PRIM&R AER 2023

Single IRB Coordination Models: Innovative Approaches from Four CTSAs

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

PRIM&R

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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

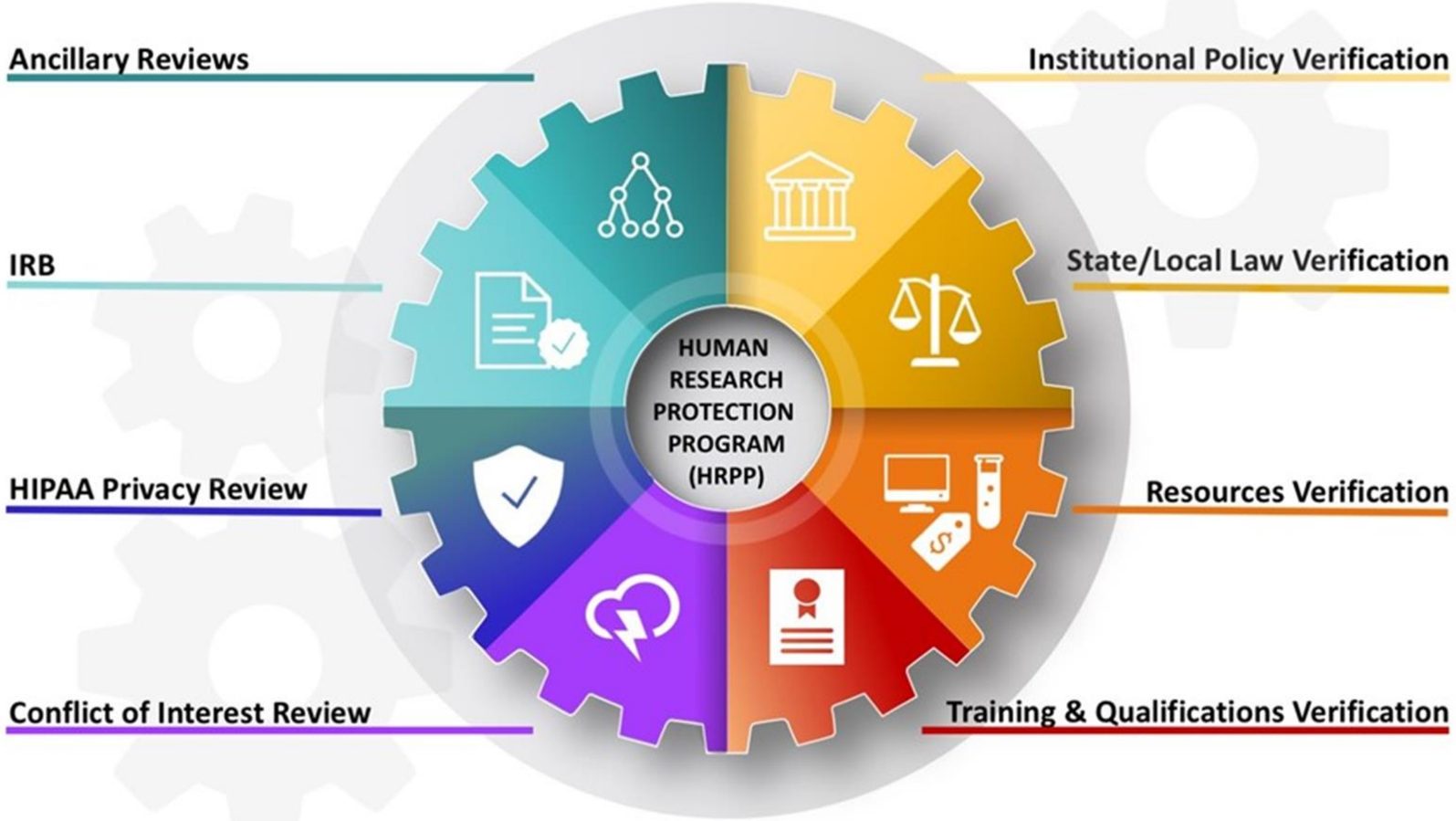
- Introduction
- Models
  - Indiana CTSI/Indiana University HRPP: liaison model
  - University of Utah HRPP: multiple/hybrid models
  - Wake Forest School of Medicine CTSI: decentralized model
  - Vanderbilt University Medical Center: decentralized model
- Leveraging the IRB Reliance Exchange (IREx)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



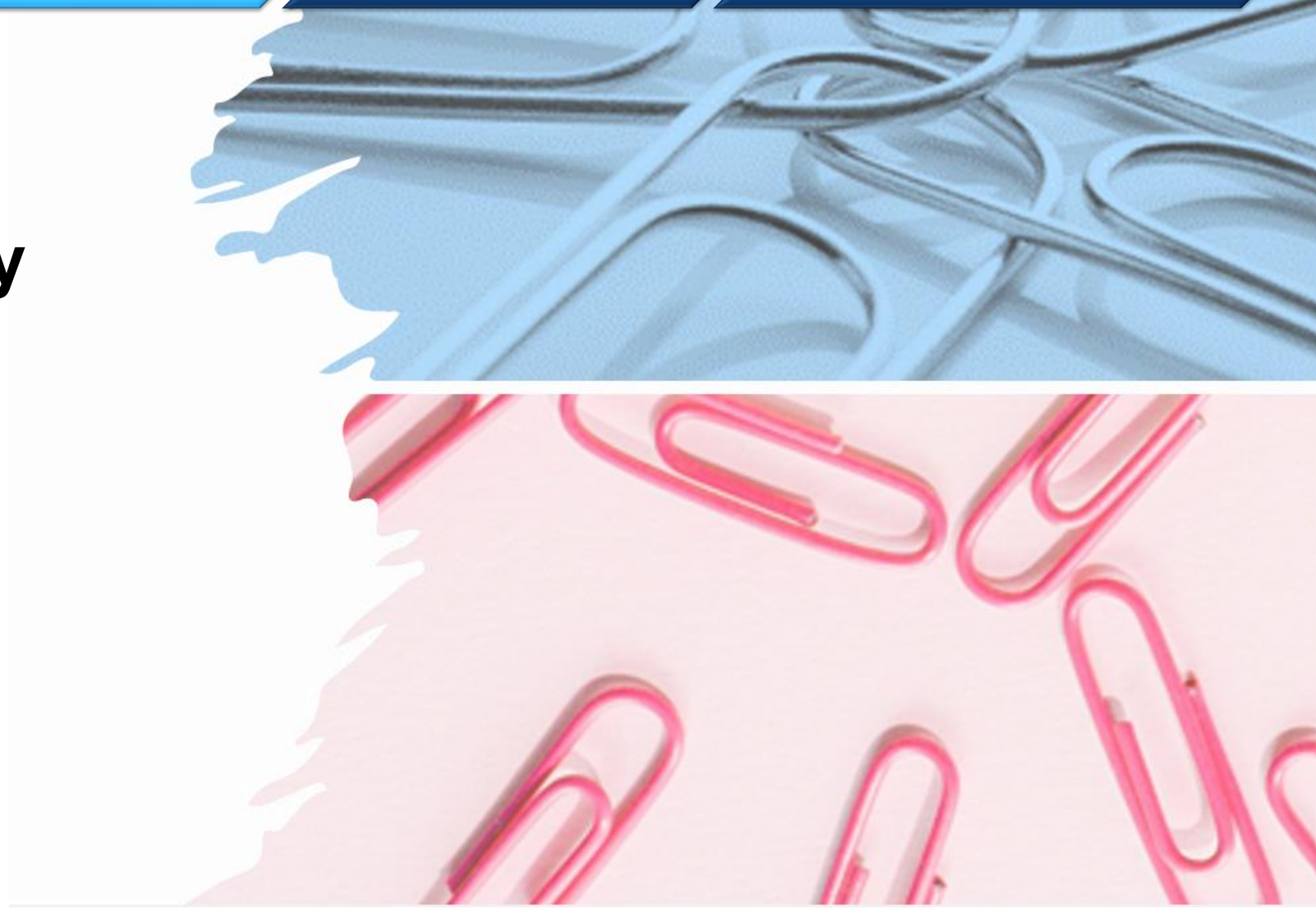
Why sIRB Coordination?

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

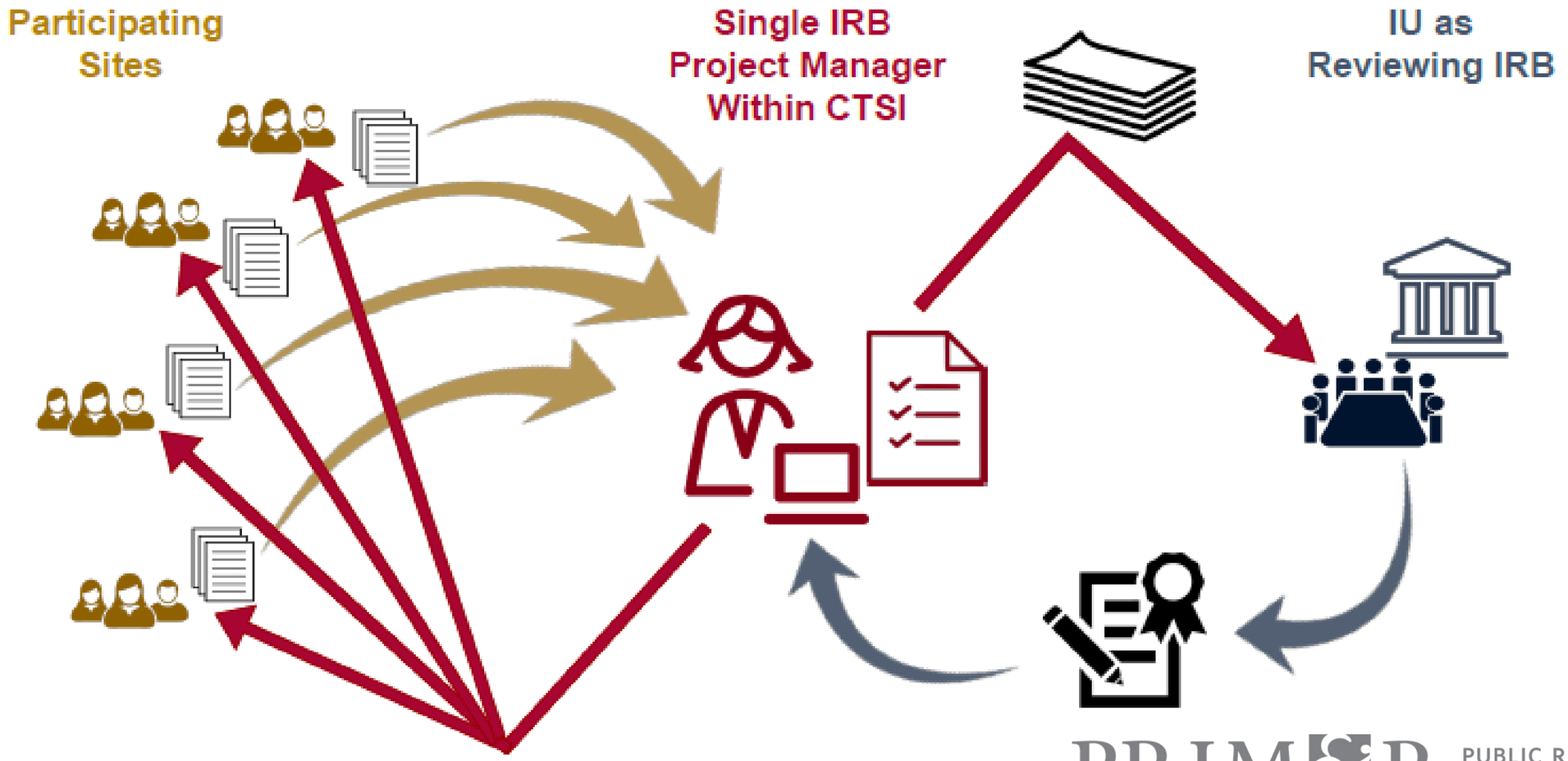
- Coordinating IRB submissions and site additions when an academic IRB serves as the sIRB for a multisite study
- Differing IRB and institutional policies and processes
- Closed or unfamiliar IRB systems for external sites

Indiana University

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



Liaison Model



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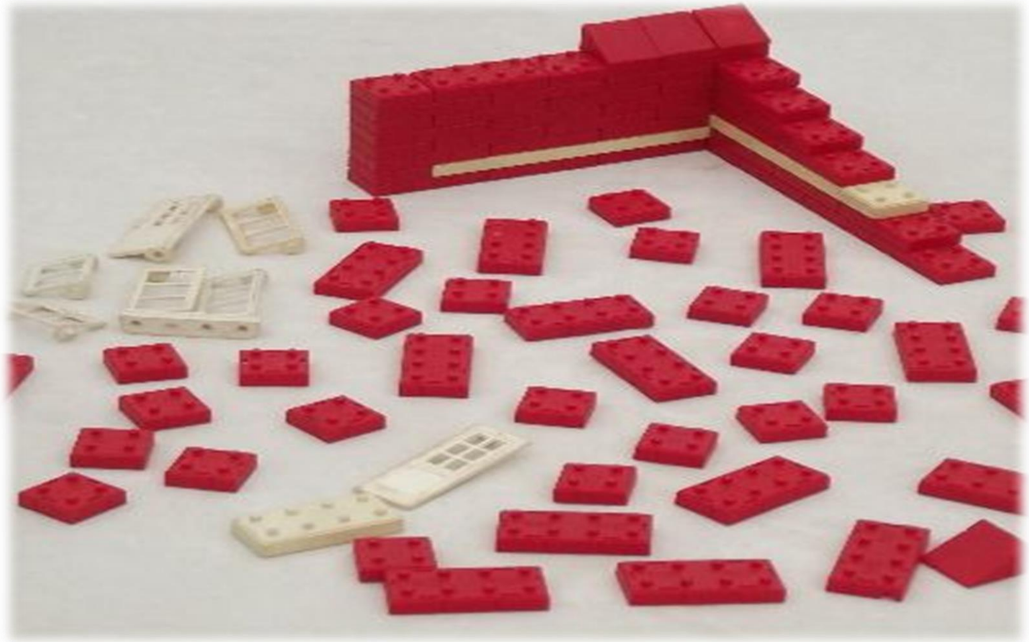
Delineation of Duties



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

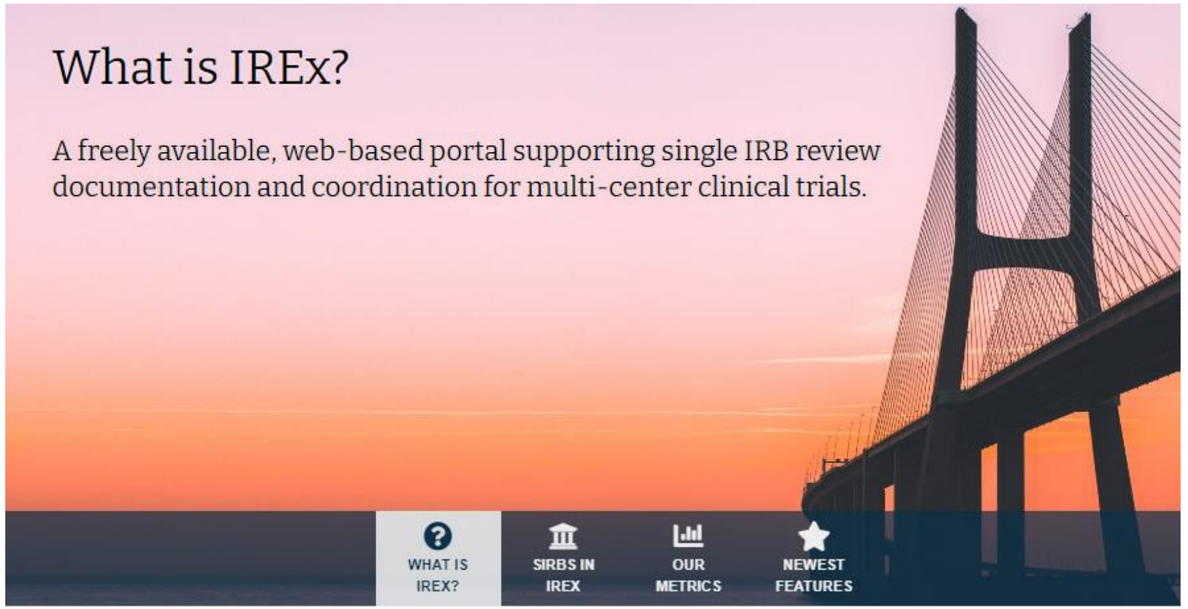
- Introduction of people on call
- Overview of the study
- Explain reliance process
- Discuss initial email
- Explore attached documents

Tools: SMART IRB and IREx

SMART IRB

Supporting single IRB review
Advancing collaborative research

IREx IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW



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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

IREx IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

RELYING SITE HRPP

Reliance Documentation

SITE STUDY TEAM

Local Requirements

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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

IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

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*

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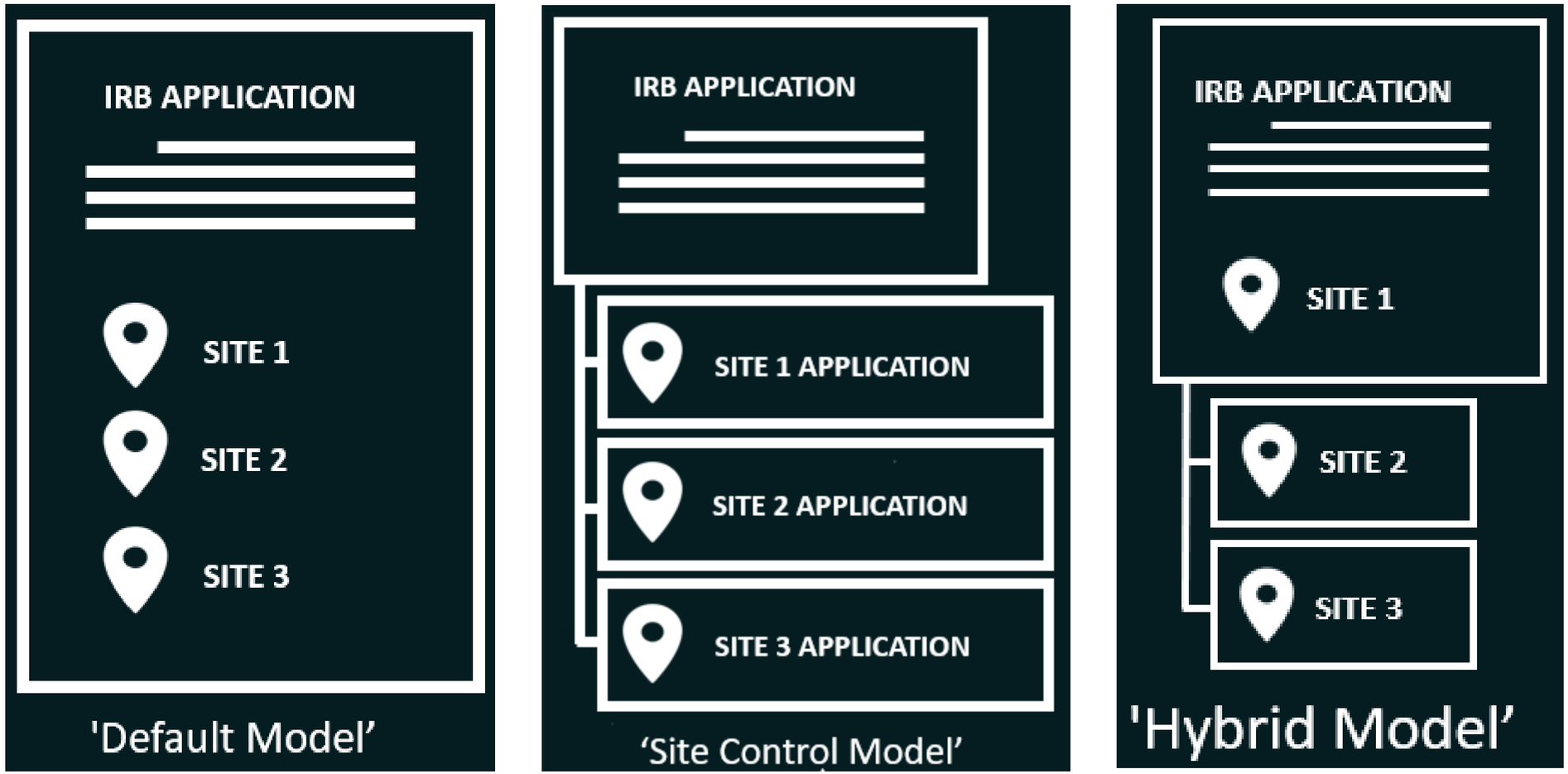
Submission Models



Standard/Default Model

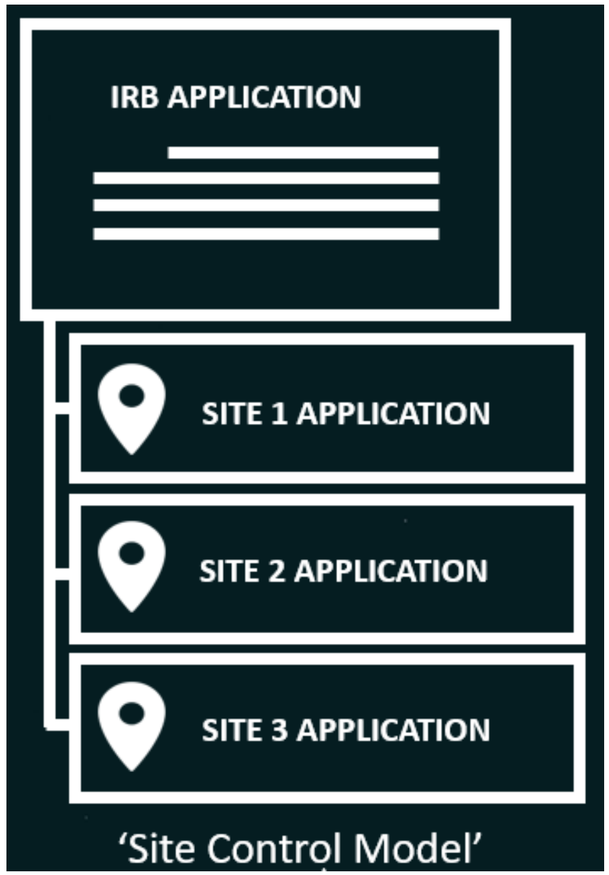
Pros

- 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

Decentralized Model Division of Responsibilities

Single IRB	Lead Study Team
Create & oversee sIRB intake process & requests	Add participating sites (PSites) to IREx
Provide resources & educational materials for study teams	Request PSites executed required agreements via IREx, as needed
Review & approval study	Grant PSite study team access to study in IREx
Create study in IREx	Monitor PSite progress completing local documentation in IREx
Oversee flexible elements of reliance in IREx	Export site documentation from IREx
Document executed IAAs and indemnification in IREx, if required	Submit “site additions” to sIRB eIRB system
	Upload PSite approvals to IREx

Pros & Cons of Decentralized Model

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

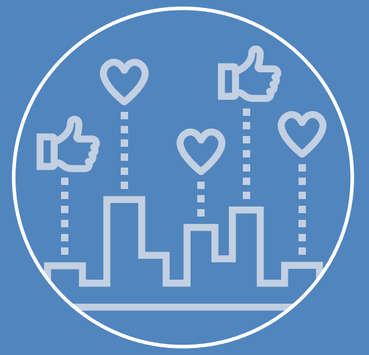
Customize sIRB preferences

*(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

Automated tracking of site progress and email communications

Coordination Challenges & IREx Solutions

Coordinating Communications

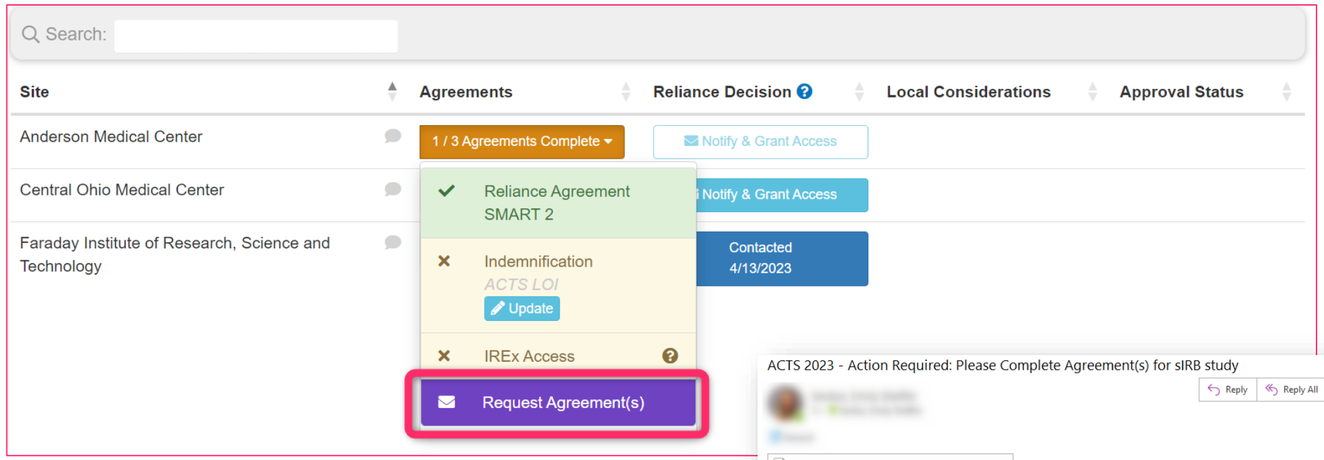
Understanding the sIRB process & steps

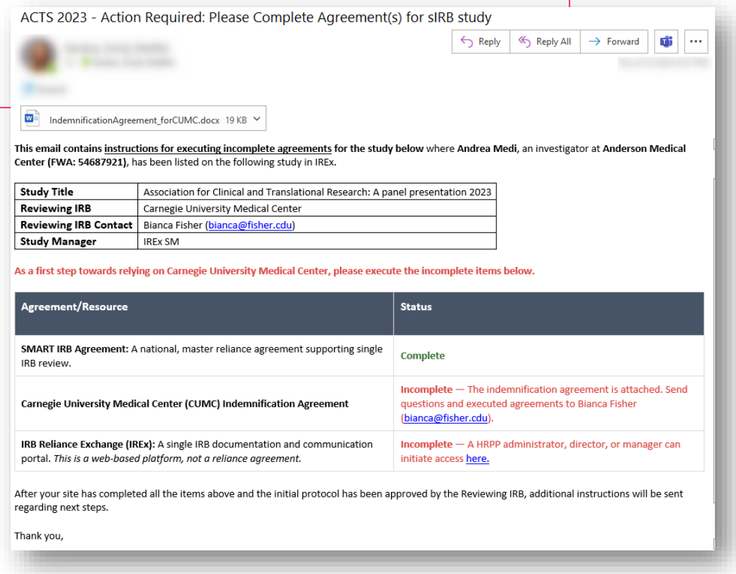
Multiple FWAs engaged for a single study team

Capturing & tracking documentation

Capturing & disseminating approvals

General support




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

Reply | Reply All | Forward

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.

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,

Coordination Challenges & IREx Solutions

- Coordinating Communications
- **Understanding the sIRB process & steps**
- Multiple FWAs engaged for a single study team
- Capturing documentation
- Capturing & disseminating approvals
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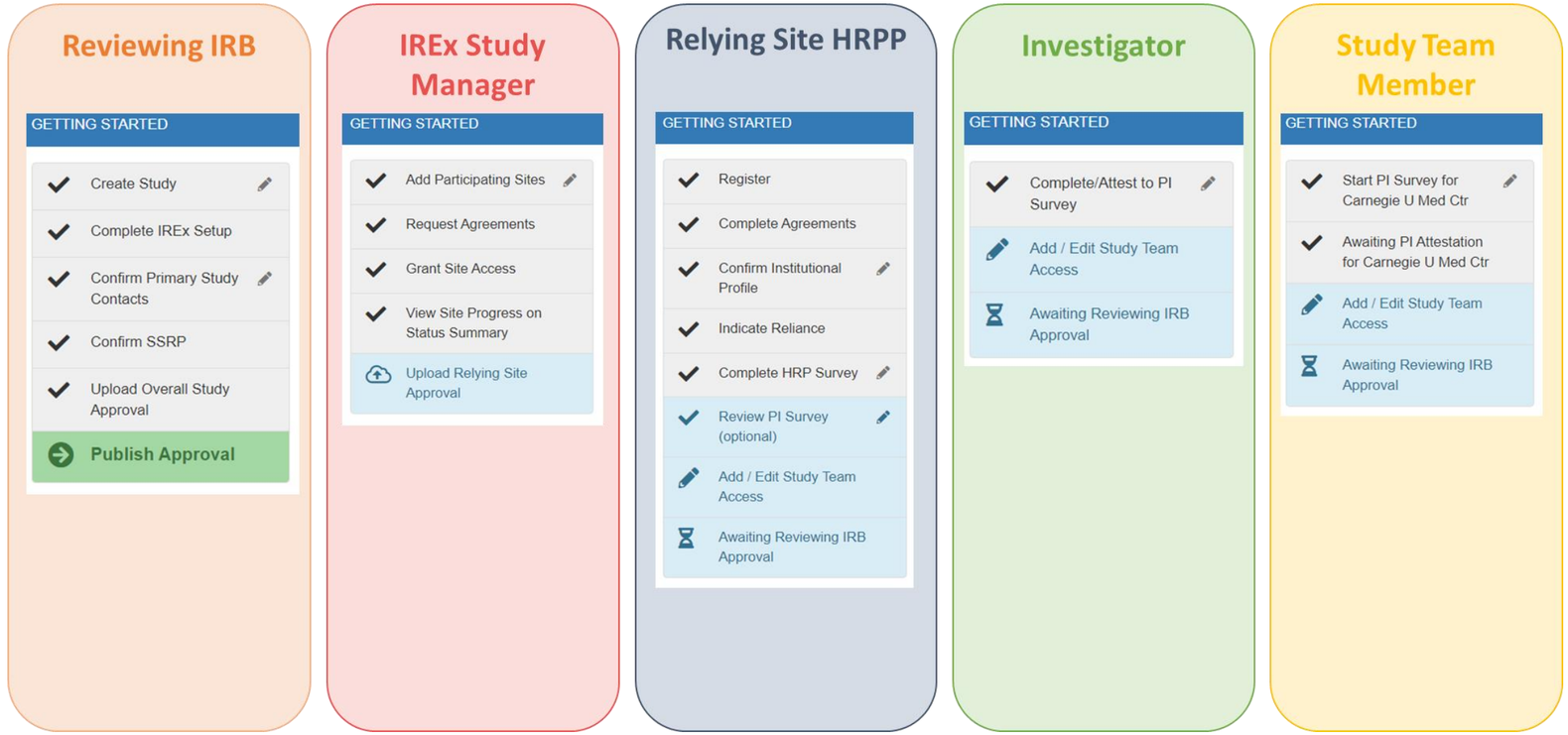

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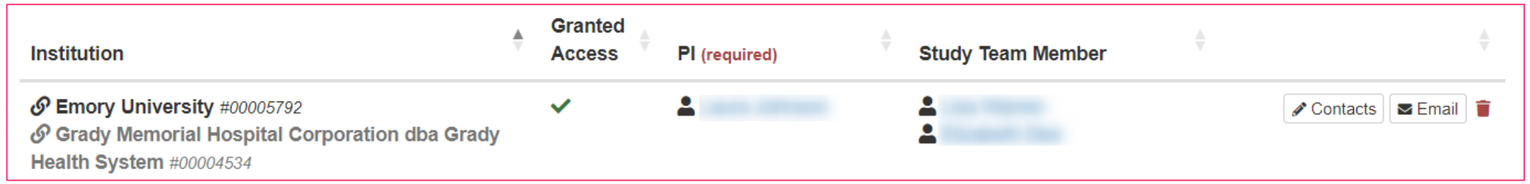

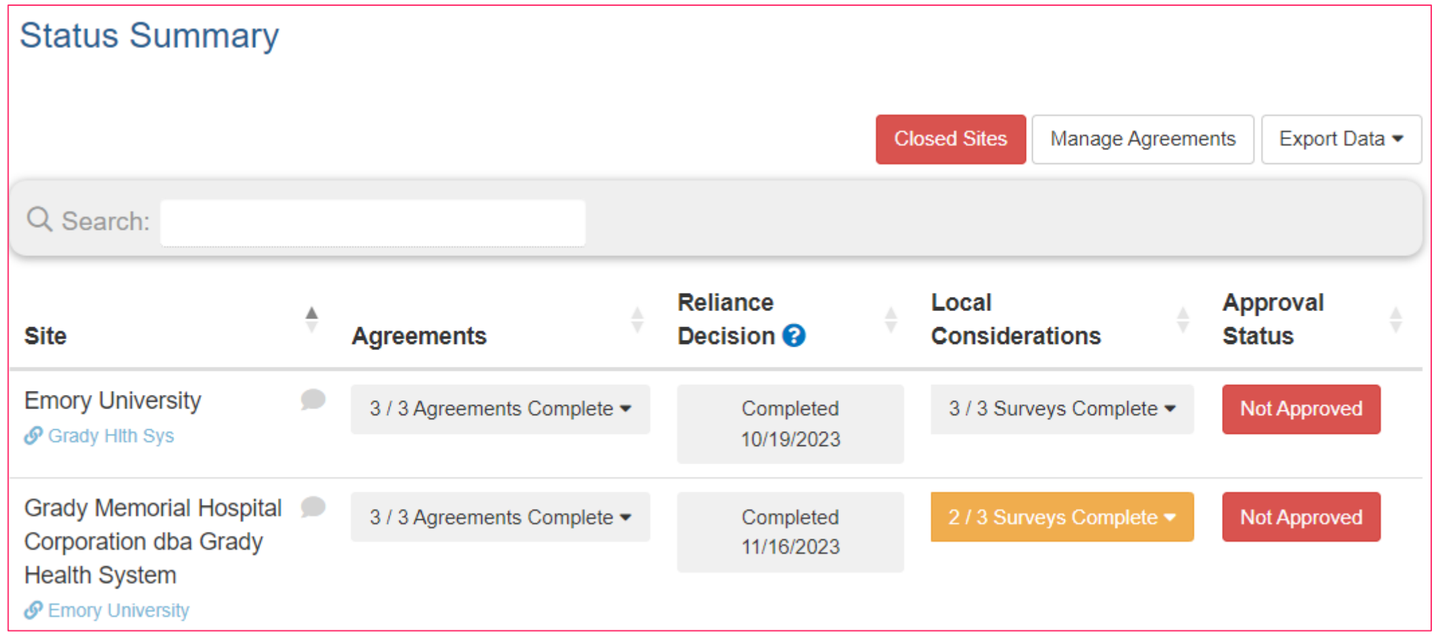

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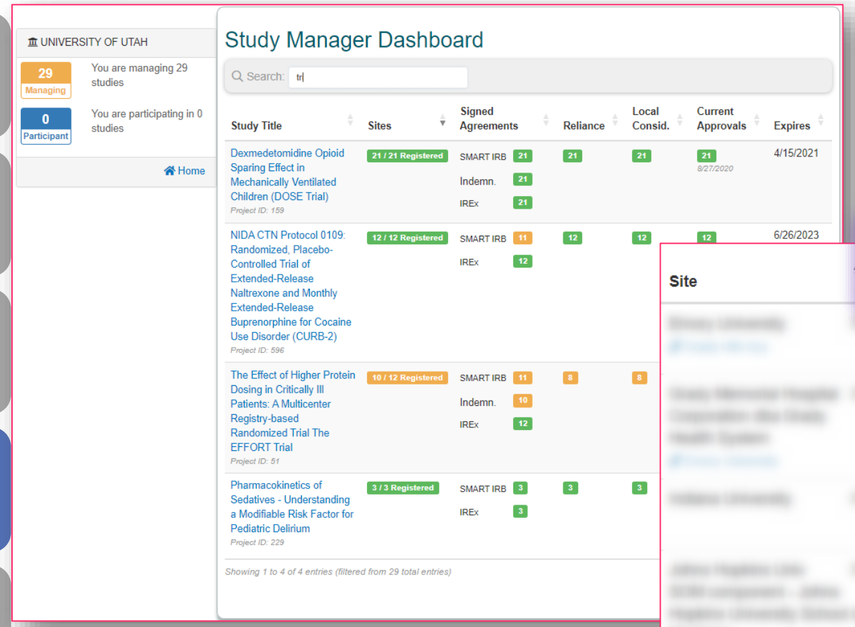

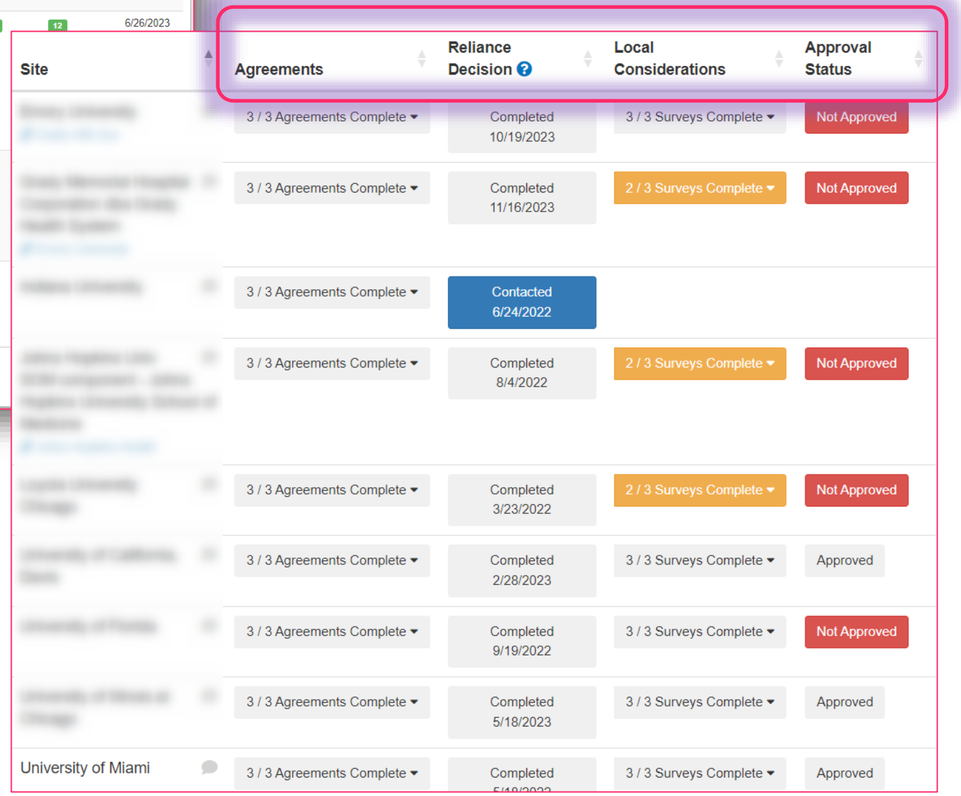

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Coordination Challenges & IREx Solutions

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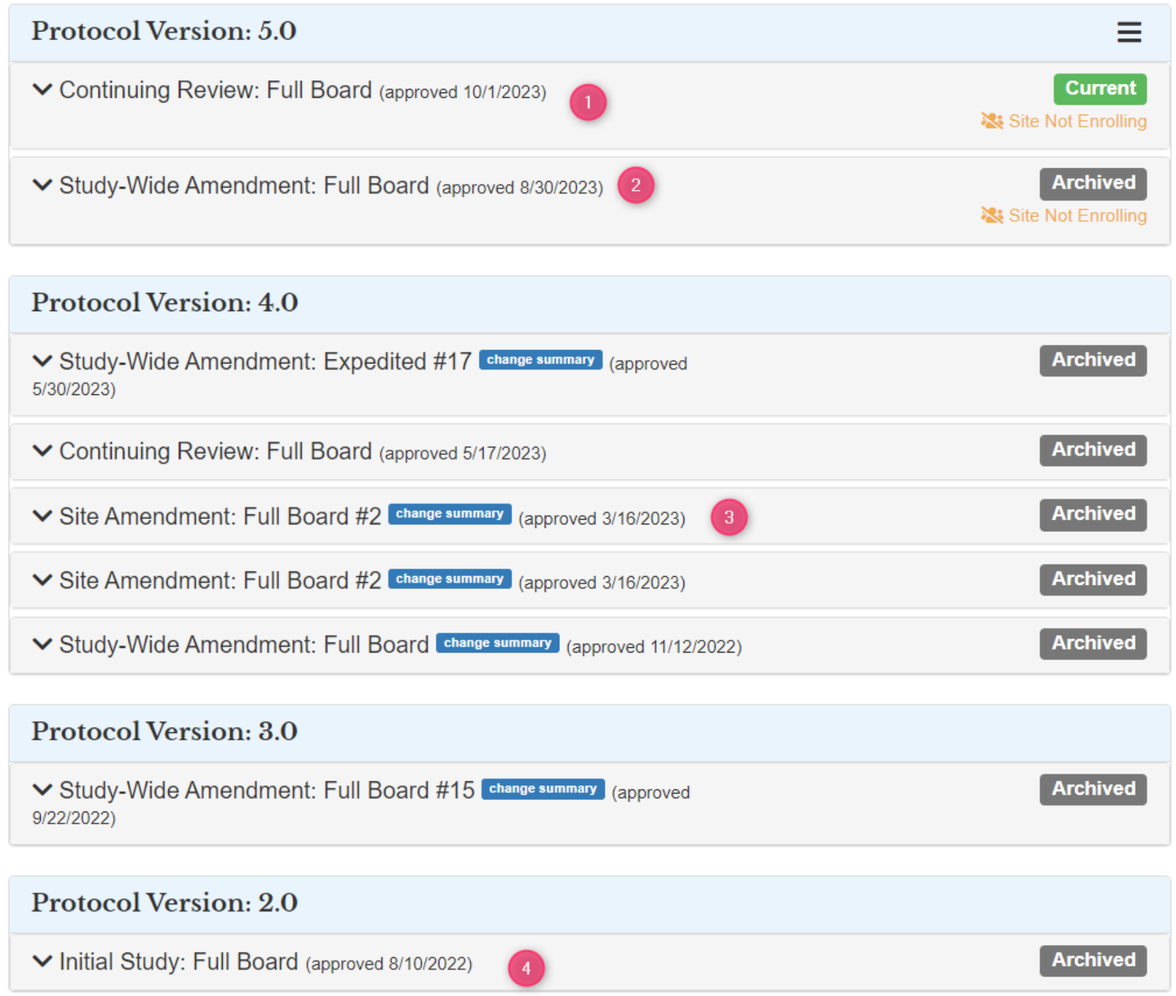

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- **General support**

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)

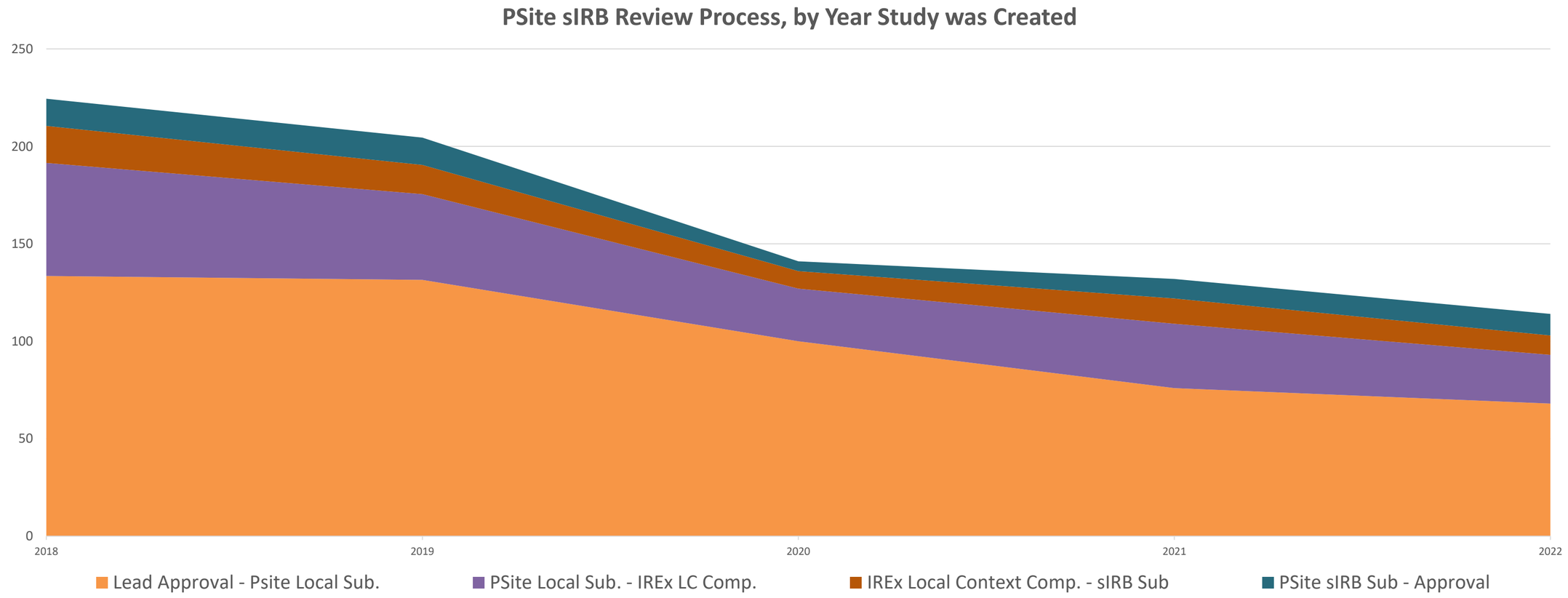
430 Unique sites relying on an sIRB

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



Questions?

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Contact Information

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Amy Trullinger: ajtrull@iupui.edu

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Thank You!

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