

Unlocking Single  
IRB Review with  
IREx:  
Keys to Efficiency  
for Lead Study  
Teams



**IRB Reliance Exchange**

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

**Emily Serdoz, MPA**

*Assistance Director for Regulatory  
Infrastructure*

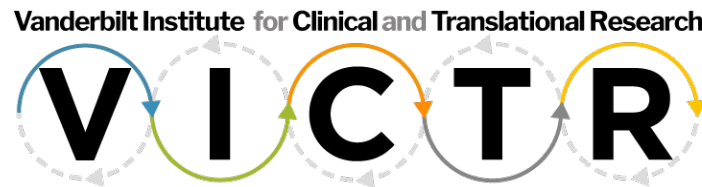
Vanderbilt Institute for Clinical and  
Translational Research

Vanderbilt University Medical Center

# Disclosures

Funding for the IREx platform is support by the National Center for Advancing Translational Sciences (NCATS):

- ***Clinical and Translational Science Award (UL1TR002243)***



- ***Trial Innovation Network - Trial Innovation Center (U24TR004437)***

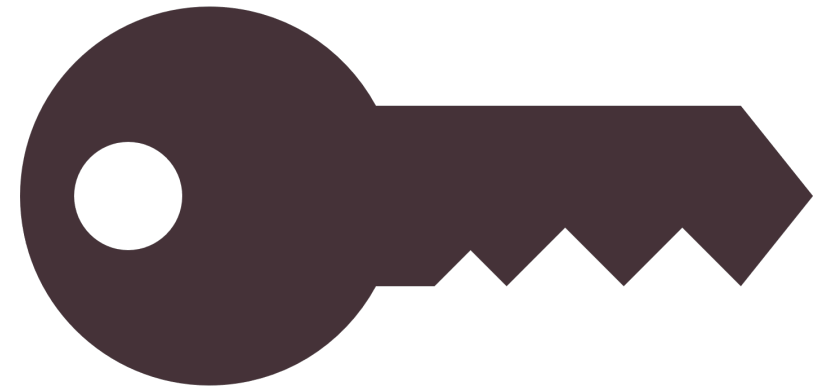


# Goals

- To orient lead study teams to the basics of the single IRB review process
- To highlight critical milestones in the single IRB process
- To describe how the IREx platform helps lead study teams manage the single IRB process for relying sites

# Keys to Efficient Single IRB Review

- **Understand** the basics: Single IRB 101
- **Designate** a lead study team point of contact
- **Manage** communication & documentation
- **Request** to use IREx!
- **Access** IREx Resources



Understand the basics: *Single IRB 101*

# Key Terminology



**sIRB = Single IRB** (aka **Reviewing IRB**) is the “**IRB of record**” to which authority for IRB review and oversight has been ceded by another institution.



**HRPP / HRPO / HRPA** = **H**uman **R**esearch **P**rotection **P**rogram | **O**ffice | **A**dministrator  
The organization’s department, office, or person responsible for ensuring the organization complies with all applicable human subjects regulations and policies.



**Relying Sites** = the institutions relying on the sIRB (aka Participating Site, Study Site, Local Site)



**Federal Wide Assurance #** (FWA) = a unique identifier assigned by the Office for Human Research Protections (OHRPP)

# Key Infrastructure



Master Common Reciprocal Institutional Review Board Authorization Agreement

A **reliance agreement** used to outline the responsibilities of the sIRB vs. relying sites

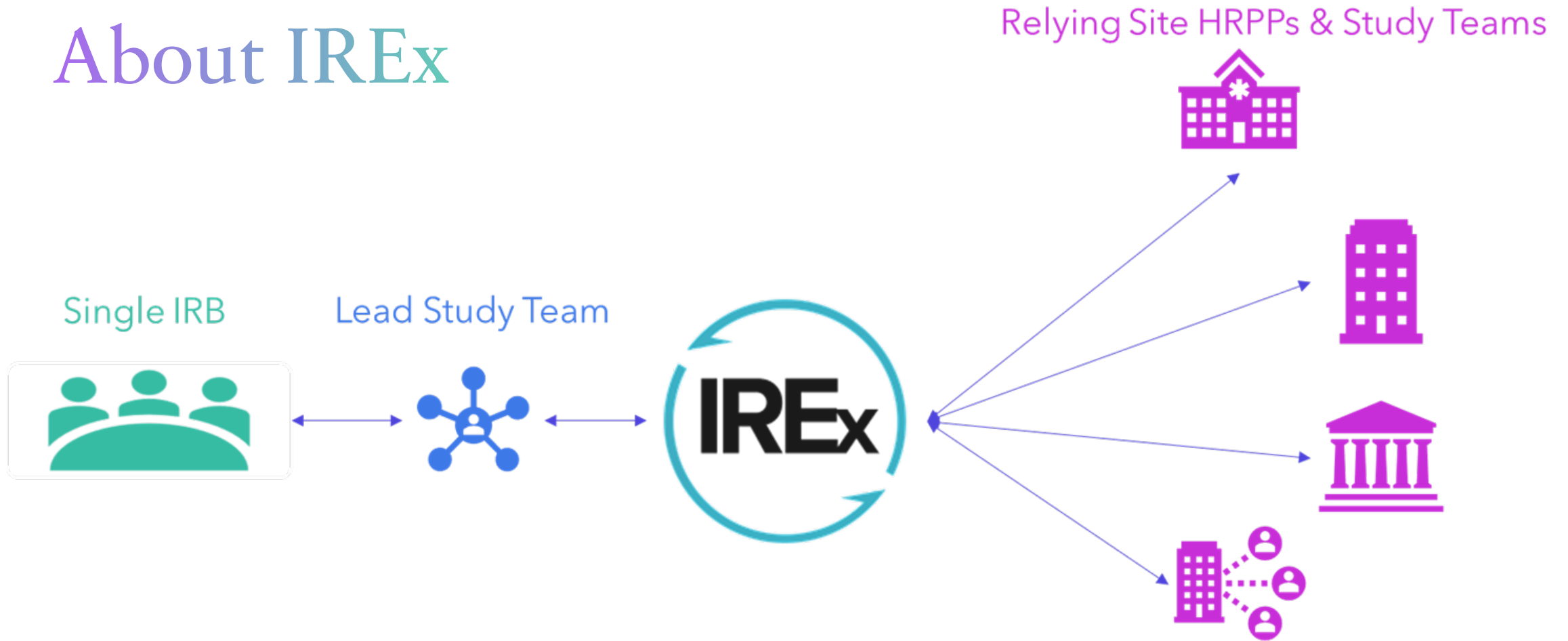


**IRB Reliance Exchange**

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

An **online tool** to manage the sIRB requirements and streamline communications for any multisite study (2+ sites)

# About IREx



A freely available **online tool** used to **help relying sites complete the single IRB documentation** and **allow the lead study team to manage the process for each site**. It also serves as **the hub that the lead study uses to disseminate all study approvals**.

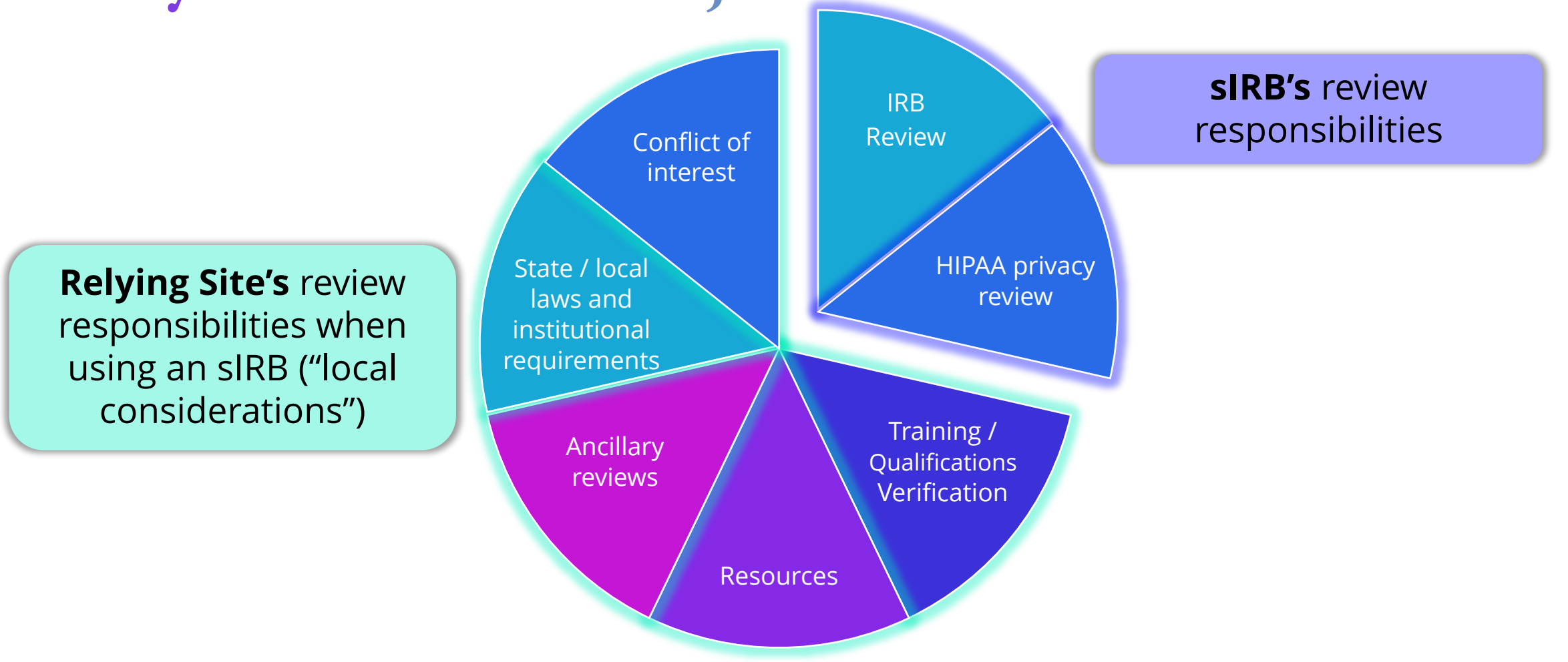


# Key Human Subjects Reviews

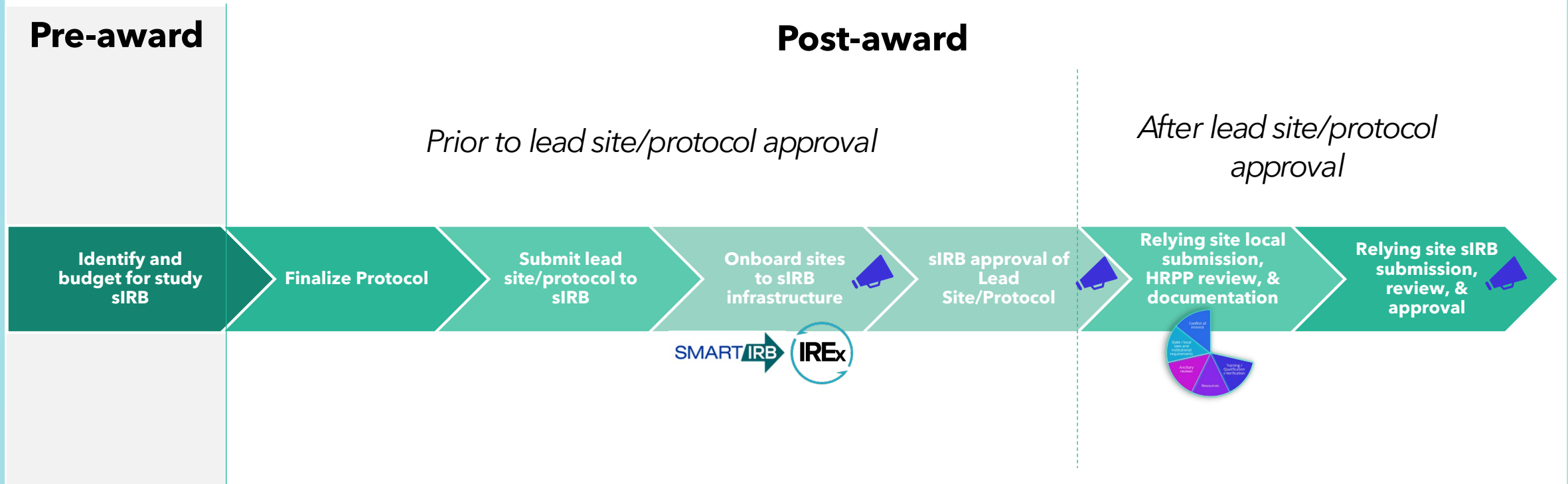


For **single site** studies, ONE organization coordinates all of these reviews.

# Key Human Subjects Reviews



# Key Timepoints



**Key to Efficiency:** *Designate a lead study  
team point of contact*

AKA IREx Study Manager

# sIRB Review Requires Coordination by the Lead Study Team

SMART IRB

**Purpose of form:** The Home Institution for the Overall Principal Investigator and/or Lead Study Team can use this form to provide them with guidance regarding the additional responsibilities accrued in assuming that role, particularly when the SMART IRB Standard Operation Procedures are followed. Language in this document should be adapted to reflect local processes.

## Overall Principal Investigator/Lead Study Team Guidance and Checklist

As the Overall Principal Investigator for a study for which research activities involving human subjects will be overseen by a single IRB for all or most sites, you should be aware of your additional responsibilities in assuming that role. Once you have agreed to collaborate with investigators at another institution(s) and intend to use a single IRB for oversight of this study:

- You should contact the IRB administration or relevant Human Research Protection Program (HRPP) personnel at your institution to:
  - Discuss whether your home institution's IRB can act as the single IRB for all or some institutions participating in this study or whether another external IRB would be appropriate.
  - Identify who will act in the role of the Lead Study Team (e.g., your own study team, a coordinating center, or both). The Lead Study Team assumes additional responsibilities when single IRB review will be used.
  - Provide them with details about the study, including the studywide protocol and template consent document(s), which will help facilitate the discussion with your local IRB/HRPP.
  - Identify all sites that will be engaged in human subjects research and thus need IRB coverage.
- If your institution agrees to single IRB for the study, you will need to ensure the Lead Study Team:
  - Provides a reliance request to the Overall PI's home institution using the process required by that institution.
- Works in collaboration with the Reviewing IRB to determine and document specific roles and responsibilities for communicating and coordinating key information to Relying Institutions; this includes developing a plan for communicating with collaborators across the lifetime of the study (i.e. regular conference calls, site initiation procedures and training materials).
- Promptly responds to questions or requests for information from study teams and IRB/Human Research Protection Program personnel at institutions who are relying on the single IRB.
- Participates in conference calls regarding a study as requested.
- Provides the Site Investigators with the IRB policies of the Reviewing IRB. This includes, but is not limited to, policies for reporting unanticipated problems, noncompliance, and subject complaints.
- Provides participating Relying Site Study Teams with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).
- Prepares and submits IRB applications on behalf of all sites, including initial reviews, local amendments, personnel updates, local reportable events, and studywide information for continuing review.
  - As part of preparing the IRB application, the Lead Study Team (or designee) must
    - Have a mechanism in place to obtain and collate information from Relying Site Study Teams and/or Relying Site Points of Contacts (POCs), depending on who is designated to provide that information at the Relying Institution, regarding local variations in study conduct, such as recruitment materials and process, consent process and language, and subject identification processes.
    - Assist Relying Site Study Teams and/or POCs at the Relying Institution(s), depending on who is designated to provide that information, in ensuring consent documents follow the Reviewing IRB's template form and include applicable site-specific required language from each Relying Institution.
- Notifies Site Investigators of all Reviewing IRB determinations and communications, including those for initial review, continuing review, amendments, and reportable events.
- When agreed upon in coordination with the Reviewing IRB, promptly reports to the Site Investigator (or designee on the Relying Site Study Team) any unanticipated problems involving risks to subjects or others research-related subject injuries, or significant subject complaints that are related to or may affect subjects participating in the research (i.e., the specific study or studies ceded to the Reviewing IRB) at the Relying Institution.
- If a Relying Site Study Team does not provide the Lead Study Team (or designee) with the required information before the continuing review application is submitted to the Reviewing IRB, reports the absence of this information as part of the continuing review and notifying affected Relying Site Study Team of lapse in approval for their site and any applicable corrective action plans.
- Providing access, upon request, to study records for audit by the Relying Institution, the Reviewing IRB, and other regulatory or monitoring entities.
- Follow all requirements of the Relying Institution with regard to ceded review, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a Relying Institution.

[https://smartirb.org/assets/files/PI\\_checklist.pdf](https://smartirb.org/assets/files/PI_checklist.pdf)

## Perspective

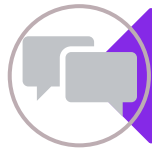
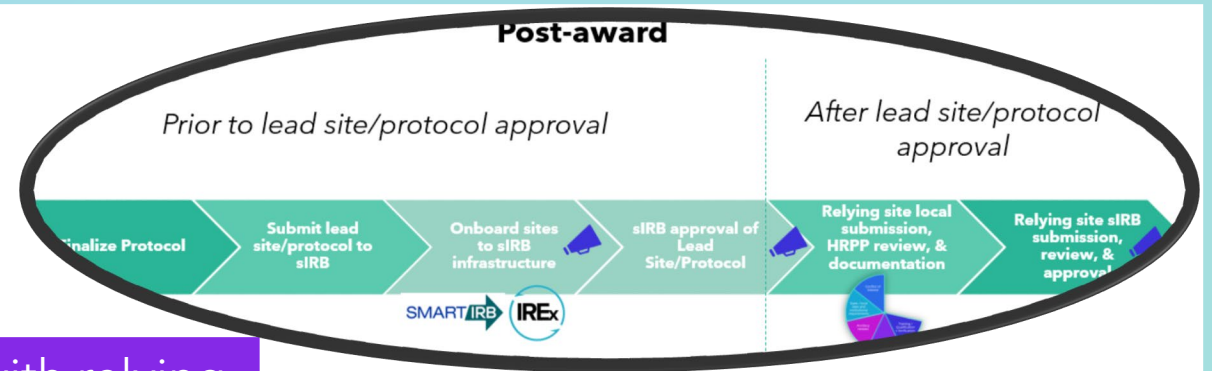
### Creation of a Single Institutional Review Board for Collaborative Research in Nephrology: The APOLLO Experience

J. Brian Moore,<sup>1</sup> S. Carrie Smith,<sup>2,3</sup> Laurie P. Russell,<sup>4</sup> Emily S. Serdoz,<sup>1,3</sup> Natalie A. Dilts,<sup>1,3</sup> Amir A. Alexander,<sup>1,4</sup> David M. Reboussin,<sup>4</sup> Benjamin M. Bagwell,<sup>5</sup> Mitzie H. Spainhour,<sup>5</sup> Amber M. Reeves-Daniel,<sup>5</sup> Deborah J. Wesley-Farrington,<sup>1</sup> Lijun Ma,<sup>1,5</sup> and Barry I. Freedman,<sup>1,5</sup> for the APOLLO Consortium\*

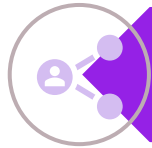
CJASN ■ 1–4, 2023. doi: <https://doi.org/10.2215/CJN.000000000000197>

In conclusion, WFU successfully implemented a single IRB model for APOLLO, consistent and compliant with its determinations, and maintained reasonable timelines for approval. **Communication and collaboration between multiple groups was pivotal. We recommend identifying an IREx Study Manager with sufficient effort dedicated to the study.** Without the coordination, support, and resources available from researchers, staff, and collaborators, these processes would have been more burdensome, onerous, and time-consuming.

# Key Responsibilities of the Lead Study Team



Communicate process & requirements with relying sites



Disseminate lead site approval documents to relying sites



Track relying site documentation



Submit relying site documentation to the sIRB



Share approvals with relying sites

# IREx Can Help: *Lead Study Team Checklist*

The screenshot shows the IREx Status Summary page. A sidebar on the left, titled 'Carnegie U Med Ctr GETTING STARTED', contains a checklist of tasks. The first task, 'Upload Overall Study Approval', is highlighted in green and circled in purple. Other tasks include 'Publish Approval', 'Add Participating Sites', 'Grant Site Access', 'View Site Progress on Status Summary', and 'Upload Relying Site Approval'. The main content area shows a table of sites with their agreement completion status and actions.

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

### Status Summary

Export Data

Site	Agreements	Reliance Decision	Local Considerations	Approval Status
Anderson Medical Center	2 / 2 Agreements Complete	+ Add PI Info		
Bridge University	1 / 2 Agreements Complete	Notify & Grant Access		
Carnegie University	2 / 2 Agreements Complete	Notify & Grant Access		
Mellon University Medical Center	2 / 2 Agreements Complete	Notify & Grant Access		
Peabody Institute of Medicine	1 / 2 Agreements Complete	Notify & Grant Access		

# IREx Can Help: *Status Summary*

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

Carnegie U Med Ctr  
GETTING STARTED

- Upload Overall Study Approval
- Publish Approval
- Add Participating Sites
- Grant Site Access
- View Site Progress on Status Summary
- Upload Relying Site Approval

### Status Summary

Export Data

Site	Agreements	Reliance Decision	Local Considerations	Approval Status
Anderson Medical Center	2 / 2 Agreements Complete	Add PI Info		
Bridge University	1 / 2 Agreements Complete	Notify & Grant Access		
Carnegie University	2 / 2 Agreements Complete	Notify & Grant Access		
Mellon University Medical Center	2 / 2 Agreements Complete	Notify & Grant Access		
Peabody Institute of Medicine	1 / 2 Agreements Complete	Notify & Grant Access		



# IREx Can Help: *Dashboard for All Studies*

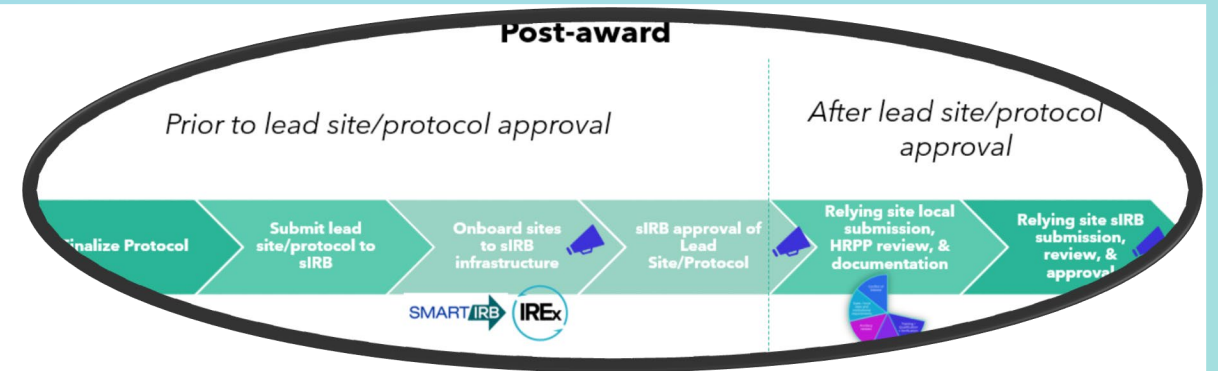
## Study Manager Dashboard

Search: 30

Study Title	Sites	Signed Agreements	Reliance	Local Consid.	Current Approvals	Expires
F... S... E... A... Project ID: 160	33 / 33 Registered	SMART IRB 33 Indemn. 32 IREx 33	33	33	25 8/30/2023	7/25/2024
:... Project ID: 302	13 / 16 Registered	SMART IRB 16 IREx 15	12	12	13 4/21/2023	4/12/2024
T... a... T... (... M... Project ID: 430	5 / 5 Registered	SMART IRB 5 IREx 5	5	5	6 11/3/2022	11/2/2023

Key to Efficiency: *Communications &*  
*Documentation*

# Key Communications



- ❑ Request required agreements be completed
- ❑ Distribute sIRB instructions & documents after lead site approval
- ❑ Disseminate sIRB approval of sites

# IREx Can Help: *Request Agreements*

Mellon Univ. Med Ctr  
GETTING STARTED

- Upload Overall Study Approval
- Publish Approval
- Add Participating Sites
- Grant Site Access
- View Site Progress on Status Summary
- Upload Relying Site Approval

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

### Status Summary

Site	Agreements	Reliance Decision	Local Considerations
Anderson Medical Center	2 / 2 Agreements Complete	+ Add PI Info	
Bridge University	1 / 2 Agreements Complete	Notify & Grant Access	
Carnegie University	2 / 2 Agreements Complete	Notify & Grant Access	
Midwest University Medical Center	2 / 2 Agreements Complete	Notify & Grant Access	
Peabody Institute of Medicine	1 / 2 Agreements Complete	Notify & Grant Access	

- Reliance Agreement
- IREx Access
- Request Agreement(s)**

SM Training - Action Required: Please Complete Agreement(s) for sIRB study

Serdoz, Emily Sheffer  
To: Serdoz, Emily Sheffer  
General  
Mellon\_JAA.rtf 95 KB

Dear HRPP(s) and Site Investigator,

This email contains **instructions for executing incomplete agreements** for the study below where PI Pete Ruso, an investigator at Peabody Institute of Medicine (FWA: 01201033), has been listed on the following study in IREx.

Study Title	IREx Study Manager Training Screenshots
Reviewing IRB	Mellon University Medical Center
Reviewing IRB Contact	Kate Austen ( <a href="mailto:ka@mellon.edu">ka@mellon.edu</a> )
Study Manager	Samantha Mango

As a first step towards relying on Mellon University Medical Center, please execute the incomplete items below.

Agreement/Resource	Status
<b>SMART IRB Agreement:</b> A national, master reliance agreement supporting single IRB review.	<b>Incomplete</b> — The HRPP can follow the steps to join SMART IRB <a href="#">here</a> or execute the reliance agreement attached. Send questions and executed agreements to Kate Austen ( <a href="mailto:ka@mellon.edu">ka@mellon.edu</a> ).
OR <b>Mellon IRB Authorization Agreement August 2020</b>	
<b>IRB Reliance Exchange (IREx):</b> A single IRB documentation and communication portal. <i>This is a web-based platform, not a reliance agreement.</i>	<b>Complete</b>

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,

# IREx Can Help: Communicate sIRB Instructions

Mellon Univ. Med Ctr  
GETTING STARTED

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

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

### Status Summary

Site	Agreements	Reliance Decision	Local Consent
Anderson Medical Center	2 / 2 Agreements Complete	+ Add PI Info	
Bridge University	1 / 2 Agreements Complete	📧 Notify & Grant Access	
Carnegie University	2 / 2 Agreements Complete	📞 Contacted 9/20/2023	
Midwest University Medical Center	2 / 2 Agreements Complete	📧 Notify & Grant Access	
Peabody Institute of Medicine	1 / 2 Agreements Complete	📧 Notify & Grant Access	

SM Training - IREx Access and Single IRB Instructions

Serdoz, Emily Sheffer  
To: Serdoz, Emily Sheffer  
Wed 9/20/2023 9:13 AM

Dear HRPP(s) and Study Team,

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

IREx PI has been listed as an investigator at Midwest University Medical Center (FWA: 00951753). All study team members included on this email now have access to the study in IREx.

Study Title	IREx Study Manager Training Screenshots
Study Link	<a href="https://staging.irbexchange.org/s/project/6912130">https://staging.irbexchange.org/s/project/6912130</a>
Reviewing IRB	Mellon University Medical Center
Reviewing IRB Contact	Kate Austen (ka@mellon.edu)
Study Manager	Samantha Mango

**Next Steps:**  
The overall/lead site approval is available in IREx. Use these documents to...

**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
<b>SMART IRB Agreement:</b> A national, master reliance agreement supporting single IRB review.	Complete
<b>IRB Reliance Exchange (IREx):</b> A single IRB documentation and communication portal. <i>This is a web-based platform, not a reliance agreement.</i>	Complete

**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?](#)

# IREx Can Help: *Disseminate Site Approvals*

Dear Liaisons and Study Contacts,

Mellon University Medical Center has shared IRB approval for your institution, Carnegie University, in IREx for the study below:

<b>Study Title:</b>	Metabolomics of Neurocognitive Risk for Dementia in Diabetes
<b>Type of Review / Approval:</b>	Initial Study: Expedited
<b>Expiration Date:</b>	11/18/2022
<b>Study Link:</b>	<a href="https://staging.irbexchange.org/s/project/007">https://staging.irbexchange.org/s/project/007</a>

#### Principal Investigators & Study Contacts:

**\*NEW\*** We've made accessing your approval documents more user friendly - use this [Quick Guide](#) to see the changes.

If you have any questions about your approval or future submissions, please contact the Study Manager (Coordinating Center/ Lead Study Team) or Reviewing IRB. If needed, contact information is listed on the study page above the study title in IREx.

*Thank you for using IREx,  
The IREx Team*

## Carnegie University

### Protocol Version: 1

Initial Study: Full Board (approved 7/13/2023)

Current

#### Study Info

**IRB Number:**  
**Type of Study:** Minimal Risk (f)(3)  
**Reviewing IRB Decision:** approved  
**Review Cycle:** No Further Review Required

#### Key Dates

**Submitted for Local Review:** 7/25/2023  
**Local Review Conducted:** 7/25/2023  
**Local Review Completed:** 7/25/2023  
**Reviewing IRB Submitted:** 7/12/2023  
**Reviewing IRB Reviewed:** 7/13/2023  
**Reviewing IRB Approved:** 7/13/2023

#### Documents

Download All

#### Global Documents

Download

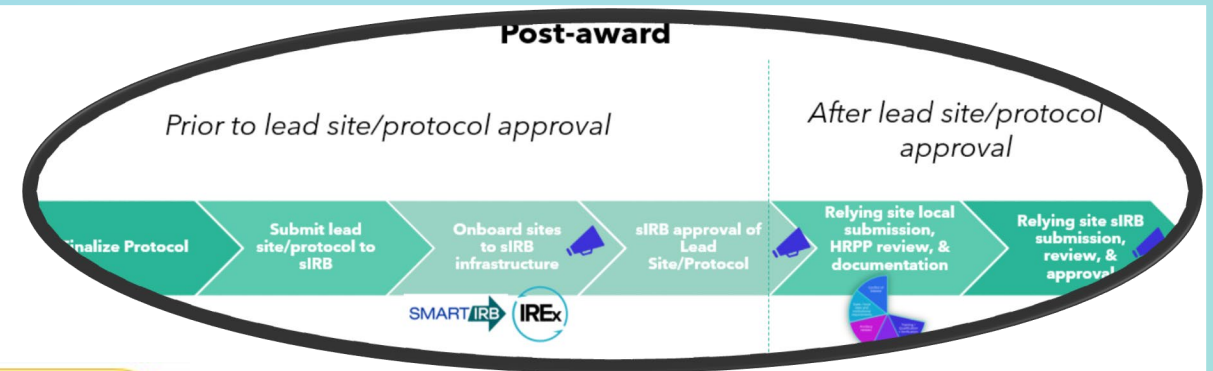
Type	Name	Date Approved
Protocol 1	<a href="#">ConsultMgmt_PlanningWVCC_20230327.docx</a>	7/4/2023
IRB Approval Documentation	<a href="#">IREx_SSRP_QuickGuide_EDIT for Relying HRPP.docx</a>	7/4/2023
IRB Application	<a href="#">Major IREx Workflow Improvements.docx</a>	7/4/2023

#### Site Specific Documents

Download

Type	Name	Date Approved
IRB Approval Documentation	<a href="#">IRB FAL (17).pdf</a>	7/13/2023
Consents & Assents	<a href="#">ConsentForm_Carnegie.pdf</a>	7/13/2023

# Key Documentation



Participating Site HRPP	Investigator	Coordinator
<b>GETTING STARTED</b>	<b>GETTING STARTED</b>	<b>GETTING STARTED</b>
<ul style="list-style-type: none"> <li>✓ Register</li> <li>✓ Complete Agreements</li> <li>✓ Confirm Institutional Profile</li> <li>✓ Indicate Reliance</li> <li>✓ Complete HRP Survey</li> <li>✓ Review PI Survey (optional)</li> <li>Add / Edit Study Team Access</li> <li>Awaiting Reviewing IRB Approval</li> </ul>	<ul style="list-style-type: none"> <li>✓ Complete/Attest to PI Survey</li> <li>Add / Edit Study Team Access</li> </ul>	<ul style="list-style-type: none"> <li>✓ Start PI Survey for Carnegie U Med Ctr</li> <li>✓ Awaiting PI Attestation for Carnegie U Med Ctr</li> <li>Add/Edit Study Team Access</li> </ul>

## Relying Site Documentation

- ❑ **Reliance decision**
- ❑ **Institutional Profile** - relatively static organization-level information from the HRPP
- ❑ **HRP Survey** - study specific information from the HRPP
- ❑ **PI Survey** - documentation of site differences from the protocol, if any



# IREx Can Help: *Automated Notifications*

Site	Agreements	Reliance Decision	Local Considerations	Approval Status
Anderson Medical Center	2 / 2 Agreements Complete	<a href="#">Add PI Info</a>		
Bridge University	1 / 2 Agreements Complete	<a href="#">Notify &amp; Grant Access</a>		
Carnegie University	2 / 2 Agreements Complete	Completed 9/20/2023	3 / 3 Surveys Complete	Not Approved
Midwest University Medical Center	2 / 2 Agreements Complete	Started 9/20/2023	1 / 3 Surveys Complete	Not Approved
Peabody Institute of Medicine	1 / 2 Agreements Complete	<a href="#">Notify &amp; Grant Access</a>		

SM Training - IREx: Notification of Reliance

Serdoz, Emily Sheffer  
To: Serdoz, Emily Sheffer  
Wed 9/20/2023 9:30 AM

General

6912130-558473-IREx\_Reliance\_Notification-2023-09-20-084815.pdf 63 KB

Dear all,

This email confirms that **Carnegie University** has agreed to rely on the **Mellon University Medical Center** IRB using the following agreement(s):

- SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement

Study Title	IREx Study Manager Training Screenshots
Study Short Title	SM Training
IREx Project ID	6912130
Reviewing IRB	Mellon University Medical Center (FWA #00001111)
Relying Institution	Carnegie University (FWA #32322829)
Study Link	<a href="https://staging.irbexchange.org/s/project/6912130">https://staging.irbexchange.org/s/project/6912130</a>

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

Thank you,  
The IREx Team

Dear Study Manager and Reviewing IRB Liaison,

An HRPP Liaison completed registration for the study as shown below:

Study Title	Metabolomics of Neurocognitive Risk for Dementia in Diabetes
Site	Midwest University Medical Center (#00951753)
PI	Barry Freedman ( <a href="mailto:bfreedma@mumc.edu">bfreedma@mumc.edu</a> )
PI Access	Barry Freedman now has access to the study.

If you have questions about this site's registration, please contact [IREx HRPP](#).

**STUDY LINK:** <https://test.irbexchange.org/feature-branch/public/s/project/3095211>

Thank you,  
IREx Administrator



# IREx Can Help: *Automated Tracking*

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

Status Summary

Manage Agreements | Export Data

Site	Agreements	Reliance Decision	Local Considerations	Approval Status
Anderson Medical Center	2 / 2 Agreements Complete	Add PI Info		
Bridge University	1 / 2 Agreements Complete	Notify & Grant Access		
Carnegie University	2 / 2 Agreements Complete	Completed 9/20/2023	3 / 3 Surveys Complete	Not Approved
Midwest University Medical Center	2 / 2 Agreements Complete	Started 9/20/2023		Approved
Peabody Institute of Medicine	1 / 2 Agreements Complete	Notify & Grant Access		

- ✓ Institutional Profile  
Confirmed: 9/20/2023
- ✓ HRP Survey  
Completed: 9/20/2023
- ✓ PI Survey  
Completed: 9/20/2023  
PI Attested: 9/20/2023
- ✉ Email study personnel

Dear IREx Study Manager(s),

Carnegie University has completed the local considerations for the study below.

<b>Study Title:</b>	Metabolomics of Neurocognitive Risk for Dementia in Diabetes
<b>Reviewing IRB:</b>	Mellon University Medical Center
<b>Study Link:</b>	<a href="https://test.irbexchange.org/feature-branch/public/s/project/507062">https://test.irbexchange.org/feature-branch/public/s/project/507062</a>

### Next Steps

1. **PRE-SCREEN LOCAL CONSIDERATIONS**
  - Pre-screen the HRP and PI surveys and the consent form, if applicable, for completion (e.g., is any information missing from the consent form sections; does the language provided read properly). Consent forms are uploaded to the PI survey.
  - To request changes, reach out to the local study team who can make changes to the PI Survey and work with their HRPP if changes are needed for the HRP Survey.
  
2. **EXPORT LOCAL CONSIDERATIONS FROM IREx**

Allow up to ten minutes for the Export feature to be available for download. From the Status Summary tab on your study page, click the "Export Data" button and select "Export Local Considerations" to download the local considerations for this site. These files will be included in the export:

  - Notification of Reliance Letter
  - HRP Survey responses (PDF)
  - PI Survey responses (PDF)
  - Institutional Profile (PDF)
  - Site-specific consent forms, if applicable for this study.
  - Other documents that are uploaded to the HRP or PI Surveys and the Institutional Profile. The survey type will be included in the file name (e.g., [Institutional Profile]\_filename)
  
3. **SUBMIT THE SITE TO THE SIRB FOR REVIEW**

If you have questions about how to submit to the Reviewing IRB, contact the Reviewing IRB Liaison(s): LaDonna Liaison ([Lliaison@sirbmc.cdu](mailto:Lliaison@sirbmc.cdu)).

Thank you,  
IREx Administrator

Key to Efficiency: *Request to use  
IREx!*



Using single IRB consultations to meet the educational needs of investigative teams

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“To streamline the SIRB review process, **the use of electronic systems to coordinate the flow of information and the timing of actions is often key**... The platform TIN SIRBs use to document reliance is the **IRB Reliance Exchange system, or IREx**. This platform connects institutions’ IRBs, HRPPs, and study teams; enables documentation of reliance relationships in a central location; and captures local review and institutional profiles.”

## Perspective

### Creation of a Single Institutional Review Board for Collaborative Research in Nephrology: The APOLLO Experience

J. Brian Moore,<sup>1</sup> S. Carrie Smith,<sup>2,3</sup> Laurie P. Russell,<sup>4</sup> Emily S. Serdoz<sup>1b</sup>,<sup>3</sup> Natalie A. Dilts<sup>1b</sup>,<sup>3</sup> Amir A. Alexander<sup>1b</sup>,<sup>4</sup> David M. Reboussin,<sup>4</sup> Benjamin M. Bagwell,<sup>5</sup> Mitzie H. Spainhour,<sup>5</sup> Amber M. Reeves-Daniel,<sup>5</sup> Deborah J. Wesley-Farrington,<sup>1</sup> Lijun Ma<sup>1b</sup>,<sup>5</sup> and Barry I. Freedman<sup>1b</sup>,<sup>5</sup> for the APOLLO Consortium\*

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In conclusion, WFU successfully implemented a single IRB model for APOLLO, consistent and compliant with its determinations, and maintained reasonable timelines for approval. **Communication and collaboration between multiple groups was pivotal. We recommend identifying an IREx Study Manager with sufficient effort dedicated to the study.** Without the coordination, support, and resources available from researchers, staff, and collaborators, these processes would have been more burdensome, onerous, and time-consuming.

# IREx Utilization

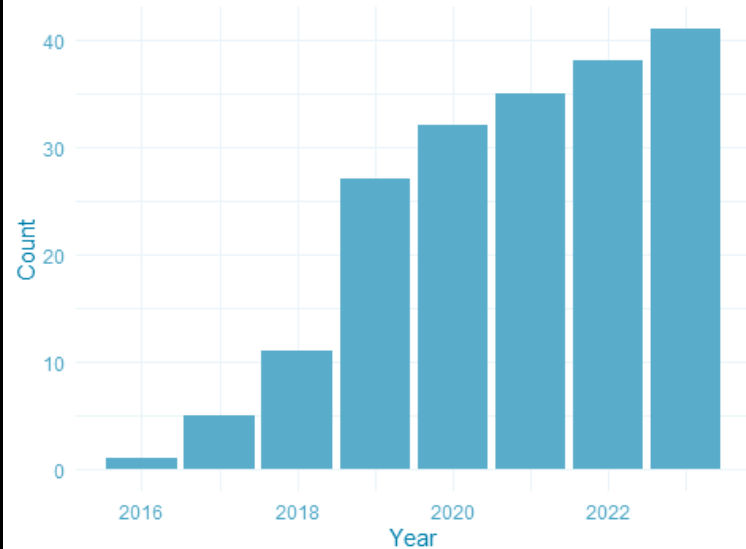
Participating Institutions **512**

Studies **573**

Studies Created by Year



Cumulative sIRBs Joined by Year



## Relying HRPP Use of IREx

NAME	STUDY PARTICIPATION	INSTITUTIONAL PROFILE
Children's Hospital of Philadelphia <b>AAHRPP</b>	73	<a href="#">updated 4/4/2023</a>
University of Michigan <b>AAHRPP</b> <b>CTSA</b>	63	<a href="#">updated 8/29/2023</a>
Stanford University <b>AAHRPP</b> <b>CTSA</b>	61	<a href="#">updated 8/24/2023</a>
Duke University Health Systems, Inc. <b>AAHRPP</b> <b>CTSA</b>	58	<a href="#">updated 8/7/2023</a>
University of California, Los Angeles <b>AAHRPP</b> <b>CTSA</b>	58	<a href="#">updated 6/15/2023</a>

Institution Name	# of Studies
<b>*NEW*</b> sIRB in Q1 of 2023	
Ann & Robert H. Lurie Children's Hospital of Chicago	4
Ball State University	1
Baylor College of Medicine	1
Baystate Health, Inc	3
Children's Hospital of Los Angeles <b>*NEW*</b>	1
Cincinnati Children's Hospital Medical Center	1
Dartmouth-Hitchcock Clinic	2
Duke University Health Systems, Inc.	9
Emory University	3
George Washington University	1
Indiana University	3
Intermountain Healthcare	1
Johns Hopkins University School of Medicine	22
Louisiana Department of Health	1
Louisiana State University A and M	5
Louisiana State University Health Science Center at New Orleans	31
Louisiana State University Health Science Center at Shreveport	1
MaineHealth <b>*NEW*</b>	1
Memorial Sloan Kettering Cancer Center	1
Nationwide Children's Hospital	9
Ochsner Clinic Foundation	5
Pennington Biomedical Research Center	49
St. Jude Children's Research Hospital	1
The Ohio State University <b>*NEW*</b>	1
Tulane University	41
University of Alabama Birmingham	3
University of California, San Francisco	42
University of Colorado, Denver	2
University of Maryland Baltimore	2
University of Massachusetts Medical School	1
University of Mississippi Medical Center	1
University of Pittsburgh	5
University of Rochester	6
University of Texas Southwestern Medical Center	8
University of Texas, MD Anderson Cancer Center	4
University of Utah	68
University of Wisconsin – Madison	2
Vanderbilt University Medical Center	137
Virginia Commonwealth University	2
Wake Forest University Health Sciences	27
Woman's Hospital Foundation	2

Key to Efficiency: *IREx Resources*

# Our Best Resource: The IREx Team!

- Training
- Special projects

**Natalie Dilts**



- Manager, Application Development

**Bryce Embry**



- Resources & Materials

**Katelyn Benhoff**



- Study Support
- User Training

**David Crenshaw**



- Materials Development
- Study support

**Kaysi Quarles**



- Study Support
- Evaluation

**Tiffany Chen**



- Program Manager

**Emily Serdoz**



- Study Support
- User Training

**Bridget Swindell**



- System Development

**Linda Tan**



- Application Developer

**Jason Tan**



- Application Developer

**Evan Wimberly**



# IREx Resources

**Website:**  
<https://IRBExchange.org>

Visit the [Study Manager Resources Page](#)

**Email Us:**  
[admin@irbexchange.org](mailto:admin@irbexchange.org)

Request a [Study-specific training](#) for your team

## USING IREX AS THE LEAD STUDY TEAM/ COORDINATING CENTER

[Join a Training](#)

**MANAGE SITE ACCESS AND COMMUNICATIONS**

- Use IREx to manage site access to studies and facilitate communication with study teams and IRBPs.

**TRACK SITE READINESS FOR SIRB REVIEW**

- Use IREx to monitor site progress completing study-specific site decisions and local considerations.

**EXPORT SITE-SPECIFIC RELIANCE DOCUMENTATION**

- Use IREx to centrally capture and download site study-specific documentation needed for submission to the IRB.

**UPLOAD AND DISSEMINATE SITE APPROVALS**

- Use IREx to capture site approvals and stream-line related communications to study teams and IRBPs.

### RESOURCES FOR USING IREX

<p><b>Use IREx as the Study Manager (SM)</b></p> <ul style="list-style-type: none"> <li>Download SM overview</li> <li>SM all abbreviated</li> </ul>	<p><b>Add / Remove Sites on a Study</b></p> <ul style="list-style-type: none"> <li>Manage site access</li> <li>Download Guide</li> </ul>	
<p><b>IREx Template Instructions</b></p> <ul style="list-style-type: none"> <li>Use IREx to send site instructions</li> <li>Instructions on required agreements</li> <li>Instructions on eIRB process</li> </ul> <p>Download Template</p>	<p><b>Capture Approval Documents in IREx</b></p> <ul style="list-style-type: none"> <li>Distinguish document types</li> <li>Improve sorting and grouping</li> <li>How site access approval documents</li> </ul> <p>Watch Video</p>	<p><b>Upload Initial Approvals: Overall and Sites</b></p> <ul style="list-style-type: none"> <li>Download Overall approval upload guide/ppt</li> <li>Download SITE approval upload guide/ppt</li> </ul> <p>Watch SITE UPLOAD Video</p>
<p><b>Upload Study-wide Amendment Approvals</b></p> <ul style="list-style-type: none"> <li>Changes that apply to all sites</li> </ul> <p>Download guide/ppt</p> <p>Watch Video</p>	<p><b>Upload Continuing Review Approvals</b></p> <ul style="list-style-type: none"> <li>Changes for a single site</li> </ul> <p>Download guide/ppt</p> <p>Watch Video</p>	<p><b>Upload Site Amendment Approvals</b></p> <ul style="list-style-type: none"> <li>Changes for a single site</li> </ul> <p>Download guide/ppt</p> <p>Watch Video</p>
<p><b>Closing a Study in IREx</b></p> <ul style="list-style-type: none"> <li>How to upload a study closure</li> </ul> <p>Download guide/ppt</p> <p>Watch Video</p>	<p><b>Closing a Site in IREx</b></p> <ul style="list-style-type: none"> <li>How to upload a site closure</li> </ul> <p>Download guide/ppt</p> <p>Watch Video</p>	<p><b>About Combo Sites</b></p> <ul style="list-style-type: none"> <li>Plagiarizing multiple IRBs</li> <li>IRB site requirements</li> </ul> <p>Download Guide</p>

### STUDY MANAGER STEP-BY-STEP GUIDE

**Table of Conte**

- SUBMIT THE LEAD SITE TO THE SIRB**
  - The SIRB will review the submission and create a submission ID.
  - You will receive access to IREx via an email.
  - While you wait for the SIRB to approve the lead site, you can add participating sites to the study.
- ADD PARTICIPATING SITES TO THE STUDY**
  - Click Add Participating Site button.
  - Search and add site (IRB/IC) or by IRB search a consortium.
  - As you type, the site from drop-down menu will appear.
  - You can add site name/IRB name/IRB ID.
  - Enter the IRB ID if not, save the site.
- REQUEST REQUIRED AGREEMENTS (IF APPLICABLE)**
  - On the Status Summary page, any Institution Agreements Complete button with a drop-down arrow.
  - Click the purple Request Agreements button to send an email notification to the site.
- UPLOAD INITIAL SIRB APPROVAL FOR THE LEAD SITE/OVERALL STUDY & PUBLISH**
  - Click Upload Overall Study Approval in your Getting Started Checklist.
  - Change the Status to Approved and indicate the reviewing type & cycle. All required files and documents will be highlighted in red.
  - Enter the dates for when it was submitted, approved, reviewed, and expires.
  - Upload your documents.
  - Remember to click Accept Draft if the original protocol uploaded to IREx was approved or click Review Draft if it was not during the review.
  - In which case be sure to change the version case BEFORE uploading the new protocol file.
  - Replace or accept other draft documents, as needed.
  - NOTE: If applicable, include a site-specific consent template or part 3 consent template in the global documents.
  - Upload Documents
  - Click Publish button to make the approved global documents visible to the participating sites once they have study access. Check the box at the bottom of the Review & Publish page and click Save. Leave the box unchecked and click Save if you want to return to Publish Approval later.
- NOTIFY & GRANT ACCESS TO SITES**
  - Click Grant Site Access on your Getting Started Checklist, this will open your Status Summary page.
  - Click the Notify & Grant Access button to alert sites of their access to the study in IREx. This sends an email to the IRB and study team to prompt them to connect around their local reliance process, give them study access, and includes single IRB instructions for the study. The study team can use the Study Link in the email to log into IREx and approve the site-specific IRB approval documents for their local submission (if applicable).
  - Only sites that have joined IREx can be notified.
  - You can notify sites at different times depending on when they are being onboarded to the study.

### IRB Reliance Exchange 'IREx'

@IRBRelianceExchange 34 subscribers 30 videos

IRB Reliance Exchange (IREx) is a web-based portal freely available to sup... >

irebexchange.org

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# What Our Users Say:

<https://www.irbexchange.org/p/what-our-users-say/>

"..thanks to IREx I was able to onboard the sites to the study in a methodical, rapid and organized process, including preparation of site-specific consent documents."

**"...The IREx support team has been accessible and helpful to solve any user issue on demand."**



**Ariela**

Study Manager, MGH

"We consider IREx to be the "helping hand" to facilitate increased collaboration among the LA CaTS institutions by building trust and executing the once uncharted territory of full reliance... **If we are the Lead (sIRB), we usually insist on using the IREx platform.** We have included this information in our local IRB reliance request form so our investigators are aware of our preference."



**Michelle**

HRPP Liaison, PBRC

"I think IREx is useful for study teams who have yet to create their own system of organizing the single IRB process. It's **easy for them to keep track of which sites have filled out which forms and the email notifications help to understand what activity has occurred by relying sites** in IREx. But most of all I like that **IREx has amazing customer service.** For me this is the key to long-term success of the IREx platform."



**Jessica**

HRPP Liaison, UCSF