use IREx to track site progress towards reliance and initial IRB approval.

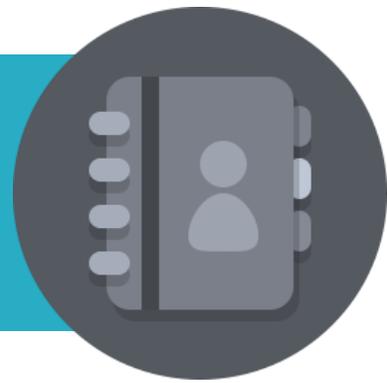
You will receive notifications from IREx as sites complete the required steps.

If you have questions about using IREx, you can email us your questions (admin@irbexchange.org) or request additional training.

*Thank you for using IREx,
The IREx Team*

EMPOWER THE IREX STUDY MANAGER

(Lead Study Team or Coordinating Center)



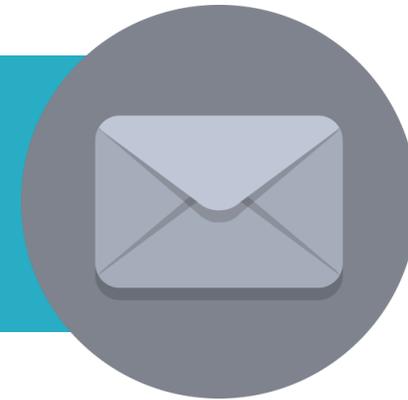
IREx IRB Liaisons Permissions

- Create studies in IREx
- Confirm study-specific reliance plan (SSRP)
- Upload overall/lead site approvals
 - Initial
 - Continuing review
 - Study amendments (affecting all sites)
- Perform all “IREx Study Manager” activities

IREx Study Manager Permissions

- Add other IREx Study Managers
- Add sites and list their PI
- ***New*** Indicate when to send the IREx study notification to PS HRPPs (*requires SSRP be completed by sIRB*)
- Export local considerations
- Upload Relying Site approvals
 - Initial
 - Continuing review
 - Study amendments
 - Site amendments (e.g., PI change)

NOTIFYING SITE HRPPS OF STUDIES IN IREX



Participant Status Summary Export Survey Data

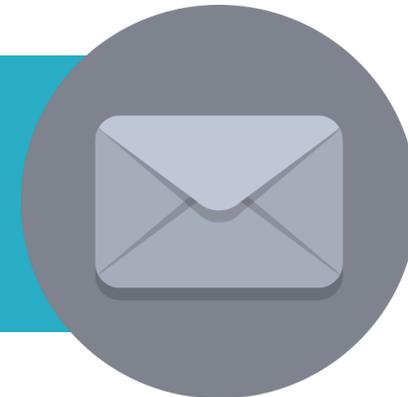
Search:

Site	SMART IRB	IREx Portal Agreement	Reliance Decision	Local Context	Approval Status (current version)
Albert Einstein College of Medicine	✓	✓	Notify HRPP		Approval Not Ready
Baystate Health, Inc	✓	✓	Notify HRPP		Approval Not Ready
Boston Children's Hospital	✓	✓	Add PI Info		Approval Not Ready
Boston Medical Center	✓	✓	Notify HRPP		Approval Not Ready
Duke University Health Systems, Inc.	✓	✓	Contacted 10/18/2018		Approval Not Ready
Johns Hopkins University	✓	✓	Notify HRPP		Approval Not Ready
Wake Forest Baptist Medical Center	✓	✗	Incomplete		Approval Not Ready

After the sIRB has confirmed the SSRP for the study...

- IREx SM manually notifies site HRPP of the study.
 - Sites can no longer be contacted without listing their local PI
 - Local PI is copied on notification email

IREX STUDY NOTIFICATION



Dear Liaison(s) and Study Investigator,

Carnegie University Medical Center (FWA:00009856) has been listed as a participating site in IREx for the following study:

TITLE: A Cluster Randomized Multi-center Baseline Assessment of Carbon Dioxide Emission (ACE)

REVIEWING IRB: Vanderbilt University Medical Center

LOCAL INVESTIGATOR: James Anderson

NEW →

NEW →

What do I do with this email?

Study PI: Many HRPPs require a local submission to initiate the single IRB (sIRB) process at their institution. Reach out to your Human Research Protection Program (HRPP)/IRB Liaisons on this email to find out what you need to do to initiate the sIRB process at your site. You receive access to the study in IREx *after* your HRPP logs in to confirm your site is participating and lists you on the study.

HRPP Liaisons:

- 1) If you have not received a local submission, you may want to contact your study PI (cc'd here) to let him/her know how they can initiate reliance at your institution.
- 2) When you are ready, login to [IREx](#) confirm your site's engagement by registering for the study and provide access to your local PI. This is not a cede decision. **Email the contact(s) below if the wrong FWA is listed or another FWA should also be listed. You will receive a new email with the correction:**
 - Taylor Jansen (tjansen@vumc.org)
 - Adrian Leto (aletto@vumc.org)
 - Teresa Banks (tbanks@vumc.org)
- 3) Use the Getting Started checklist on the IREx study page to walk you through ceding review and any other required steps.

Need Help?

Access the user quick guides and other materials from the [IREx Participating Site HRPP Resources](#) and [IREx Participating Study Teams Resources](#).

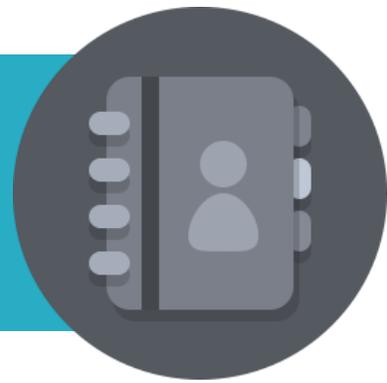


Should we cc the IREx Study Manager on these emails?

- + Confirmation that email notification went out and can follow up with the study team
- Could follow up with relying site HRPP

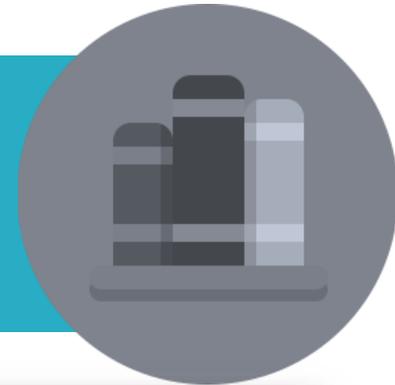
EMPOWER THE IREX STUDY MANAGER

(Lead Study Team or Coordinating Center)



- **What **YOU** do before naming IREx Study Manager(s) for a study:**
 - Educate the Study Manager(s) on the sIRB process
 - Provide reliance instructions so they can educate and inform site study teams on the requirements and sIRB process
 - Discuss when sites should be notified of studies in IREx
 - Instruct them to attend or request IREx training
- **What **IREX** does to support Study Managers**
 - Offer standing or ad hoc trainings
 - Sends automated notifications as site complete their steps
 - The IREx Team sends manual updates on (1) site progress and (2) how to use the Status Summary
 - Resources: https://rocket.app.vumc.org/index.php?doc_id=21990

USING IREX TO CAPTURE LOCAL CONSIDERATIONS/CONTEXT



- **Standardize** questions and processes
- **Centralize** the collection of information (minimize need to provide access to folks outside your institution)
- **Guarantee** HRPP sign off
- **Facilitate** site-specific tracking and documentation on a study-by-study basis

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

Participant Status Summary

Export Survey Data

Search: _____

Site	SMART IRB	IREx Portal Agreement	Reliance Decision	Local Context	Approval Status (current version)
Carnegie University Medical Center	✓	✓	Completed 03/01/2018	3 / 3 Surveys Complete	3 / 3 Surveys Complete
Central Ohio Medical Center	✓	✓	Started 04/25/2018	0 / 3 Surveys Complete	Approval Not Ready
Columbus University	✓	✓	Contacted 06/13/2018	0 / 3 Surveys Complete	Approval Not Ready
Hartford College of Medicine	✗	✗	Incomplete	0 / 3 Surveys Complete	Approval Not Ready
Mellon University Medical Center	✓	✓	Completed 03/01/2018	3 / 3 Surveys Complete	Approved
Peabody Institute of Medicine	✓	✓	Started 04/25/2018	1 / 3 Surveys Complete	Approval Not Ready

Approval Status (current version) dropdown menu:

- ✓ Institutional Profile
- ✓ Local Context
- ✓ PI Survey
- ✗ Email study personnel

Want more info? Sign up for a training:

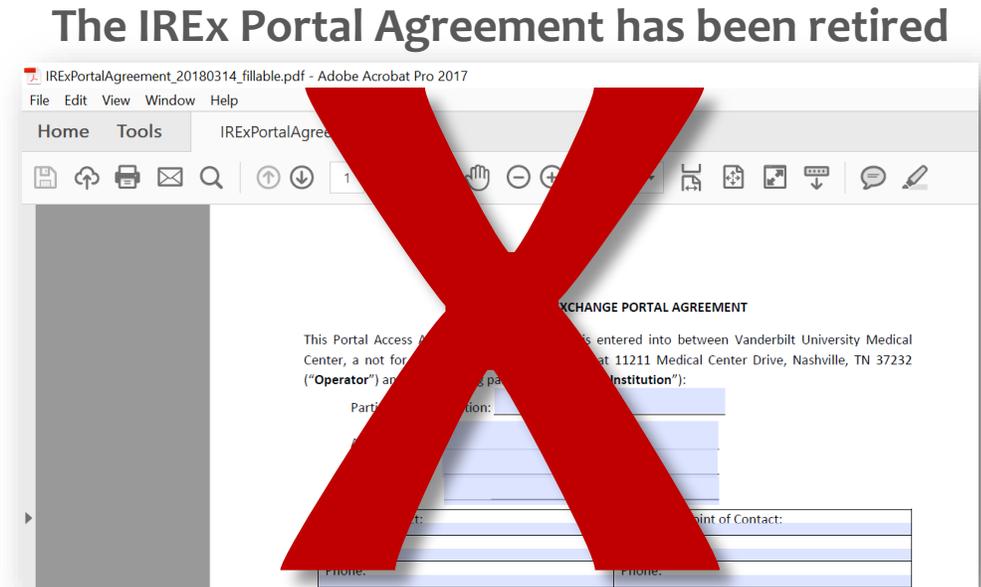
<https://attendee.gototraining.com/rt/485841592003962113>

IREx switches to Terms of Use

NEW PROCESS FOR JOINING IREX



- **WHAT DOES THIS MEAN FOR ME?**
 - In early November, the first time you and anyone from your institutions logs in you will be asked to accept the terms of use.
- **HOW DO NEW SITES JOIN?**
 - The HRPP Director or Manager can create their institutions access via the link on the [IREx Members Page](#).



IREx Resources Update

[IREx Videos on YouTube](#)

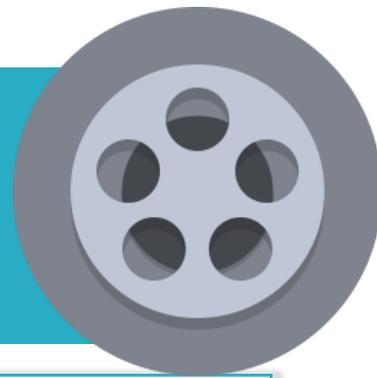
[IREx Institutional Profile is Public](#)

[Reliance Instruction Template](#)

[Request a Demo or Training](#)

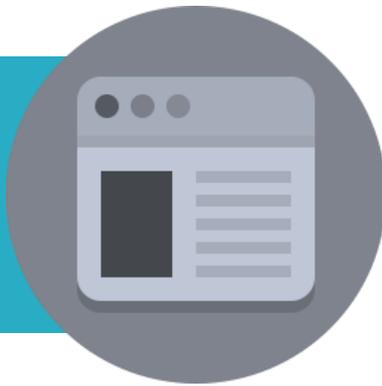
IREX VIDEOS ON YOUTUBE

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



Video Title	Approximate Length	Link
What is IREx?	~2 minutes	https://www.youtube.com/watch?v=Nv94eUByIMg&t=11s
How to: Register and Cede Review	4 minutes	https://www.youtube.com/watch?v=-yW-TS-z6So
What is the Study Specific Reliance Plan (SSRP)?	90 seconds	https://www.youtube.com/watch?v=T9FbOV6oN7U
How HRPP / IRB Liaisons use the IRB Dashboards	90 seconds	https://www.youtube.com/watch?v=TKyoZg_yhf4&t
How to Add/Remove Study Team Members from a study in IREx	2 minutes	https://www.youtube.com/watch?v=f_hKS8nqbb8
Using IREx as a Participating Site Study Team	4 minutes	https://www.youtube.com/watch?v=iKjO47Qslws
New Features Highlight (coming October 26)		
How to Add Amendments (study-wide and site-specific)		

IREX INSTITUTIONAL PROFILE IS PUBLIC



IREx IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

members 214 studies 81 LOGIN

About Resources FAQs Contact

214 IREx member institutions.

Not in IREx yet?
HRPPs/IRBs: [Create your account here](#).
Study Teams/Investigators: [Request access for your institution here](#).
[your HRPP or IRB director/manager will be notified of your request to join.]

[Download the IREx Quick Guide to the Institutional Profile.](#)

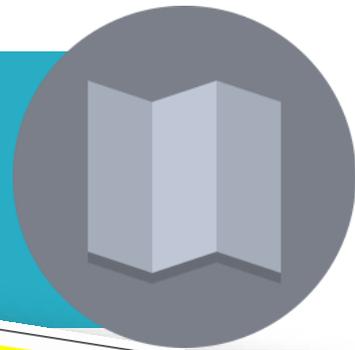
NAME	INSTITUTIONAL PROFILE	LOCATION	LIAISON(S)
Advanced Neurology Specialists	updated 04-03-18	Great Falls, MT	Laura Armstrong
Advarra, Inc. AAHRPP	incomplete	Columbia, MD	Lauri Carille Kathleen Rankin
Albert Einstein College of Medicine CTSA	updated 03-23-18	Bronx, NY	Melissa Epstein Rui Ferreira Stefanie Juell
Allegheny Health Network Research Institute	updated 09-19-18	Pittsburgh, PA	Chris Back Dawnmarie DeFazio
Allina Health HRPP	updated 05-02-18	Minneapolis, MN	Gayle Kusch Cassie Myers Christine Roering Megan Ryan

TRANSPARENCY

HIGH QUALITY DATA
SHARING

STREAMLINE ACCESS TO
INFORMATION

RELIANCE INSTRUCTIONS TEMPLATE



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

• Process

- Finalized by the sIRB
- Disseminated to relying site study teams by the lead study team/ccc

• Content

- Points of contact for IREx and the sIRB
- Process for relying on the sIRB:
 - Required agreements and systems used to support the sIRB process
 - Responsibilities of the site PI/study team
 - Responsibilities of the site's HRPP

STUDY INFORMATION:

Study:
Lead Study Site:
Lead Study PI:
Coordinating Center:
Central/Single IRB:

sIRB Name will serve as the single IRB of Record ("sIRB") using the SMART IRB Model Review Board Authorization Agreement ("SMART IRB Agreement") to establish a single IRB of Record. IREx is also using the IRB Reliance Exchange platform ("IREx") to capture all sIRB local considerations and facilitate communications between the sIRB and PI Research Protection Programs/Offices (HRPPs).

STUDY POINTS OF CONTACT (POCs)

Primary Study	IRB	IREx
		admin

NEXT STEPS FOR RELYING ON THE sIRB
The steps below must be completed before the sIRB can begin to rely on your institution. It is the responsibility of research administration officials at your institution to ensure:

1. **Site PIs/study teams should SHARE THIS INSTRUCTIONS of the SMART IRB agreement and initiate IREx access.**
 - SINGLE RESOURCES**
 - SMART IRB Agreement:** A national, master reliance agreement supporting single IRB review. Access the agreement supporting single IRB review. Access the [FAQs](#) if you have questions about eligibility requirements or key provisions.
 - IRB Reliance Exchange (IREx):** A single IRB document and communication portal. To access IREx, your institution has to have an account on IREx. The human research protections administrator or IRB director/manager initiates an institution's access.
(Note: A portal agreement is no longer required.)
2. **Site PIs/study teams prepare an agreement to rely on the sIRB.**
 - a. Seek guidance from the HRPP in order to rely on the sIRB.
 - b. Consent form process: **Include** review all informed consent sections of these documents. **please do not make any**
 - c. Submit the consent forms and

Note to PIs/Study Teams: many HRPPs require a local submission before the following steps can be completed.

3. **Your HRPP will complete the steps below in IREx. Please share these instructions with your HRPP.**
 - a. **Confirm your site's engagement:** Login to IREx and search for the study on dashboard. Click on the study title and register the FWA(s) that (s)are engaged in research for this study. This is not an indication of reliance.
Important: if your site is listed wrong or if you need to list an additional FWA that is engaged for your site, please contact the sIRB POC listed above.
 - b. **Indicate willingness to rely on [sIRB Name]:** To indicate that your institution will rely on the sIRB, click the steps in the Getting Started Action List. The actions include providing your local study personnel, your local IRB #, key dates (optional), and accepting the Study-Specific Reliance Plan (SSRP). The SSRP is the sIRB's plan for handling HIPAA, auditing and reporting, as well as other flexible parts of the reliance agreement.
 - c. **Complete or confirm the information in your Institutional Profile.** In order to participate as a relying site, sections 1, 2 and 3 of the Institutional Profile, must be completed. Information collected in these sections help the sIRB know how best to work with your site and provide proper review in the context of your specific participant population.
****delete all of 3.d. if not capturing local considerations in IREx****
 - d. **Provide your local context.**
 - i. **Complete the study-specific local context.** In order for the sIRB to complete the IRB review for your site, your institution must provide the requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local site ancillary reviews, relevant to the research that would affect the conduct or approval of the research at your institution, as well as upload the informed consent documents with your local site information for this study.
 - ii. **Review the information provided by your local study team in the PI Survey regarding the conduct of the study at your site, if necessary.** Your local study team will provide information about the conduct of the study at your site (e.g., consenting, recruitment, and DSMB plan). You will be asked to review and confirm the procedures in IREx to ensure they are permissible at your institution.
4. **Study Teams are provided access to IREx.**

Site PIs and study teams receive an email from IREx after their HRPP confirms their site's participation and lists them in IREx. Once access to IREx is granted, login to do the following:

 - a. Add other study team members at your institution, if needed.
 - b. ****delete this step if not capturing local considerations in IREx**** Complete the PI survey, which asks about the conduct of the study at your site. The PI survey can be completed before or after your HRPP completes the local context survey.

You will receive an email from IREx when the sIRB has issued approval for your site. IMPORTANT: Your local HRPP may require that you send or submit the approval letter and other approved documents before you can begin the study at your site. Please check with your local HRPP regarding the process for using reliance at your institution.

REQUEST A DEMO OR TRAINING



IREx IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

members **214** studies **81** [LOGIN](#)

[About](#) [Resources](#) [FAQs](#) [Contact](#)

Sign-up for Training

Join our interactive training sessions to learn more about IREx, meet other users across the nation, ask questions, and watch a live demo.

Click on the links below to select a time and sign up for training.

- [Reviewing IRB Trainings](#)
- [Relying HRPP Trainings](#)
- [Lead/Relying Study Team Trainings](#)
- [Using IREx to Capture Local Considerations](#)

You can also request a live IREx demo for your team [here](#).

[WHAT IS IREX?](#) [JOIN IREX!](#) **SIGN UP FOR TRAINING**

Next Call

- January 18, 2019 @ 1 PM ET/10 PT
- Performance Sites that engage multiple FWAs