

PRIM&R AER 2023

Single IRB Coordination Models: Innovative Approaches from Four CTSA's

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Session C3, 12/3/2023, 3:45pm



PRIM&R

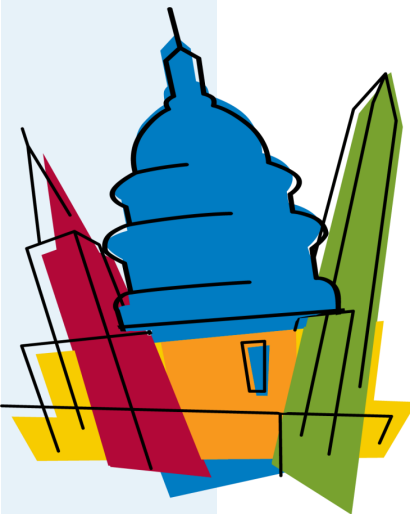
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Washington, DC

SBER Conference
December 3, 2023
Washington, DC

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Disclosures

Annie Risenmay: *I have no relevant personal/professional/financial relationship(s) with respect to this educational activity.*

Emily Serdoz: *I have no relevant personal/professional/financial relationship(s) with respect to this educational activity.*

Amy Trullinger: *I have no relevant personal/professional/financial relationship(s) with respect to this educational activity.*



Learning Objectives

1. Identify coordination challenges faced by IRBs and study teams throughout the Single IRB review process
2. Describe operational models/essential tools for centralizing study/reliance documentation and communication between site study teams, IRBs, HRPPs, etc. using tools like IREx and other electronic systems.
3. Discuss five-year metrics of Single IRB data and share outcomes.



Agenda

- Introduction
- Models
 - Indiana CTSI/Indiana University HRPP: liaison model
 - University of Utah HRPP: multiple/hybrid models
 - Wake Forest School of Medicine CTSI: decentralized model
 - Vanderbilt University Medical Center: decentralized model
- Leveraging the IRB Reliance Exchange (IREx) Supports sIRB Coordination
- Metrics/data on sIRB coordination



Terminology

- **IRB:** Institutional Review Board
- **sIRB:** Single IRB. Also referred to as central IRB or reviewing IRB.
- **HRPP:** Human Research Protection Program
- **IREx:** IRB Reliance Exchange – web-based document & communication system
- **Reliance:** When one or more relying institutions choose to accept IRB review and oversight for a research project from another institution's reviewing IRB.
- SMART IRB is *not* an IRB.
 - SMART IRB is a platform that offers a **master IRB reliance agreement** (the SMART IRB Agreement) and a **web-based system** (SMART IRB's Online Reliance System).



Single IRB Review is NOT Institutional Review

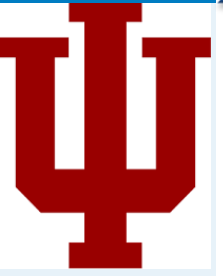


Why sIRB Coordination?

What is Single IRB Coordination and why is it necessary to the single IRB Process?

- Coordinating IRB submissions and site additions when an academic IRB serves as the sIRB for a multisite study
- Differing IRB and institutional policies and processes
- Closed or unfamiliar IRB systems for external sites

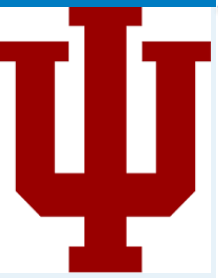




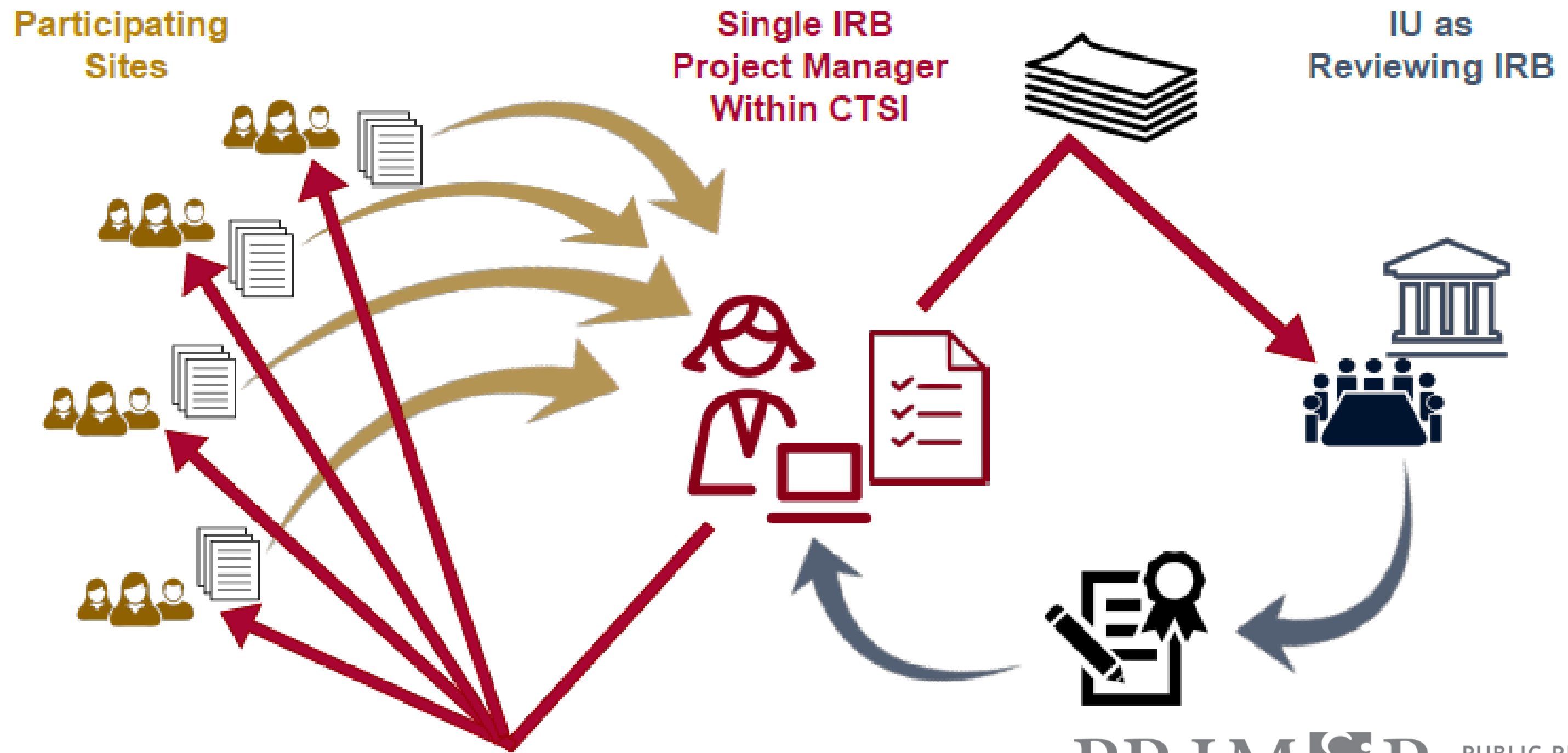
Indiana University

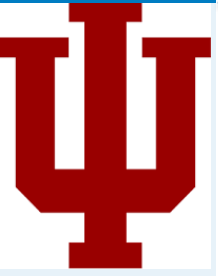
Studies reviewed by the Indiana University IRB have either centralized or decentralized sIRB support.



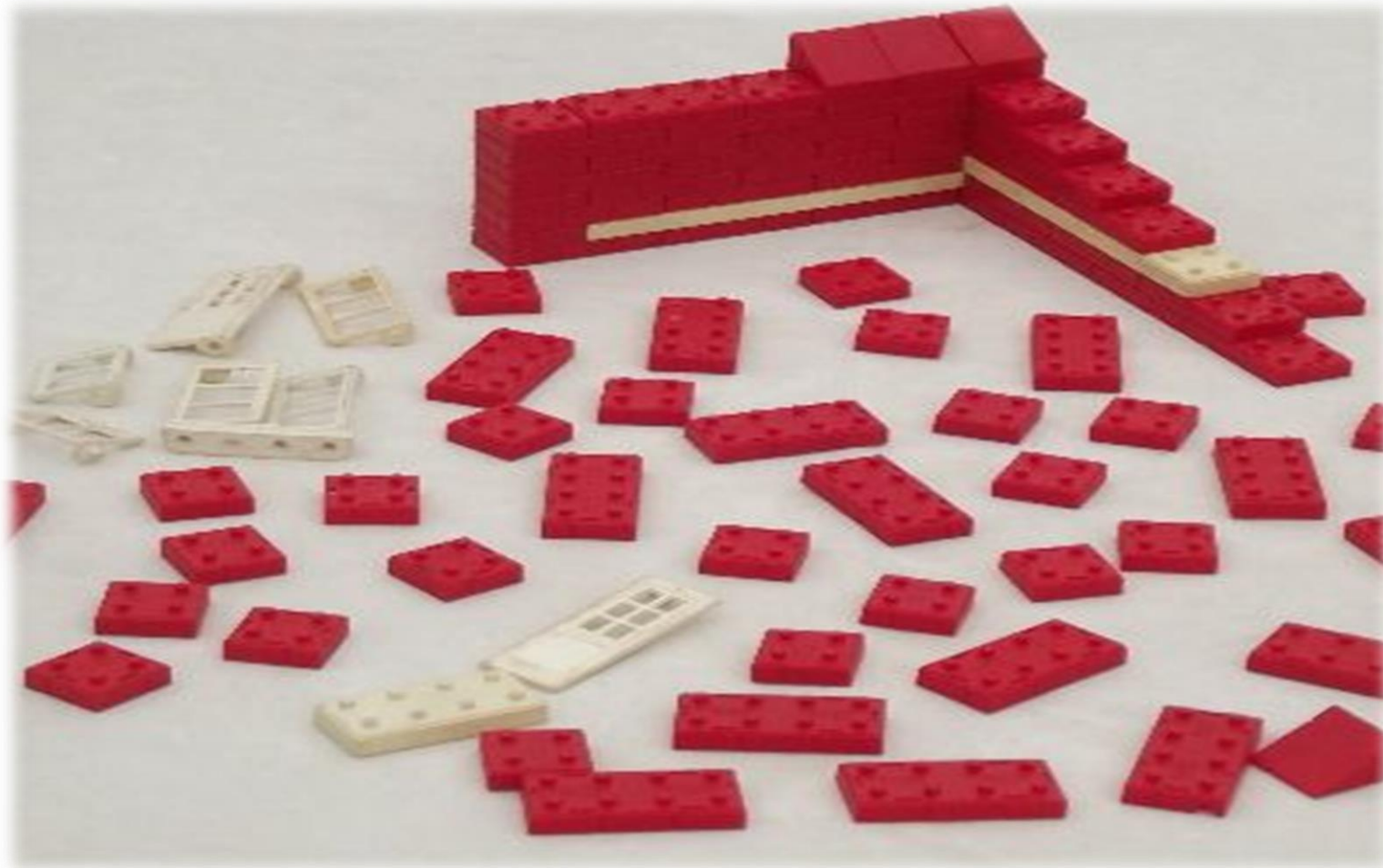


Liaison Model





Delineation of Duties



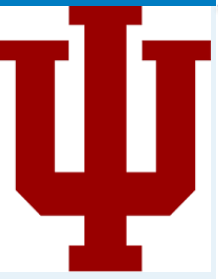
Lead Study Team:

- Initial IRB approval process
- FDA Submissions
- Development of and changes to study documents
- Maintaining study personnel
- IRB submissions for lead site only

sIRB Project Managers:

- Submit site specific amendments
- Distribute approvals and documents
- Work with sites on reliance
- Submit prompt reports for sites
- Submit renewals





Pros & Cons of Liaison Model

Pros

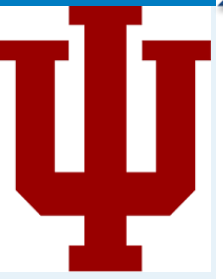
- Expertise in with single IRB
- Tools
- Early identification of possible issues
- Allows lead study team to focus on other tasks
- Frequent, direct communication with HRPP/IRB staff
- Established relationships



Cons

- There is a separate cost associated with CTSI sIRB PM support
- Less familiarity with the specifics of the protocols
- Not a full-time member of the study team
- Limited capacity



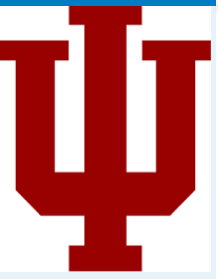


Initial Memo & Documents

- Information about the reliance process and upcoming steps
- IRB approved protocol
- Initial IRB approval letter
- Consent, Assent, and HIPAA templates
- Other IRB approved materials
- Local Context Checklist
- Relying Site Questionnaire

****Request to schedule onboarding meeting****



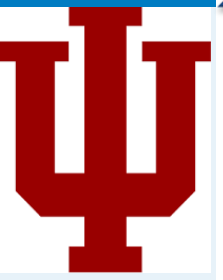


Relying Institution Onboarding Meetings



- Introduction of people on call
- Overview of the study
- Explain reliance process
- Discuss initial email
- Explore attached documents





Tools: SMART IRB and IREx



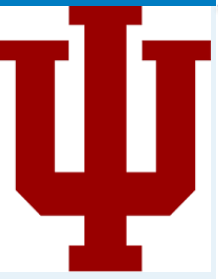
Supporting single IRB review
Advancing collaborative research



What is IREx?

A freely available, web-based portal supporting single IRB review documentation and coordination for multi-center clinical trials.

- WHAT IS IREX?
- SIRBS IN IREX
- OUR METRICS
- NEWEST FEATURES



sIRB Infrastructure & Volume

	Indiana HRPP	Indiana CTSI	Utah	Wake Forest	Vanderbilt
# of FTEs Supporting sIRB	2-3	2	3	0	3
Where FTEs work	HRPP	CTSI	HRPP	NA	HRPP
# of sIRB Studies	>77	10	150	34	150
# of Site Reliances	---	58 +14	>600	>400	294 unique 1186 total
External Investigator Access to eIRB System	No	No	Yes	No	Personnel changes + event reporting only
Charge for sIRB Review	No	Yes - % FTE	Yes	Yes	Yes



University of Utah

Studies reviewed by the University of Utah IRB use a hybrid model for sIRB support.





Reliance Consultation



- Study details
- Relying sites
- Education
- Next steps

Who's responsible?

LEAD STUDY TEAM*

- Initiate
- Intake
- Liaise

*Expert or getting educated

SINGLE IRB

- Guidance





Reliance Agreements



- IREx set-up
- Invitations
- Sites' local requirements

Who's responsible?

LEAD STUDY TEAM

Invitations

SINGLE IRB



RELYING SITE HRPP

Reliance Documentation

SITE STUDY TEAM

Local Requirements





Protocol-Only Review



- Full application
- Consent template, recruitment materials, protocol, etc.
- “Normal” IRB review process

Who's responsible?

LEAD STUDY TEAM

- Submit application
- Revision response

SINGLE IRB

- Criteria for approval
- Revisions





Initial Approval



- SIRB application approval
- Dissemination

Who's responsible?

LEAD STUDY TEAM

Distribute approval and
templates



SINGLE IRB

Approval documentation





Adding Sites



- Site HRPP review
- Local considerations
- Site-specific consent and/or other materials
- Multiple sites

Who's responsible?

LEAD STUDY TEAM

May submit application for site*

SINGLE IRB

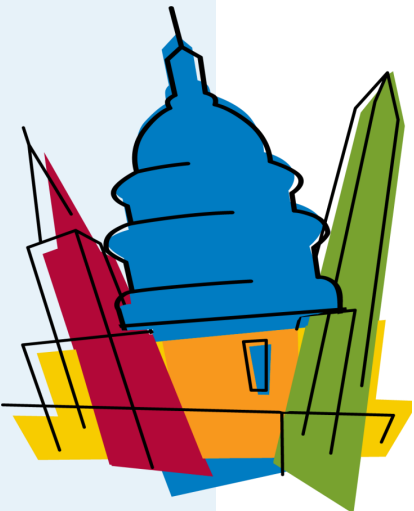
- Apply local considerations
- Review site-specific documents

RELYING SITE HRPP

- Provide community information
- Documentation of local review

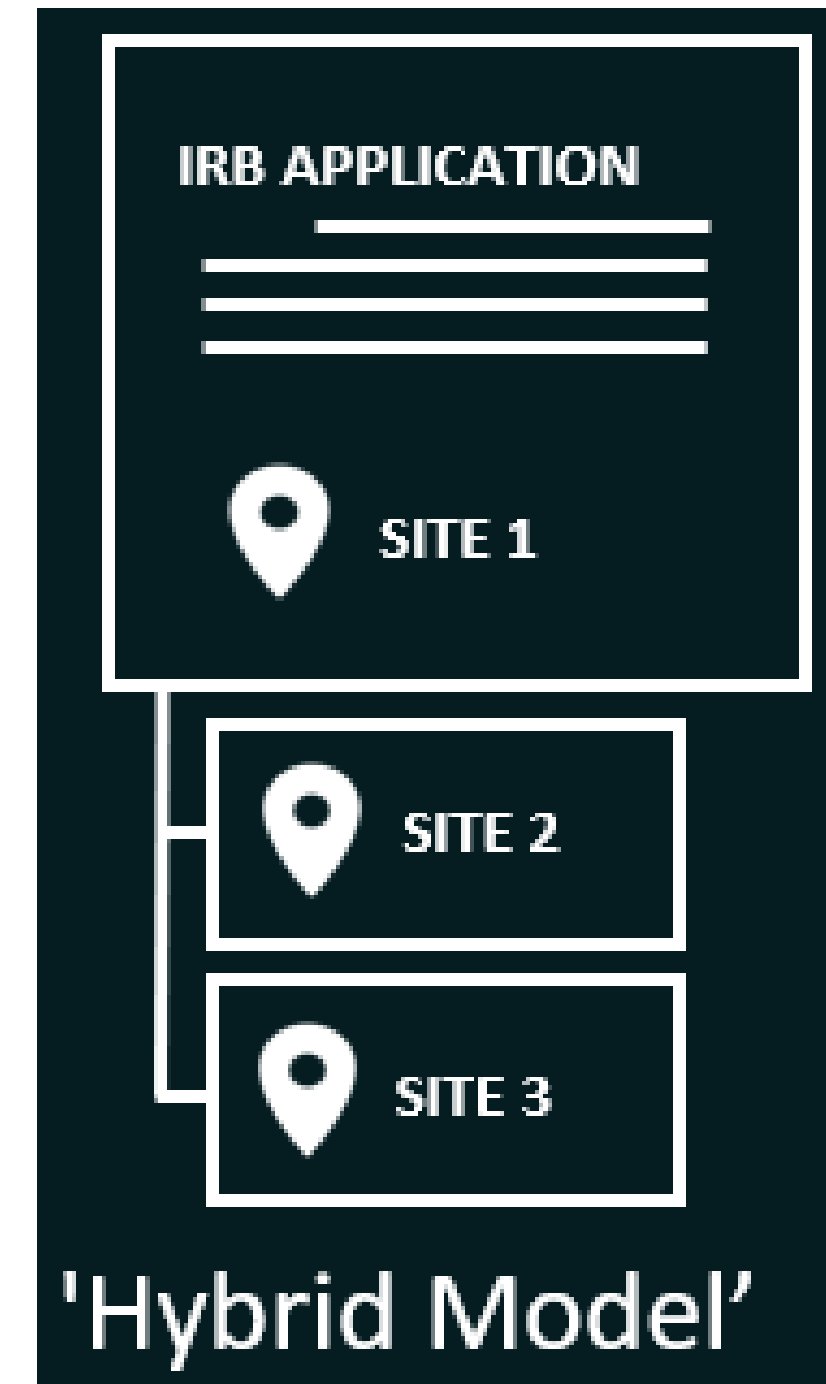
SITE STUDY TEAM

May submit own site application*





Submission Models





Standard/Default Model



Pros

- Same approval date
- Central coordination/consistency
- Knowledge of system



Cons

- Approval delays
- Lead study team burden





Site-Control Model



Pros

- Independence
- Responsibility
- Cut out “middle human”



Cons

- Learning curve
- External system access





Hybrid Model



Pros

- Lead study team decides who gets what responsibilities
- Can be flexible with independence vs. control



Cons

- Differences
- Main application sites ready at same time





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Charge for sIRB Review	No	Yes - % FTE	Yes	Yes	Yes

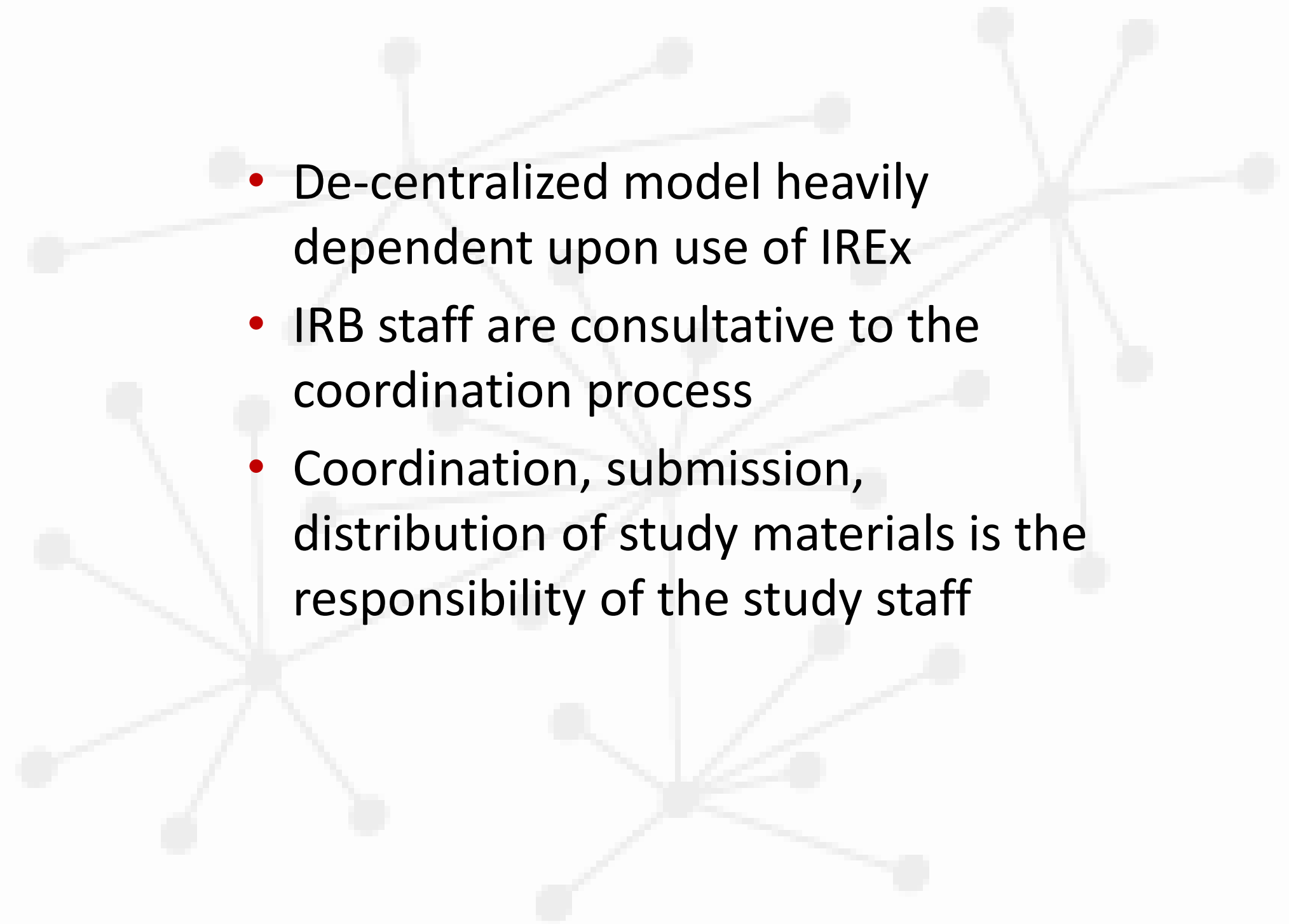




Wake Forest University

Vanderbilt University Medical Center

Studies reviewed using a
decentralized model.



- De-centralized model heavily dependent upon use of IREx
- IRB staff are consultative to the coordination process
- Coordination, submission, distribution of study materials is the responsibility of the study staff



VANDERBILT
UNIVERSITY
MEDICAL
CENTER

Decentralized Model Division of Responsibilities

Single IRB

Create & oversee sIRB intake process & requests

Provide resources & educational materials for study teams

Review & approval study

Create study in IREx

Oversee flexible elements of reliance in IREx

Document executed IAAs and indemnification in IREx, if required

Lead Study Team

Add participating sites (PSites) to IREx

Request PSites executed required agreements via IREx, as needed

Grant PSite study team access to study in IREx

Monitor PSite progress completing local documentation in IREx

Export site documentation from IREx

Submit "site additions" to sIRB eIRB system

Upload PSite approvals to IREx





Pros & Cons of Decentralized Model



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MEDICAL
CENTER

Pros

- Flexible HRPP staffing based on the study and number of sites
- Minimize coordination efforts of HRPP staff
- Lead study team is a familiar point of contact for sites
- Lead study team is a familiar contact for the IRB



Cons

- New responsibilities lead study teams with limited resources
- sIRB learning curve is steep for lead study teams, who may only do this once



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Leveraging IREx to Support sIRB Coordination

A freely available online tool to manage sIRB requirements and streamline communication for the life of a study.





Key Features



Customize sIRB preferences

(Required agreements, POCs, new - instructions for sites)*

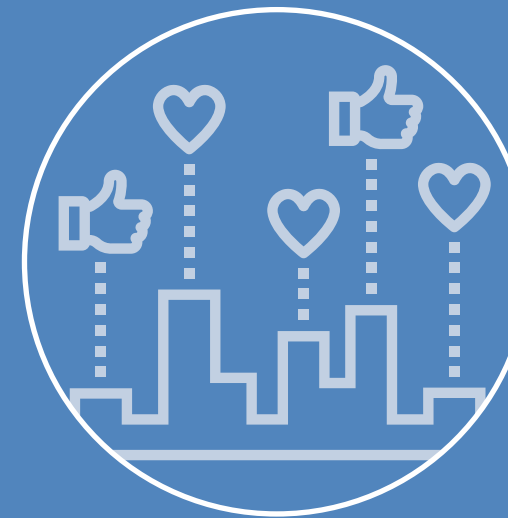


Delegate responsibilities to Lead Study Team



Capture reliance decisions

(Including use of IAAs and indemnification)



Capture local considerations

(Coming soon – update for the life of the study)



Capture approvals for life of study





Coordination Challenges & IREx Solutions

Coordinating Communications

Understanding the sIRB process & steps

Multiple FWAs engaged for a single study team

Capturing & tracking documentation

Capturing & disseminating approvals

General support

Q Search:

Site	Agreements	Reliance Decision ?	Local Considerations	Approval Status
Anderson Medical Center	1 / 3 Agreements Complete			Notify & Grant Access
Central Ohio Medical Center	<ul style="list-style-type: none"> ✓ Reliance Agreement SMART 2 ✗ Indemnification ACTS LOI Update ✗ IREx Access ? 			Notify & Grant Access
Faraday Institute of Research, Science and Technology				Contacted 4/13/2023

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

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.

Field	Value
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,





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Reviewing IRB

GETTING STARTED

- ✓ Create Study
- ✓ Complete IREx Setup
- ✓ Confirm Primary Study Contacts
- ✓ Confirm SSRP
- ✓ Upload Overall Study Approval

➔ Publish Approval

IREx Study Manager

GETTING STARTED

- ✓ Add Participating Sites
- ✓ Request Agreements
- ✓ Grant Site Access
- ✓ View Site Progress on Status Summary

☁ Upload Relying Site Approval

Relying Site HRPP

GETTING STARTED

- ✓ Register
- ✓ Complete Agreements
- ✓ Confirm Institutional Profile
- ✓ Indicate Reliance
- ✓ Complete HRP Survey
- ✓ Review PI Survey (optional)

✎ Add / Edit Study Team Access

⌚ Awaiting Reviewing IRB Approval

Investigator

GETTING STARTED

- ✓ Complete/Attest to PI Survey
- ✎ Add / Edit Study Team Access
- ⌚ Awaiting Reviewing IRB Approval

Study Team Member

GETTING STARTED

- ✓ Start PI Survey for Carnegie U Med Ctr
- ✓ Awaiting PI Attestation for Carnegie U Med Ctr
- ✎ Add / Edit Study Team Access
- ⌚ Awaiting Reviewing IRB Approval





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Institution	Granted Access	PI (required)	Study Team Member	
Emory University #00005792 Grady Memorial Hospital Corporation dba Grady Health System #00004534	✓			Contacts Email

Status Summary

Closed Sites

Manage Agreements

Export Data

Search:

Site	Agreements	Reliance Decision ?	Local Considerations	Approval Status
Emory University Grady Hlth Sys	3 / 3 Agreements Complete	Completed 10/19/2023	3 / 3 Surveys Complete	Not Approved
Grady Memorial Hospital Corporation dba Grady Health System Emory University	3 / 3 Agreements Complete	Completed 11/16/2023	2 / 3 Surveys Complete	Not Approved





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UNIVERSITY OF UTAH

29 Managing You are managing 29 studies

0 Participant You are participating in 0 studies

Home

Study Manager Dashboard

Q Search: tri

Study Title	Sites	Signed Agreements	Reliance	Local Consid.	Current Approvals	Expires
Dexmedetomidine Opioid Sparing Effect in Mechanically Ventilated Children (DOSE Trial) Project ID: 159	21 / 21 Registered	SMART IRB 21 Indemn. 21 IREx 21	21	21	21 8/27/2020	4/15/2021
NIDA CTN Protocol 0109: Randomized, Placebo-Controlled Trial of Extended-Release Naltrexone and Monthly Extended-Release Buprenorphine for Cocaine Use Disorder (CURB-2) Project ID: 596	12 / 12 Registered	SMART IRB 11 IREx 12	12	12	12	6/26/2023
The Effect of Higher Protein Dosing in Critically Ill Patients: A Multicenter Registry-based Randomized Trial The EFFORT Trial Project ID: 51	10 / 12 Registered	SMART IRB 11 Indemn. 10 IREx 12	8	8		
Pharmacokinetics of Sedatives - Understanding a Modifiable Risk Factor for Pediatric Delirium Project ID: 229	3 / 3 Registered	SMART IRB 3 IREx 3	3	3		

Showing 1 to 4 of 4 entries (filtered from 29 total entries)

Site	Agreements	Reliance Decision	Local Considerations	Approval Status
	3 / 3 Agreements Complete	Completed 10/19/2023	3 / 3 Surveys Complete	Not Approved
	3 / 3 Agreements Complete	Completed 11/16/2023	2 / 3 Surveys Complete	Not Approved
	3 / 3 Agreements Complete	Contacted 6/24/2022		
	3 / 3 Agreements Complete	Completed 8/4/2022	2 / 3 Surveys Complete	Not Approved
	3 / 3 Agreements Complete	Completed 3/23/2022	2 / 3 Surveys Complete	Not Approved
	3 / 3 Agreements Complete	Completed 2/28/2023	3 / 3 Surveys Complete	Approved
	3 / 3 Agreements Complete	Completed 9/19/2022	3 / 3 Surveys Complete	Not Approved
	3 / 3 Agreements Complete	Completed 5/18/2023	3 / 3 Surveys Complete	Approved
University of Miami	3 / 3 Agreements Complete	Completed 5/18/2023	3 / 3 Surveys Complete	Approved





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Protocol Version: 5.0			
✓ Continuing Review: Full Board (approved 10/1/2023)	1	Current	
✓ Study-Wide Amendment: Full Board (approved 8/30/2023)	2	Archived	
Protocol Version: 4.0			
✓ Study-Wide Amendment: Expedited #17 change summary (approved 5/30/2023)		Archived	
✓ Continuing Review: Full Board (approved 5/17/2023)		Archived	
✓ Site Amendment: Full Board #2 change summary (approved 3/16/2023)	3	Archived	
✓ Site Amendment: Full Board #2 change summary (approved 3/16/2023)		Archived	
✓ Study-Wide Amendment: Full Board change summary (approved 11/12/2022)		Archived	
Protocol Version: 3.0			
✓ Study-Wide Amendment: Full Board #15 change summary (approved 9/22/2022)		Archived	
Protocol Version: 2.0			
✓ Initial Study: Full Board (approved 8/10/2022)	4	Archived	



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General support

THE IREX TEAM

- Admin@IRBExchange.org available anytime
- Training for lead study teams provide 2x month, and PRN
- Training for relying study teams (e.g., IREx can attend site coordinator call)
- Videos & user guides
- Study-specific tips sent to lead study teams as sites onboard to the study & the sIRB process





IREx: By the numbers

591 Studies

44 sIRBs using IREx

513 Member institutions

780 Study Managers (lead study team/ CCC)

430 Unique sites relying on an sIRB

3700 Reliances documented

2914 Relying sites w/ initial sIRB approval

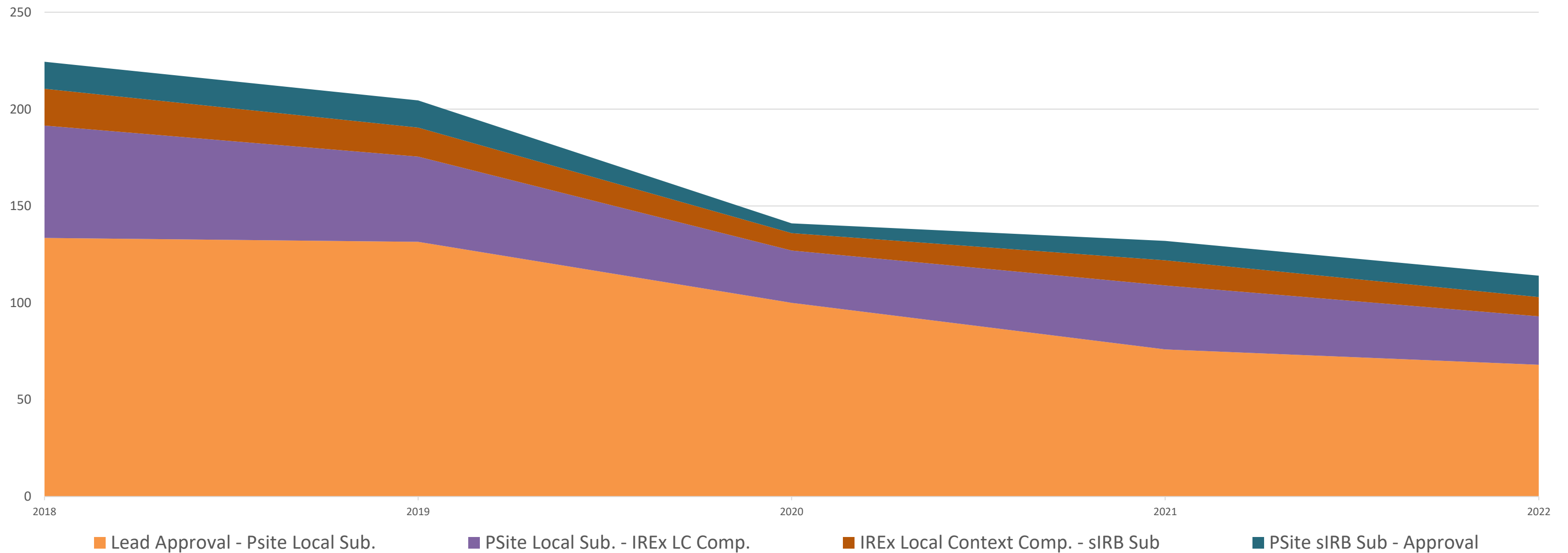
22K+ Site approvals posted to IREx



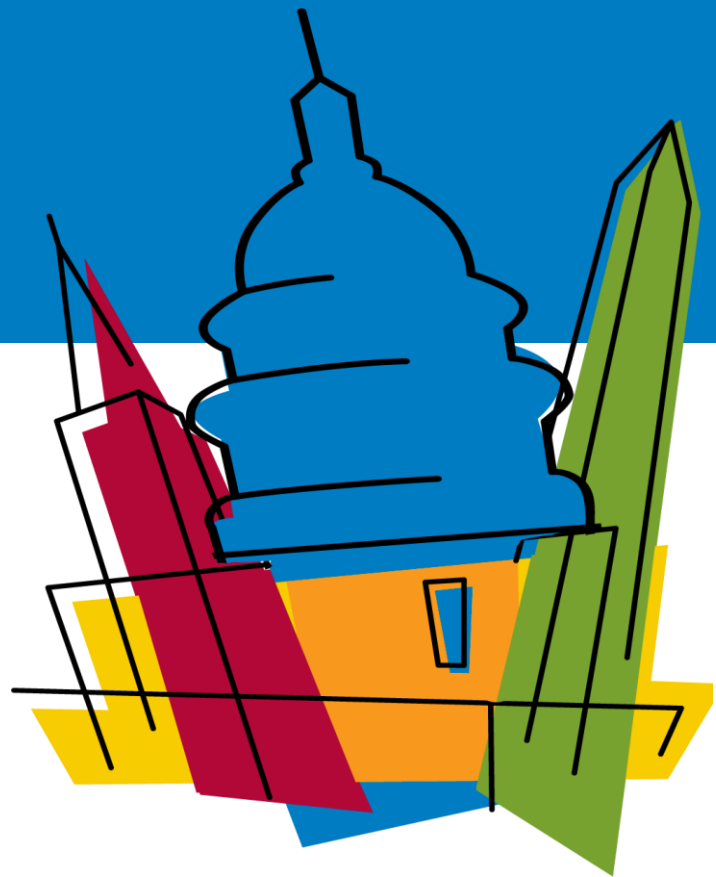


Median Time from Lead Site Approval to PSite Approval by the sIRB

PSite sIRB Review Process, by Year Study was Created



Questions?



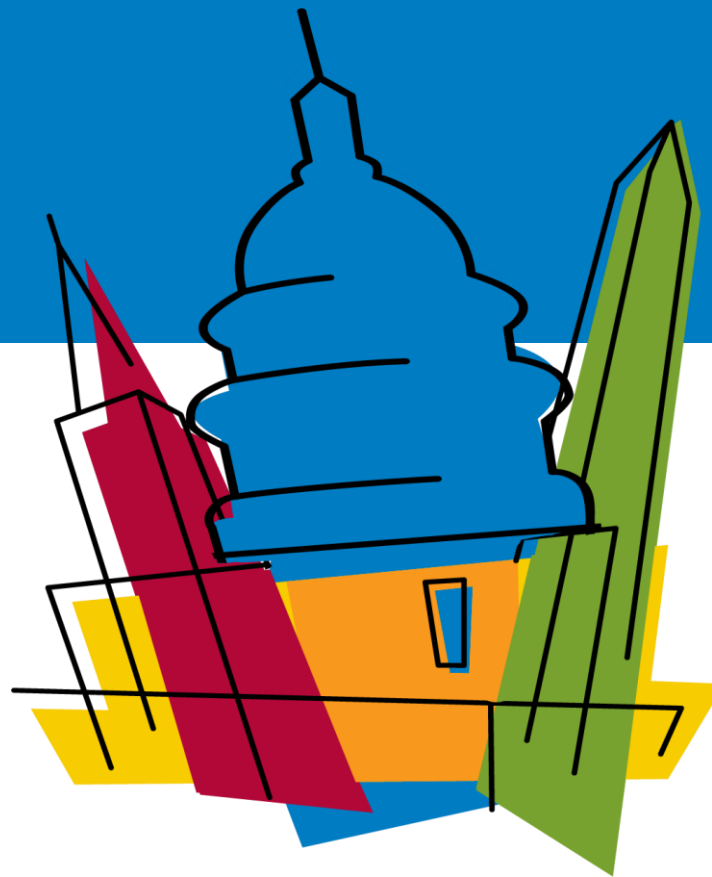
PRIM&R PUBLIC RESPONSIBILITY IN
MEDICINE AND RESEARCH

Contact Information

Annie Risenmay: annie.risenmay@hsc.utah.edu

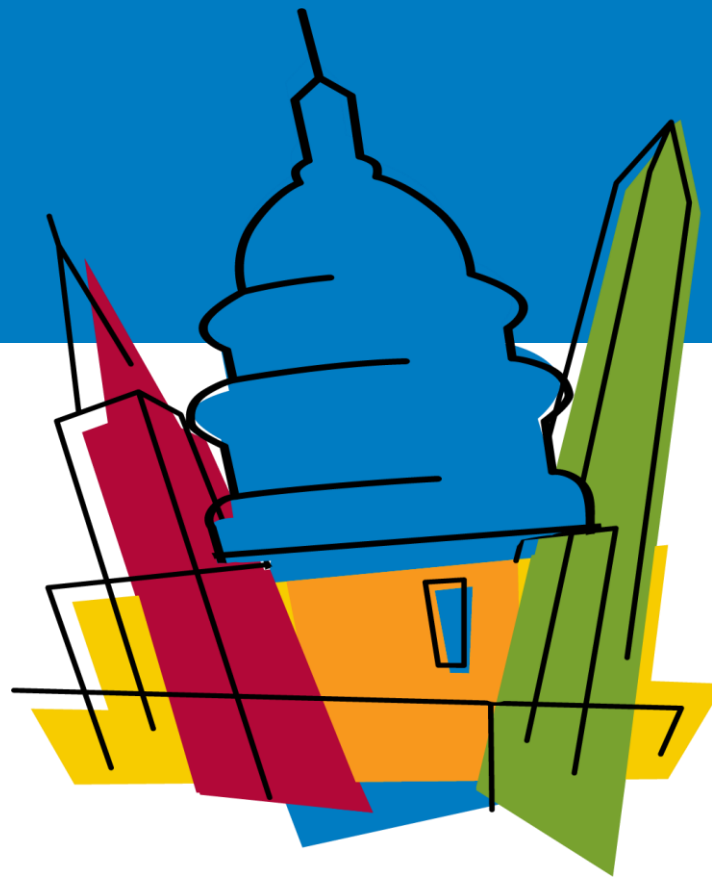
Emily Serdoz: emily.serdoz@vumc.org

Amy Trullinger: ajtrull@iupui.edu



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Thank You!



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