



## SMART TALK

A Community Forum to Explore  
Issues Surrounding Single IRB  
Review

This project has been funded in whole or in part with Federal funds from the National Center for Advancing Translational Sciences, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N950C00008.

# FYI

Questions are welcome! Please post these under 'Q/A'

Discussion with fellow attendees should be posted under 'Chat'

A link to today's recording will be emailed to attendees. A recording will be posted on the SMART IRB website

Your feedback is valued! Please complete the survey at the end of the SMART Talk! The survey will be emailed as well.

# What Is SMART IRB?



## **SMART IRB is...**

A federally funded project to support institutions and researchers in the implementation of single IRB



## **SMART IRB provides...**

An IRB reliance agreement  
An Online Reliance System to initiate and track reliance  
Zero Cost Education, Guidance, and Resources



## **SMART IRB is NOT...**

An IRB  
An electronic system for Reviewing IRBs to receive studies for review

# Reach out to a SMART IRB Ambassador



Aaron Kirby  
*Harvard Catalyst*



Polly Goodman  
*Harvard Catalyst*



Jeremy Lavigne  
*Harvard Catalyst*



Ada Sue Selwitz  
*University of  
Kentucky*



Carissa Minder  
*Washington  
University in St. Louis*



Kathy Lawry  
*AAHRPP*



Nichelle Cobb  
*AAHRPP*



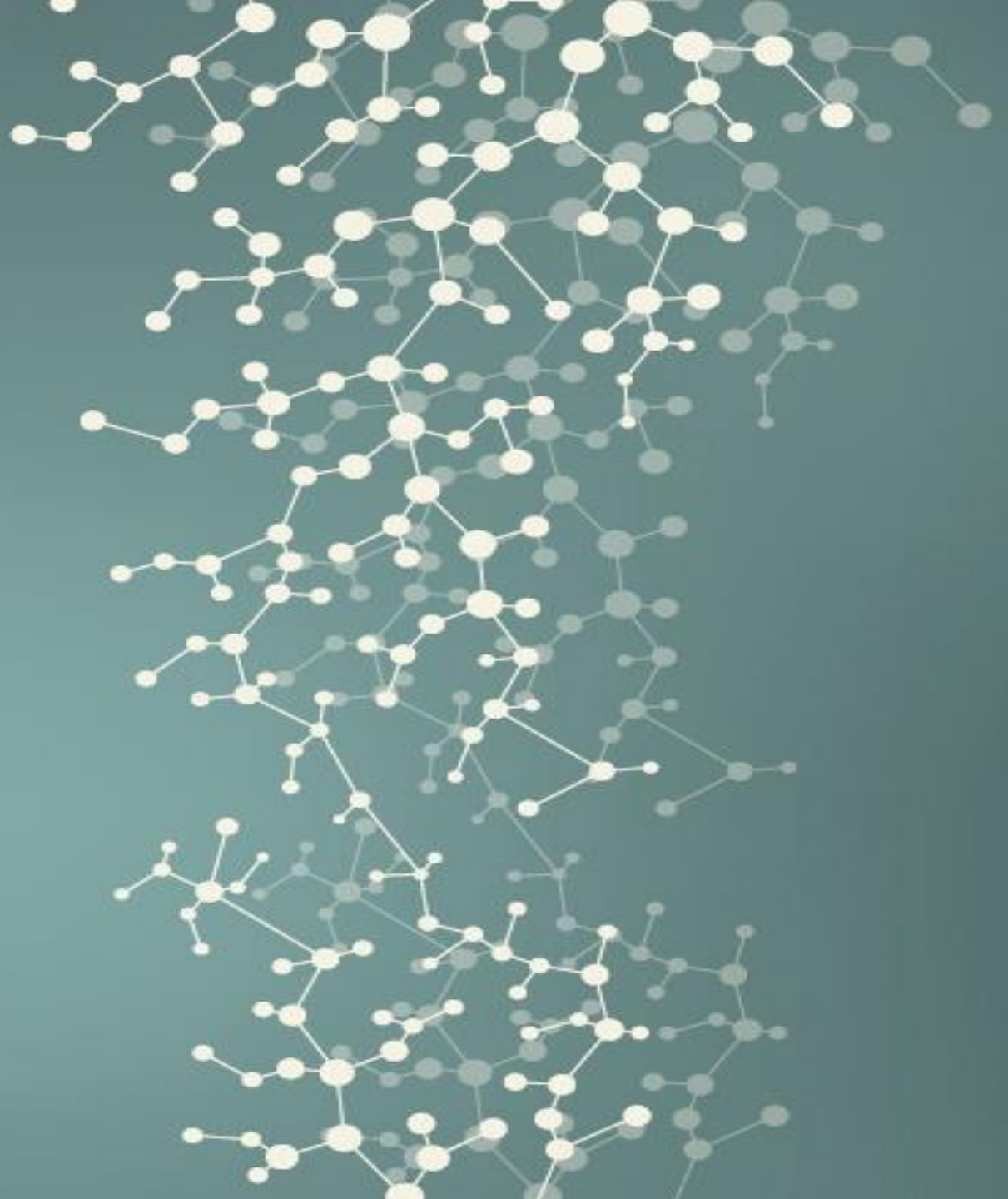
Stacey Goretzka



Lubabah Helwani

Find your SMART IRB  
Ambassador Today:  
[www.smartirb.org](http://www.smartirb.org)

# Upcoming Events





Join Us! SMART Talk (April 16, 2025, 2-3:30pm ET)

# How Shall I Staff for Single IRB? Let Me Count the Ways...Exploring Models of Reliance Staffing

Moderator:

**Nichelle Cobb**, SMART IRB Ambassador At Large + Senior Advisor

Panelists:

**Angela Braggs-Brown**, Senior Director, Human Research Protection Program, University of Cincinnati

**Malica Dock**, IRB Reliance Assistant Director, Rutgers IRB

**Leslie Howes**, Director, Office of Regulatory Affairs and Research Compliance, Harvard T.H. Chan School of Public Health

[SMARTIRB.org](https://SMARTIRB.org)

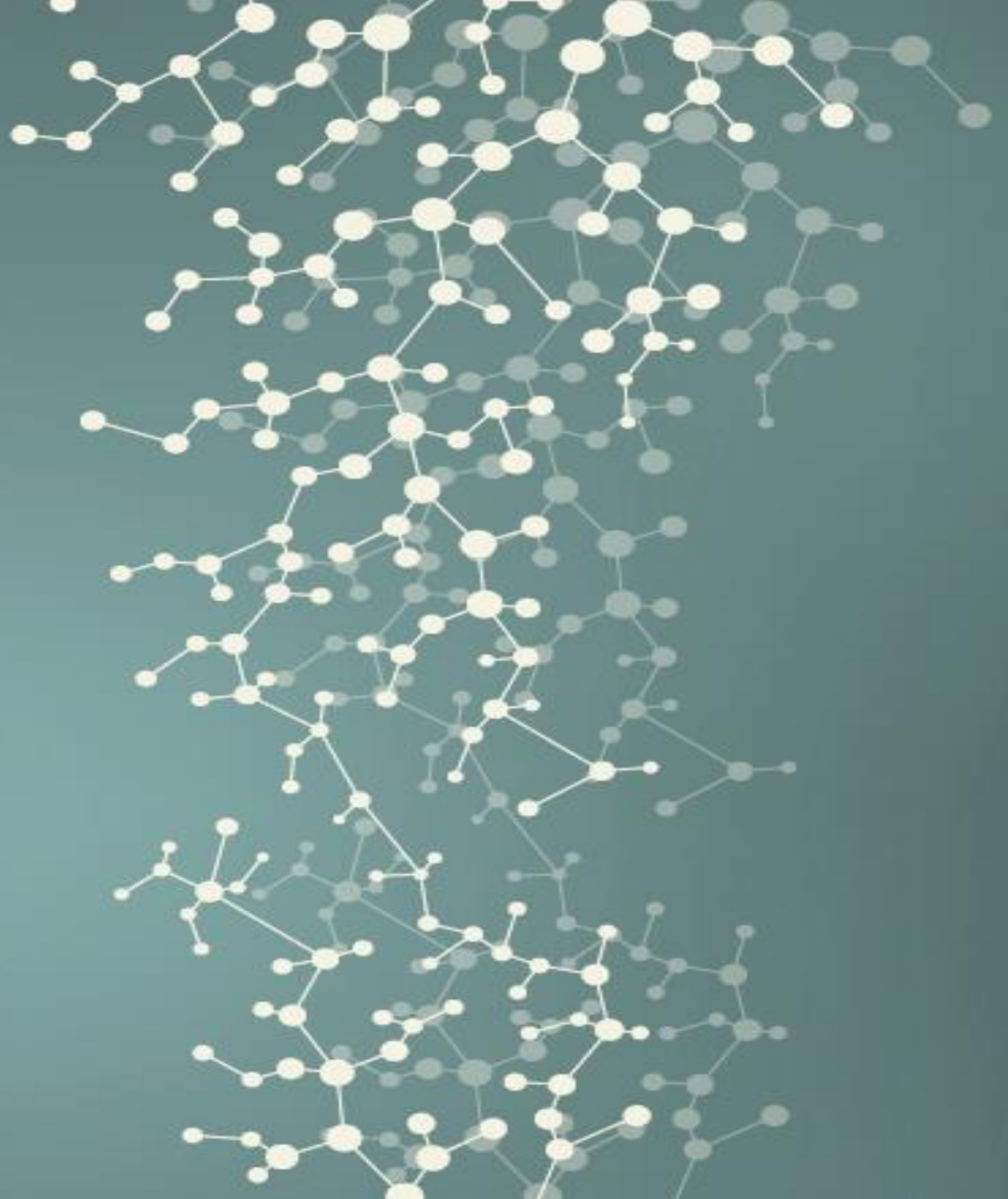
# SMART IRB Office Hours

Next Session April 2 at 2pm ET

Registration Now Open!



**SMART IRB Version 3.0**  
**Launch: Week 1**  
**Retrospective**





# 3/17/25 - V3.0 Agreement, Reliance System & Website Go Live

## SMART IRB Agreement V3.0 & Indemnification Addendum

- V3.0 Agreement must be signed for any new reliance arrangement
- Indemnification Addendum is optional

## New SMARTIRB.org website

- New agreement and accompanying resources posted
- New look for the Participating Institutions Page
- Updates resources to reflect V3.0 Agreement

## New Reliance System

- Replaces the previous Joinder and Online Reliance Systems
- Must be used to execute V3.0 Agreement

## Version 3.0 Will Replace 1.0 and 2.0

- Version 3.0 is a significant amendment of the current agreement
- Version 3.0 is not compatible with Versions 1.0 and 2.0
- Version 3.0 is the only option to join and use for new reliance arrangements

Type of Request	SMART IRB Agreement Version(s)
New Reliance Requests, Newly joining institutions, New Site added to an existing reliance request	SMART IRB Agreement V3.0
Legacy Reliance Requests	SMART IRB Agreement V1.0 or V2.0

# Transition to the New Optional SMART IRB Indemnification Addendum

Type of Indemnification Agreement	Scope
Existing Indemnification Agreements	SMART IRB Indemnification Addendum will not supersede any separate indemnification Agreements
SMART IRB Indemnification Addendum	Applies to any requests entered into by two (or more) institutions who are signatories to the SMART IRB indemnification addendum unless a more limited scope is agreed to by the institutions
Other Indemnification Addendums	Will continue to be permitted

# The SMART IRB Reliance System

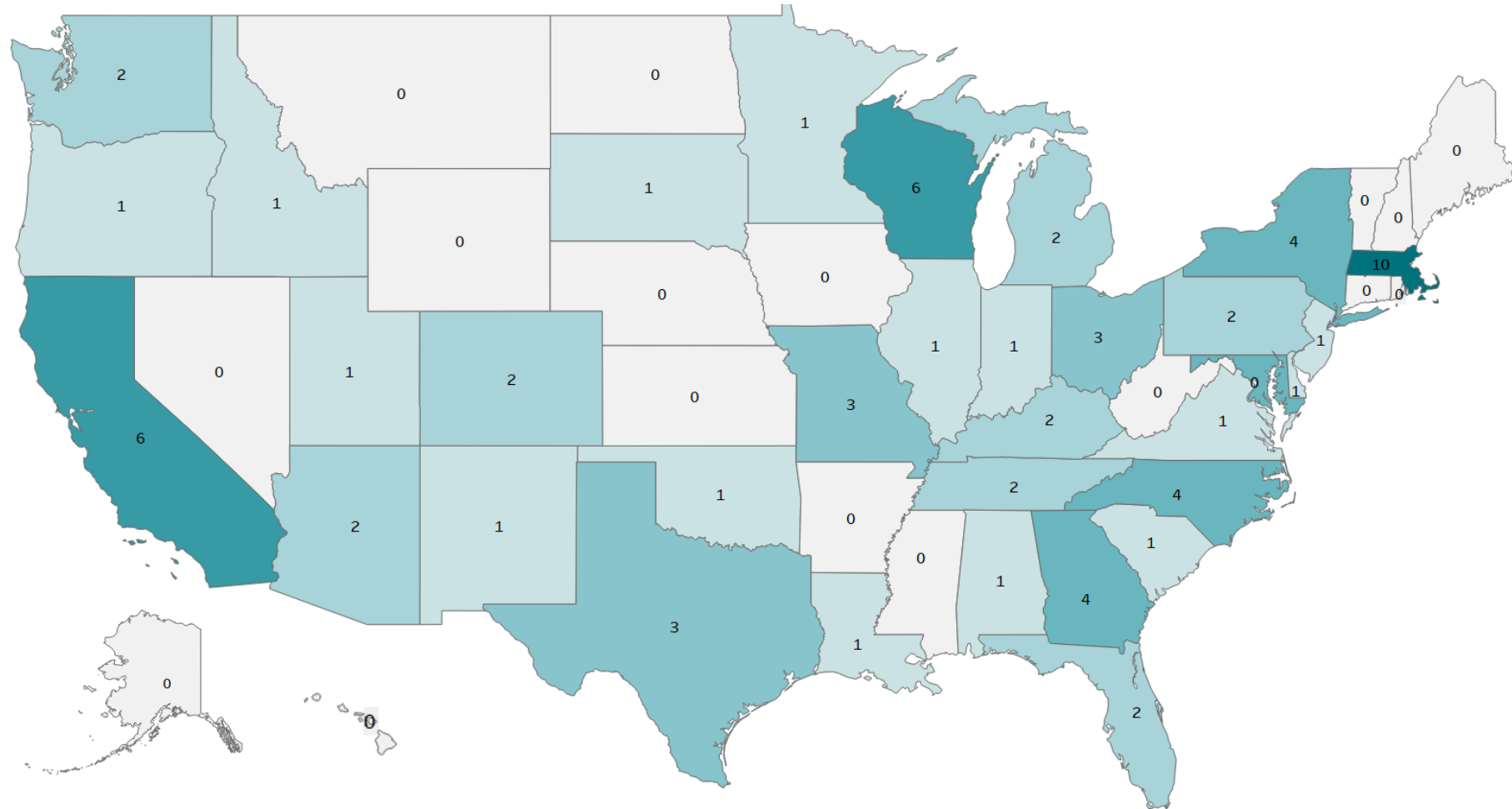
**Your single IRB home, where institutions can:**

- Join SMART IRB Reliance Agreement V3.0
- Create/update institutional profiles
- Manage user permissions
- Request, track, and document reliance arrangements\*
  - \*Institutions must have joined SMART IRB Reliance Agreement V3.0 to be able to request, track, and document any new reliance arrangements.

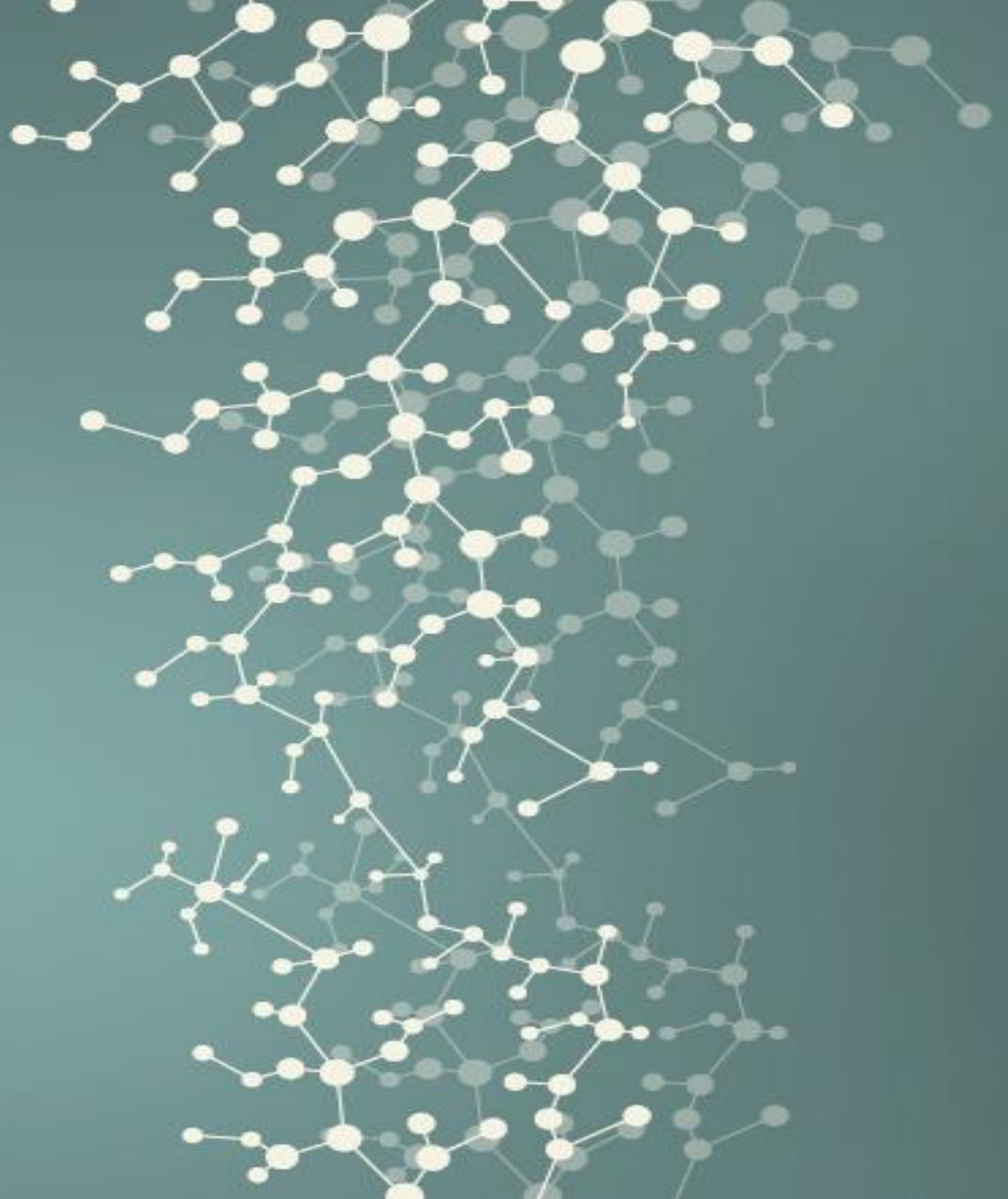
# Ready to Launch: Week 1 Retrospective (3/17-3/21)

78 Institutions across 33 states joined Version 3.0 during week 1!

- NIH: the 1st signatory
- 27 CTSA Hubs
- 50 Universities/AMCs
- 18 Hospital Systems
- 5 Commercial IRBs
- 30 Institutions awaiting signature
- 109 Signatories to date (as of 03/25)!

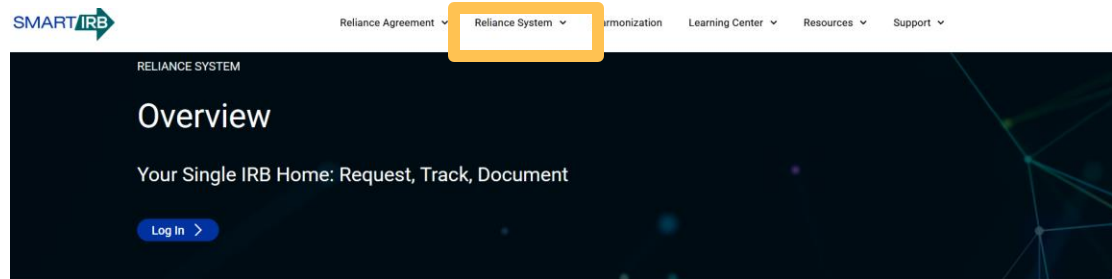


# SMART IRB Resources, User Guides, and More





# Reliance System Overview



## Reliance System Overview

With the SMART IRB Reliance System, seamlessly request, track, and document reliance arrangements with other **Participating Institutions\***.

### Join SMART IRB & Manage Institutional Details

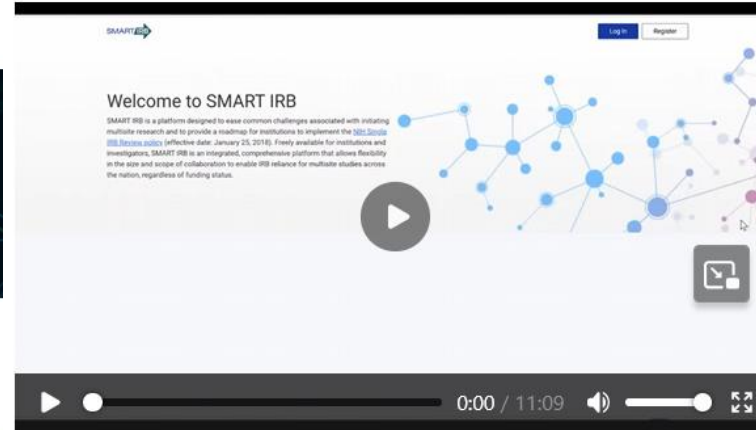
(for Institutional Leadership and IRB/HRPP Administrators/Staff only)

- Join SMART IRB Reliance Agreement V3.0
- Sign the optional Indemnification Addendum
- Manage Institutional Profile(s)
- Establish user permissions
- Access institutional sIRB activity reports

### Request, Track, & Document Single IRB Arrangements

(for Investigators/Study Team Members and IRB/HRPP Administrators/Staff)

- Simplify selection of a single IRB
- Manage communication with institutions & investigators
- Clearly request edits & identify next steps
- Track reliance details for your studies
- Add new sites at any time



[Download Video Transcript](#)

Step-by-step guidance to support Reliance System users.

## Study Teams

Learn how investigators and study team members can centrally request, track, and document reliance arrangements for their studies.

[View Guides >](#)

## Points of Contact (POCs)

Learn how IRB/HRPP administrators or staff and/or institutional leadership can join the SMART IRB Agreement, manage institutional information and user permissions, and track and document their institution's reliance arrangements.

[View Guides >](#)

## Legacy

If your institution has not yet joined SMART IRB Agreement V3.0 (but participates in V1.0 or V2.0), you may use the Reliance System to view arrangements documented in the legacy Online Reliance System, but your institution will not be able to initiate any new requests.

[View Guides >](#)

## Video Chapters

- ▶ [Introduction to the Reliance Request Process \(0:00\)](#)
- ▶ [Who can submit requests \(0:46\)](#)
- ▶ [Creating a New Request \(1:07\)](#)
- ▶ [Adding a New Site to a Request \(3:57\)](#)
- ▶ [Providing Site Details \(5:34\)](#)
- ▶ [Reliance Pre-check \(7:47\)](#)
- ▶ [Reviewing IRB Decision \(8:37\)](#)
- ▶ [Tracking Request Status \(9:07\)](#)
- ▶ [Entering a Site's Reliance Decision \(9:27\)](#)
- ▶ [Issuing Determination Letter \(9:57\)](#)

# User Guides



Reliance Agreement ▾

Reliance System

Harmonization

Learning Center ▾

Resources ▾

Support ▾



RELIANCE SYSTEM

## User Guides

Step-by-step guidance for study teams and POCs

### General Info

Freely available for institutions and investigators, the SMART IRB Reliance System allows institutions to join the SMART IRB Agreement and helps study teams and IRB/HRPP staff work together to seamlessly request, track, and document reliance arrangements with other [Participating Institutions](#).

### User Guides

#### Study Teams

Learn how investigators and study team members can centrally request, track, and document reliance arrangements for their studies.

[View Guides >](#)

#### Points of Contact (POCs)

Learn how IRB/HRPP administrators or staff and/or institutional leadership can join the SMART IRB Agreement, manage institutional information and user permissions, and track and document their institution's reliance arrangements.

[View Guides >](#)

#### Legacy

If your institution has not yet joined SMART IRB Agreement V3.0 (but participates in V1.0 or V2.0), you may use the Reliance System to view arrangements documented in the legacy Online Reliance System, but your institution will not be able to initiate any new requests.

[View Guides >](#)

USER GUIDES

## Points of Contact

Search by keyword

Learn how IRB/HRPP administrators/staff and institutional leadership can join the SMART IRB Agreement, manage institutional profiles and user permissions, and track and document reliance arrangements.

Home » User Guides » Points of Contact

### Creating a SMART IRB User Account

Signing Up

[View Instructions >](#)

Log In

[View Instructions >](#)

### Signing Reliance Agreement V3.0

Sending V3.0 to Institutional Official

[View Instructions >](#)

Managing Institutional Agreements

[View Instructions >](#)

### Signing Optional V3.0 Indemnification

Sending Indemnification to Institutional Official

[View Instructions >](#)

### Managing My Institution's Details/Profile

Updates to Institutional Details

[View Instructions >](#)

Key Points of Contact for Agreement V3.0

[View Instructions >](#)

Updates to Institutional Profile

[View Instructions >](#)

### Managing Reliance Requests

Create a New Reliance Request

[View Instructions >](#)

Reliance Decision Making

[View Instructions >](#)

Requests for Edits

[View Instructions >](#)

Navigating Determination Letters

[View Instructions >](#)

# Has your institution joined V3.0?



Reliance Agreement ▾

Reliance System ▾

Harmonization

Learning Center ▾

Resources ▾

Support ▾



Join SMART IRB  
Become a Participating Institution

Agreement

Steps to Join

Participating Institutions

## Five Steps to Join

The [SMART IRB Reliance Agreement \(V3.0\)](#) becomes available on March 17, 2025. **As of this date, signatory institutions will need to join SMART IRB Reliance Agreement V3.0 to initiate any new reliance arrangements under the SMART IRB Agreement.** Participating Institutions may also choose to join the *optional* Indemnification Addendum. [Learn more.](#)

1. Review the Agreement >
2. Log in or Register >
3. Generate your institution's Agreement. >
4. Sign and Submit Agreement >
5. Wait for Activation >

# Reviewing & Updating Institution Information

SMART IRB

Back

Sample University 2

ⓘ Edit Save Cancel

**Institution Information**

The information input into the institution details form will appear on the Agreement PDF for submission exactly as typed on this Institution Form.

To preview the SMART IRB Agreement, please download a sample agreement by visiting the [SMART IRB Website Agreements](#) Page.

Upon joining SMART IRB, your institution will be listed as a participating institution on the SMART IRB website. Provide a display name and a URL for your institution's IRB or HRPP website (or other appropriate URL) to help users learn about your institution and its IRB or HRPP activities.

Institution Legal Name\*  
Sample University 2

Any changes to this field may require re-verification of this form

Country\*  
United States of America

Street\*  
1234 Street

City\*  
Columbia

State\*  
Maryland

Zip\*  
49204

Institution Display Name  
Sample University 2

Institution IRB or HRBP website (Optional)

**Institution Type (select all that apply)**

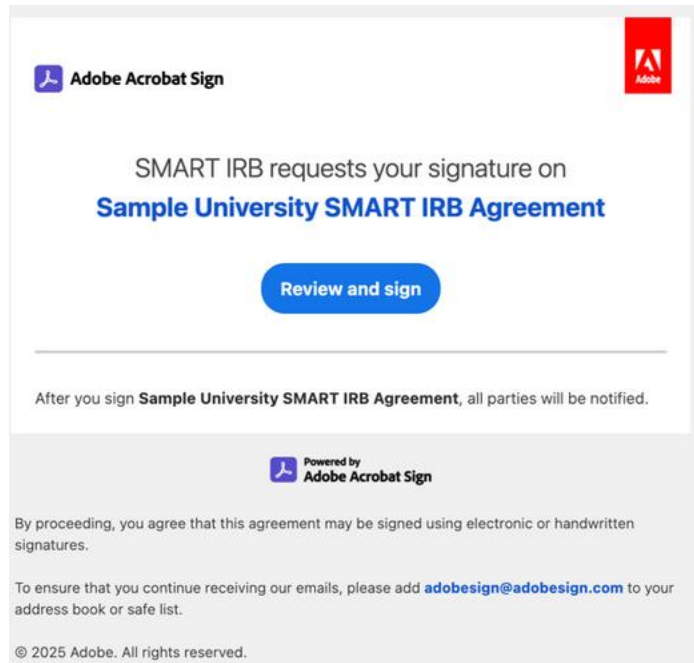
- University
- Academic Medical Center
- Cancer Center

# Sending Agreement to IO for Signature

The screenshot displays the SMART IRB web application interface. At the top left is the SMART IRB logo. The top right corner features a notification bell and a user profile icon labeled 'SI'. A vertical navigation sidebar on the left contains icons for home, institution, a highlighted 'SU' (Sample University) button, and other navigation options. The main content area is titled 'Sample University' and includes a 'Back' link. It is divided into three sections: 'New Submission' with a 'Download Agreement' button and a note that the SMART IRB 3.0 Agreement is ready for download; 'Share Agreement' with instructions to have the Signatory Official sign; and a 'Signatory Official (Institutional Official)' form. The form contains input fields for First Name (Mary), Last Name (Smith), Honorific (Dr), Phone Number ((212) 555-1212), and Email Address (smartirbuser2@outlook.com). A 'Request Signature' button is located at the bottom right of the form. A scroll bar is visible on the right side of the page.



# Signature Request Process



Adobe Acrobat Sign

SMART IRB requests your signature on  
**Sample University SMART IRB Agreement**

[Review and sign](#)

After you sign **Sample University SMART IRB Agreement**, all parties will be notified.

Powered by  
Adobe Acrobat Sign

By proceeding, you agree that this agreement may be signed using electronic or handwritten signatures.

To ensure that you continue receiving our emails, please add [adobesign@adobesign.com](mailto:adobesign@adobesign.com) to your address book or safe list.

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ADDRESS FOR NOTIFICATION  
Street:  
City, State, Zip:  
Phone:  
Email address:

I understand and affirm that Participating Institutions are strongly encouraged to use and follow the SMART IRB Standard Operating Procedures ("SMART IRB SOPs") for research covered under the Agreement, and that if institutions do not use the SMART IRB SOPs, they must communicate to each other and the Research Personnel the policies and procedures that will apply to the ceded Research.

Agreed and signed by the authorized Institutional Official/Signatory of the Participating Institution

[Click to Sign](#)

Name: Mary Smith  
Title: Dr  
Date: Jan 3, 2025

INSTITUTIONAL OFFICIAL/SIGNATORY ADDRESS  
Street: 123 K Street  
City, State, Zip Code: New York, New York, 10001  
Phone: (212) 555-1212  
Email address: sasmartirb@gmail.com



# Signature Request Process, continued

The image shows a sequence of three screenshots illustrating the signature request process:

- Left Screenshot:** A document viewer interface with a lock icon and the text: "This document requires a one time verification code". Below this, it says: "After clicking the 'Send Code' button you will receive an email sent to generalusersmartirb@gmail.com with verification code that you must enter to view the document." A "Send Code" button is visible.
- Middle Screenshot:** An email notification from smartirbdesign.com. The subject is "code requested to 'Click to sign' agreement: [DEMO USE ONLY] Sample University\_V3\_03-19-2025-18\_50\_54.pdf". The body of the email contains:
  - SMARTIRB logo and "Powered by Adobe Acrobat Sign".
  - Text: "Verification code to 'Click to sign' [DEMO USE ONLY] Sample University\_V3\_03-19-2025-18\_50\_54.pdf".
  - Large bold text: "708393".
  - Text: "Code will expire in 10 mins".
  - Text: "Please return to Acrobat Sign to verify your code and 'Click to sign' [DEMO USE ONLY] Sample University\_V3\_03-19-2025-18\_50\_54.pdf sent by SmartIRB Development (smartirbdev@gmail.com)".
- Right Screenshot:** A document viewer interface with a lock icon and the text: "This document requires a one time verification code". Below this, it says: "Please confirm your identity by entering verification code sent to the following email generalusersmartirb@gmail.com". A "Verify" button is visible next to a "Verification Code" input field.

# SMART IRB Reliance System: User Dashboard & Permissions



# User Dashboard

SMART IRB

ADMIN > Users

Export to CSV Invite User

User Role: All Status: All Show Fields: 8 fields selected Reset All Filters

Search

First Name	Last Name	Email	Last Updated Date	Role	Status	Institutions	Actions
SMART	IRB	smartirbuser1@outlook.com	Mar 2, 2025	Site Admin	Active	Sample University	
SMART IRB	User	smartirbuser2@outlook.com	Mar 2, 2025	General User	Unconfirmed	Sample University	
Jane	Smith	generalusersmartirb@gmail.com	Jan 16, 2025	General User	Active	Sample University	
Mary	Smith	sasmartirb@gmail.com	Jan 15, 2025	Site Admin	Active	Sample University	
Mary	Smith	msmith@sample.edu	Jan 3, 2025	General User	Active	Sample University	
Jane	Smith	jsmith@sample.edu	Jan 2, 2025	General User	Active	Sample University	
Sam	Jones	susmartirb@gmail.com	Jan 2, 2025	Site Admin	Active	Sample University	
Jane	Smith	sa01@sample.edu	Dec 31, 2024	Site Admin	Active	Sample University	

1 - 8 of 8 << < > >> 10

Invite User

# User Profiles



ADMIN > Users

User Role: All Status: All

First Name	Last Name	Email
SMART	IRB	smar
SMART IRB	User	smar
Jane	Smith	gene
Mary	Smith	sasm
Mary	Smith	rsm
Jane	Smith	jsmit
Sam	Jones	susm
Jane	Smith	sa01

## SMART IRB User

Status: Unconfirmed

Institutions (1) **User Details** Permissions

### User Account Details

Select the appropriate User Type and Status for the user.

First Name: SMART IRB

Last Name: User

Email Address: smartirbuser2@outlook.com

### User Type

General User  Site Admin  Super Admin

### Reliance Access Details

Slide to provide the user with access to the Reliance System. The Reliance System allows users to request, track, and document reliance arrangements on study-by-study basis.

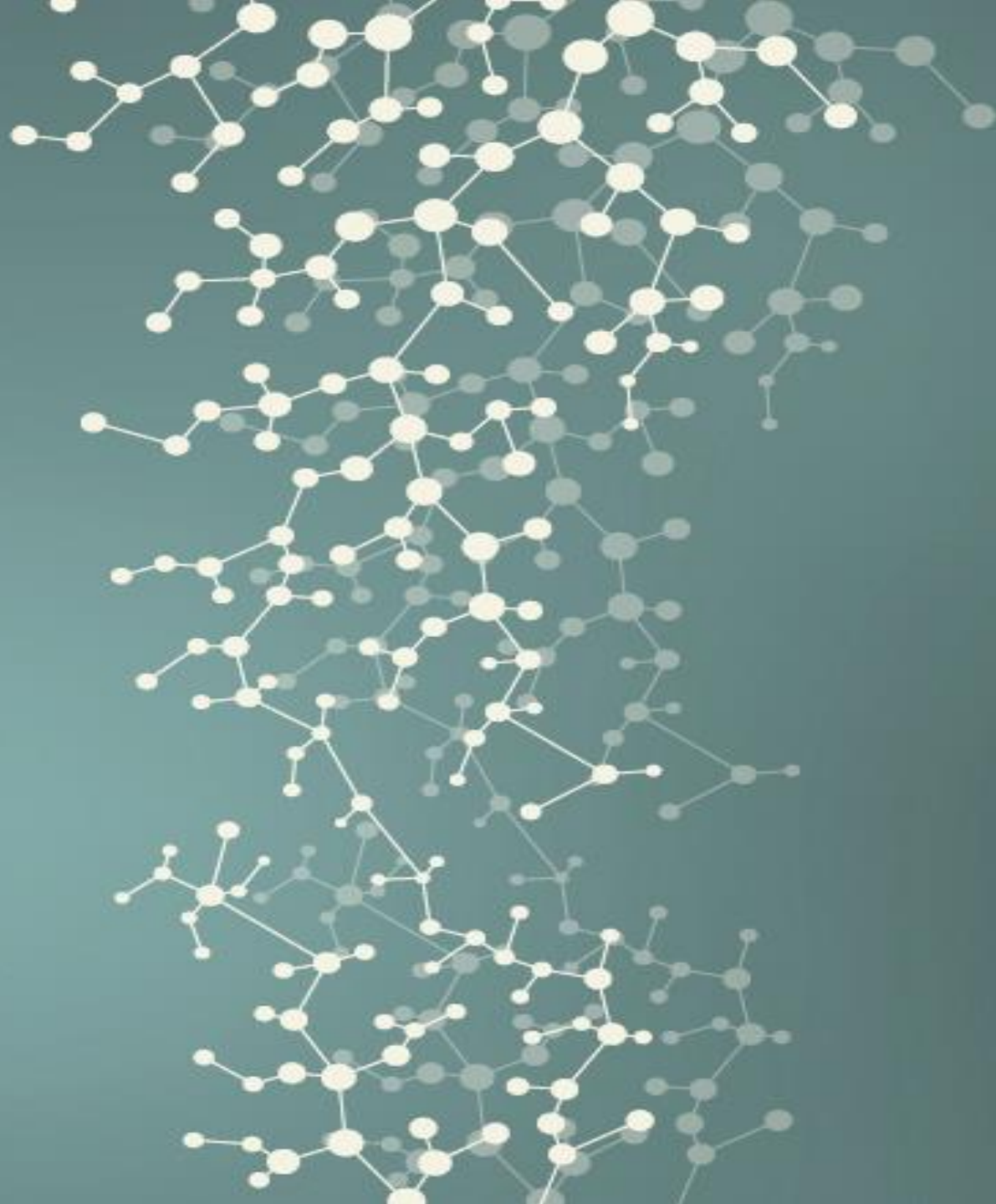
Give access to Reliance

Save

# Activating Users

The screenshot shows the SMARTIRB user management interface. On the left is a dark blue sidebar with navigation options: Global View, SITES (My Institutions, Agreements, Indemnifications), RELIANCE (All Requests), and ADMIN (Users). The main content area is for user 'Mary Smith', with tabs for Institutions (1), User Details (selected), and Permissions. The status is 'Unconfirmed'. A dropdown menu is open, showing 'Unconfirmed' (selected), 'Active', and 'Deleted'. The 'User Account Details' section includes fields for First Name (Mary), Last Name (Smith), and Email Address (msmith@sample.edu). The 'User Type' section has radio buttons for General (selected), Site Admin, and Super Admin. The 'Reliance Access Details' section has a toggle switch for 'Give access to Reliance' which is currently turned on. A tooltip is visible over the 'Active' option in the status dropdown.

# SMART IRB Checklists & Templates





# Documenting Flexibilities: Implementation Checklist

- Document flexibilities with ease!
- New ‘default’ vs ‘flexible’ implementation to increase transparency, reduce burden
- Available in Word and PDF

**SMART IRB** Purpose of Form: This form documents the terms by which participating institutions will follow for the identified research. This form is intended to be validated by Reviewing IRB POC and Relying Institution POCs.

### Implementation Checklist and Documentation Tool

Reviewing IRB Institution	
Relying Institution	
Research Study Title(s)	
Reviewing Institution PI	
Relying Institution Site Investigator	
SMART IRB Agreement Terms	<input type="checkbox"/> Default Implementation Applies <input type="checkbox"/> Flexible Implementation Applies (as outlined below)
This Implementation Checklist was completed by the following institutional representatives (Name, Role, Date):	
Reviewing Institution POC/Designee	
Relying Institution POC/Designee	

**Reviewing IRB**

1. Notification of Acceptance or Declination of Coded Review  
Section 3.2.3

[DEFAULT] OPTION 1 – Reviewing IRB Will Provide Notification  
The Reviewing IRB will notify the Overall PI (or designee), the Site Investigator(s), and involved Participating Institution(s) whether the identified research is accepted for Coded Review and, if accepted, the designation of the Reviewing IRB and Relying Institutions. This can be accomplished through the [SMART IRB Reference System](#) or another mechanism.

OPTION 2 – Another Party Will Provide Notification  
[NAME OF NOTIFYING PARTY] will notify the Overall PI and the Site Investigator(s) and involved Participating Institution(s) whether the identified research is accepted for Coded Review and, if accepted, the designation of the Reviewing IRB and Relying Institutions.

OPTION 3 – Reviewing IRB Determination Mandated By External Group  
The Participating Institutions are members of / participants in [NAME OF CLINICAL TRIAL NETWORK, IRB CONSORTIUM OR PROGRAM, OR OTHER EXTERNAL GROUP] and must follow its requirements and procedures for coded IRB review and determining the Reviewing IRB with respect to the identified research.

[www.smartirb.org](http://www.smartirb.org)  
Version: 03/20

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**SMART IRB** Purpose of Form: This form documents the terms by which participating institutions will follow for the identified research. This form is intended to be validated by Reviewing IRB POC and Relying Institution POCs.

### Implementation Checklist and Documentation Tool

Reviewing IRB Institution	
Relying Institution	
Research Study Title(s)	
Reviewing Institution PI	
Relying Institution Site Investigator	
SMART IRB Agreement Terms	<input type="checkbox"/> Default Implementation Applies <input type="checkbox"/> Flexible Implementation Applies (as outlined below)
This Implementation Checklist was completed by the following institutional representatives (Name, Role, Date):	
Reviewing Institution POC/Designee	
Relying Institution POC/Designee	

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Version DATE: 03/20

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# Resources: Letter of Acknowledgment (3 options)



**Purpose of Form:** This form documents that the following Reviewing IRB Institution will serve as Reviewing IRB for the research noted below; and the following Relying Institution has agreed to cede IRB review to the Reviewing IRB listed below.

## Letter of Acknowledgement

IRB Review will be ceded under the [SMART IRB Agreement Version 3.0](#). Questions regarding this reliance arrangement should be directed to SMART IRB institutional [Points of Contact](#).

Reviewing IRB Institution	
Relying Institution	
Research Study Title(s):	
Reviewing Institution PI	
Relying Institution Site Investigator	
SMART IRB Terms	<input type="checkbox"/> Default Implementation Applies (per <a href="#">Implementation Checklist</a> ) <input type="checkbox"/> Flexible Implementation Applies (per <a href="#">Implementation Checklist</a> )
<b>This Letter of Acknowledgment was completed by the following institutional representatives (Name, Role, Date):</b>	
Reviewing Institution POC/Designee	
Relying Institution POC/Designee	

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Version date: 03/23

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**Purpose of Form:** This form documents that the following Reviewing IRB Institution will serve as Reviewing IRB for the research noted below; and the following Relying Institution has agreed to cede IRB review to the Reviewing IRB listed below. Default terms apply.

## Letter of Acknowledgement (Default Implementation)

IRB Review will be ceded under the [SMART IRB Agreement Version 3.0](#). Questions regarding this reliance arrangement should be directed to SMART IRB institutional [Points of Contact](#).

Reviewing IRB Institution	
Relying Institution	
Research Study Title(s):	
Reviewing Institution PI/IRB#	
Relying Institution Site Investigator/IRB#	
<b>This Letter of Acknowledgment was completed by the following institutional representatives (Name, Role, Date):</b>	
Reviewing Institution POC/Designee	
Relying Institution POC/Designee	

### Default Implementation Applies

#### 1. Standard Operating Procedures: SMART IRB SOPs Will Apply

The Participating Institutions will follow the SMART IRB SOPs with respect to the identified research.

#### 2. (If HIPAA Applies) HIPAA Determinations and Actions: Relying Institution Will Provide Determination

The Relying Institution or a third party named by Relying Institution will make any HIPAA determinations or perform any HIPAA Actions in connection with the research.

**3. (If HIPAA Applies) HIPAA Authorization Language and Consent Forms: Relying Institution Will Provide**  
If HIPAA applies, the Relying Institution provide the Reviewing IRB with its own HIPAA language to be inserted into the informed consent document(s), or the Relying Institution will provide a separate HIPAA Authorization. The Reviewing IRB is under no obligation to ensure HIPAA Authorization language meet the requirements of 45 CFR 164.508(b) and (c).

**4. Conflicts of Interest: Relying Institution Will Perform Conflict of Interest Analyses Under Their Policies**  
The Relying Institution will perform their own analyses under their relevant policy(ies) with respect to disclosure and management of their Research Personnel's conflicts of interest in connection with the identified research. The

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Version date: 03/23

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**Purpose of Form:** This form documents that the following Reviewing IRB Institution will serve as Reviewing IRB for the research noted below; and the following Relying Institution has agreed to cede IRB review to the Reviewing IRB listed below. Flexible implementation applies.

## Template Letter of Acknowledgement (Flexible Implementation)

IRB Review will be ceded under the [SMART IRB Agreement Version 3.0](#). Questions regarding this reliance arrangement should be directed to SMART IRB institutional [Points of Contact](#).

Reviewing IRB Institution	
Relying Institution	
Research Study Title(s):	
Reviewing Institution PI	
Relying Institution Site Investigator	
<b>This Letter of Acknowledgment was completed by the following institutional representatives (Name, Role, Date):</b>	
Reviewing Institution POC/Designee	
Relying Institution POC/Designee	

### Flexible Implementation Apply

*[Please outline terms as mutually agreed and delete the options that do not apply; we recommend the reviewing IRB POC and relying institution POC work together to agree on flexible implementation.]*

#### 1. Standard Operating Procedures: (Default) SMART IRB SOPs Will Apply

The Participating Institutions will follow the [SMART IRB SOPs](#) with respect to the identified research.

#### Reviewing IRB SOPs Will Apply

The Participating Institutions will follow the Reviewing IRB SOPs *[insert link here]* with respect to the identified research.

#### Other Mandated SOPs Will Apply

The Participating Institutions will follow the *[insert SOP here]* for this research.

#### 2. HIPAA Determinations and Actions: (Default if HIPAA Applies) Relying Institution or Third Party Will Provide Determination

The Relying Institution or third party will make any HIPAA determinations or perform any HIPAA Actions in connection with this research on behalf of the Relying Institution.

[www.smartirb.org](http://www.smartirb.org)  
Version date: 03/23

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# Resources: Communication Plan



Purpose of the form: This form should be used to document key communication roles/responsibilities for specific studies. Reviewing IRB/HRPPs may use this form to document general expectations of study teams and relying site IRB/HRPPs, or less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team. The SMART IRB recommends this form be kept up to date with all key information throughout the life of a study.

## Communication Plan Template

### Definitions

- **REVIEWING IRB - Point of Contact (POC):** Main person responsible for addressing questions related to the Reviewing IRB's policies and procedures and review status for a ceded study
- **LEAD STUDY TEAM - Representative:** Main person responsible for communication with the Reviewing IRB and facilitating communication between relying site study teams and the Reviewing IRB regarding the ceded study
- **RELYING SITE - POC:** Main person responsible for communication with the Reviewing IRB and local study team regarding the ceded study (e.g., personnel in the local IRB office or local human research protection program personnel)
- **RELYING SITE STUDY TEAM - Representative:** Main person responsible for communication with the Lead Study Team regarding the ceded study

Role	Name, Title, Institution	Contact Information
Reviewing IRB POC		
Lead Study Team Representative		
Relying Site POC		
Relying Site Study Team Representative		
Study Name		
Overall PI (Lead PI)		
Site Investigator (Local PI)		

Area of Communication Responsibility	Responsible Party (Typical Party Identified*)	Notes
<b>CONFLICT OF INTEREST:</b> Providing applicable Relying Site Conflict of Interest management plans to the Reviewing IRB	<input type="checkbox"/> Relying Site Study Team <input type="checkbox"/> Relying Site POC <input type="checkbox"/> Lead Study Team* <input type="checkbox"/> Other, specify:	
<b>STUDY TEAM TRAINING &amp; QUALIFICATIONS:</b> Providing confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research	<input type="checkbox"/> Relying Site Study Team <input type="checkbox"/> Relying Site POC <input type="checkbox"/> Lead Study Team* <input type="checkbox"/> Other, specify:	
<b>LOCAL CONSIDERATIONS:</b> Collecting local information related to Relying Institution's local and state laws; federalwide assurance applicability (e.g. "checking the box"); institutional requirements; unique cultural, language, geography, or socioeconomic factors; or standard of care	<input type="checkbox"/> Relying Site Study Team* <input type="checkbox"/> Relying Site POC* <input checked="" type="checkbox"/> Lead Study Team <input type="checkbox"/> Other, specify:	

[www.smartirb.org](http://www.smartirb.org)

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ROLE	NAME, TITLE, INSTITUTION	CONTACT INFORMATION
Reviewing IRB POC		
Lead Study Team Representative		
Relying Site POC		
Relying Site Study Team Representative		
Study Name		
Overall PI (Lead PI)		
Site Investigator (Local PI)		

[www.smartirb.org](http://www.smartirb.org)  
VERSION DATE: 03/25

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# SMART IRB Standard Operating Procedures

- SMART IRB SOPs updated for V3.0
- SOPs apply unless alternative SOPs are specifically documented
- Available via 'Resources' -> 'Resource Library' on [www.smartirb.org](http://www.smartirb.org)



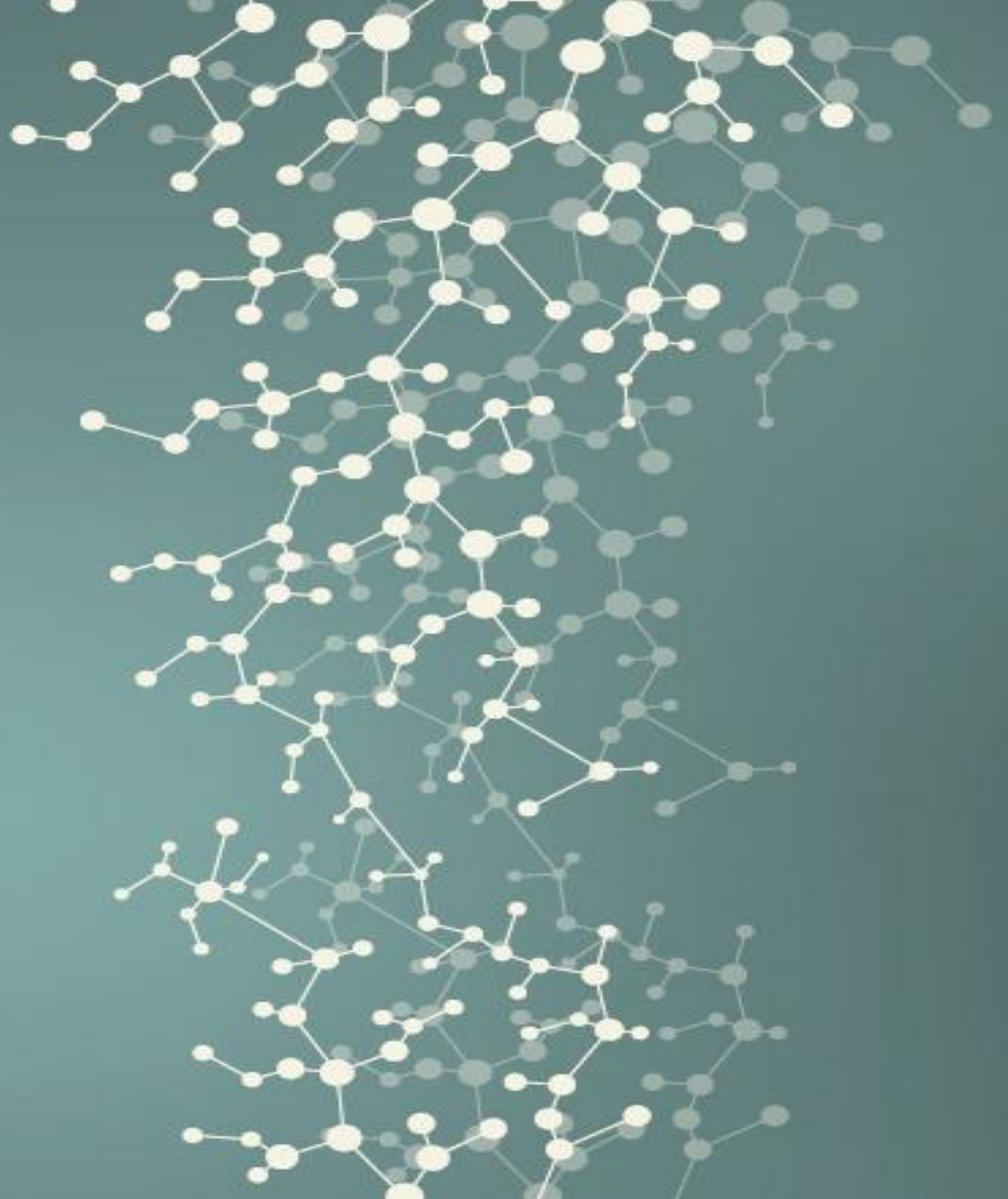


# “Legacy” and Legacy Documents

- “Legacy” refers to V2.0 or V1.0 institutions and materials
- Key documents kept for these arrangements including SOP, FAQ, checklists, and more!
- Additional materials available upon request

The screenshot shows the SMART IRB Resources Library interface. At the top, it says "RESOURCES" and "Library Flexible, ready to use, and easy to adapt". A search bar contains the text "legacy". Below the search bar, there are filter options under "Filter by" with a dropdown menu set to "Topic". The filter options are:  About Single IRB Review,  For Funding Applications,  Implementing the Agreement,  Joining SMART IRB, and  Setting up Reliance. On the right, it says "Showing 1 of 1" and "Sort by: Name". The search results show a single item titled "Legacy Agreements & Related Resources" with a "ZIP" icon. The description reads: "Includes the Legacy Agreements (SMART IRB Agreements V1.0 and V2.0), as well as key materials to support instances of reliance documented under either V1.0 or V2.0, prior to March 17, 2025. While these previously documented arrangements remain valid, Legacy Agreements may not be used for any new reliance arrangements."

# Troubleshooting: Reliance System





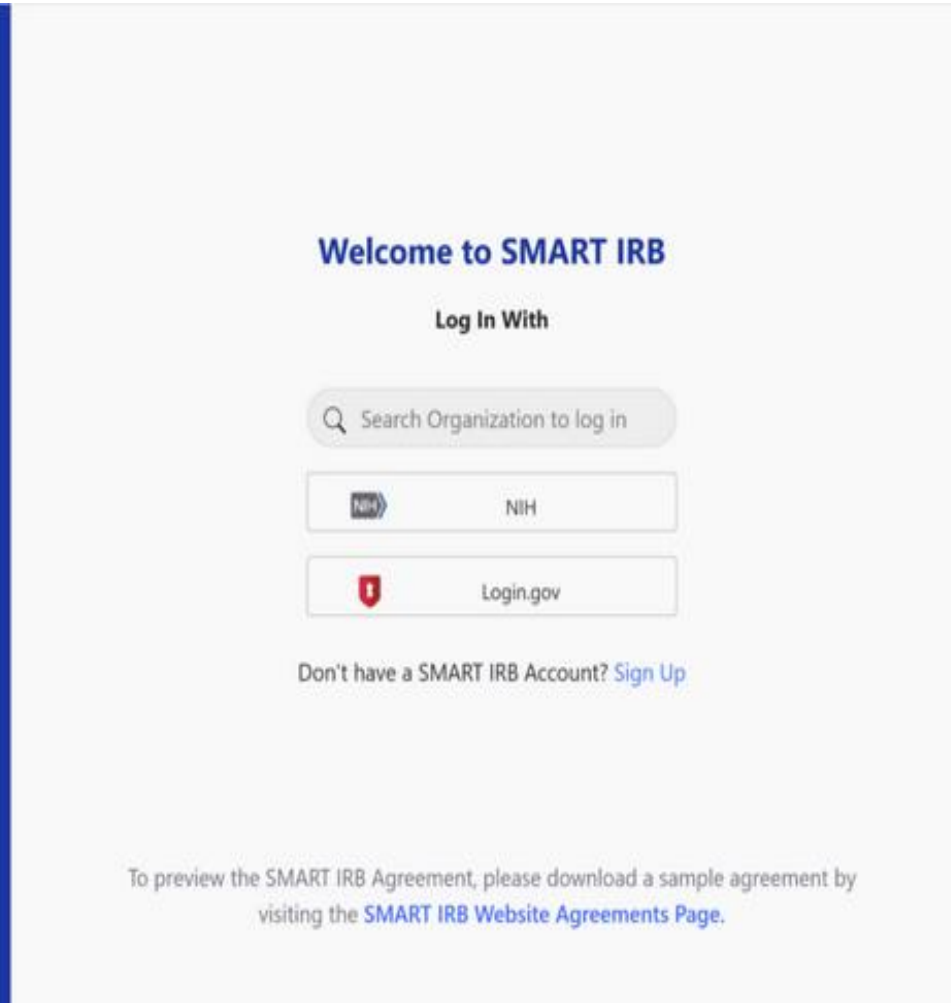
## Welcome to SMART IRB

SMART IRB is a platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the [NIH Single IRB Review policy](#) (effective date: January 25, 2018). Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation, regardless of funding status.



- **Log In** - Users with an active account in the old Joinder or Online Reliance System
- **Register** - Users that did not have an active account previously in a SMART IRB system

# Log In Options

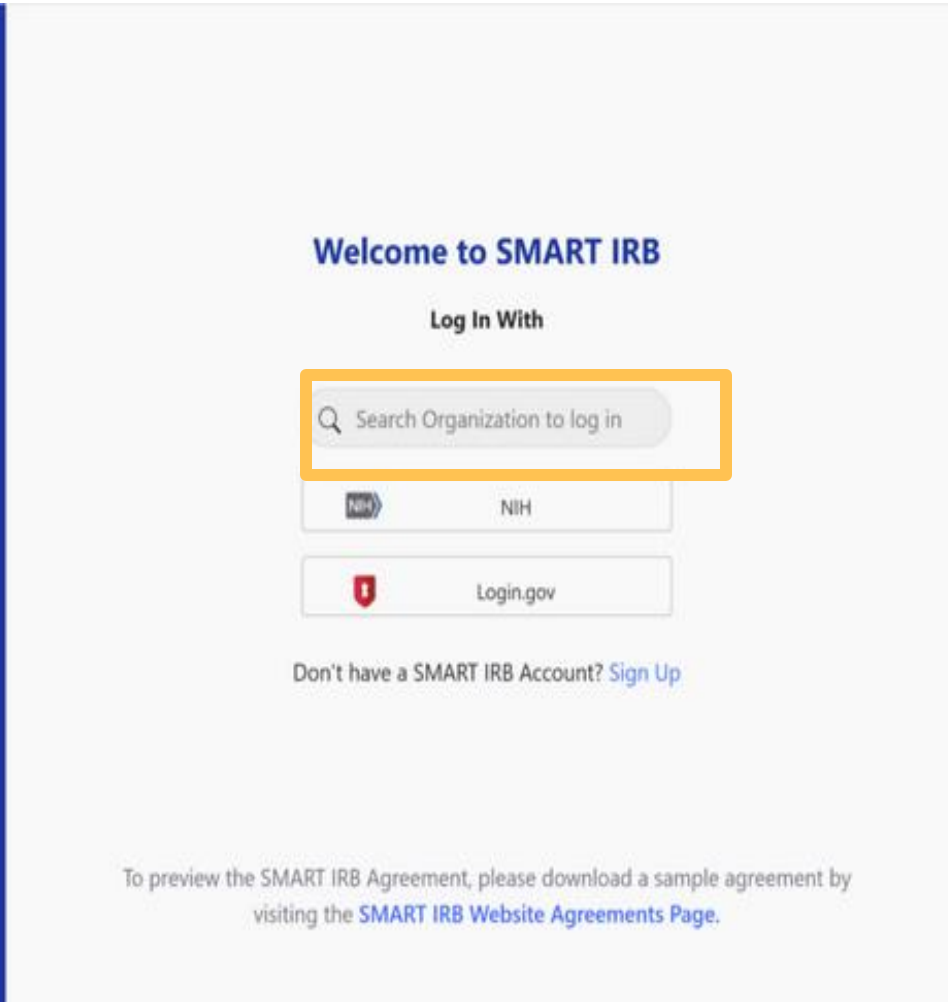


SMART IRB Reliance System has 3 Options to Log In

- **Single Sign On (SSO)**
- **NIH**
- **Login.gov**

Why? Each option meets federal requirements as **Identity & Access Management Systems (IAMS)** for secure access to sensitive information.

# Registration and Login: SSO



## Log In with SSO

- Find Institution in search box
- List is generated from InCommon Federation network database
- All SSO may be not available
- If SSO email does *not* match your SMART IRB system email, please contact the Help desk for assistance.

# Registration and Login (NIH)



## Welcome to SMART IRB

Log In With

Search Organization to log in



NIH



Login.gov

Don't have a SMART IRB Account? [Sign Up](#)

To preview the SMART IRB Agreement, please download a sample agreement by visiting the [SMART IRB Website Agreements Page](#).

New: Simplify your login experience by clicking "NIH Staff" button below.

### Sign in

#### Smart Card Login

Insert your PIV card into your smart card reader or sign in using your mobile PIV-D credentials. [Need help?](#)

Sign in



#### Authenticator App

Use your account credentials and check your phone for a one-time code or push notification. [Need help?](#)

Username

Password

[Forgot Password?](#)

Sign in

NIH NIH Staff

[Trouble signing in?](#)

# Registration and Login (Login.gov)



## Welcome to SMART IRB

Log In With

Search Organization to log in



NIH



Login.gov

Don't have a SMART IRB Account? [Sign Up](#)

To preview the SMART IRB Agreement, please download a sample agreement by visiting the [SMART IRB Website Agreements Page](#).

LOGIN.GOV



**PRODUCTION: LSAuth auth.ncats SAML IAL1** is using Login.gov to allow you to sign in to your account safely and securely.

[Sign in](#)

[Create an account](#)

### Sign in for existing users

Email address

Password

Show password

[Submit](#)

[Sign in with your government employee ID](#)

[Back to PRODUCTION: LSAuth auth.ncats SAML IAL1](#)

[Forgot your password?](#)

[Security Practices and Privacy Act Statement](#)

[Privacy Act Statement](#)

This site is protected by reCAPTCHA and the Google [Privacy Policy](#) and [Terms of Service](#) apply.

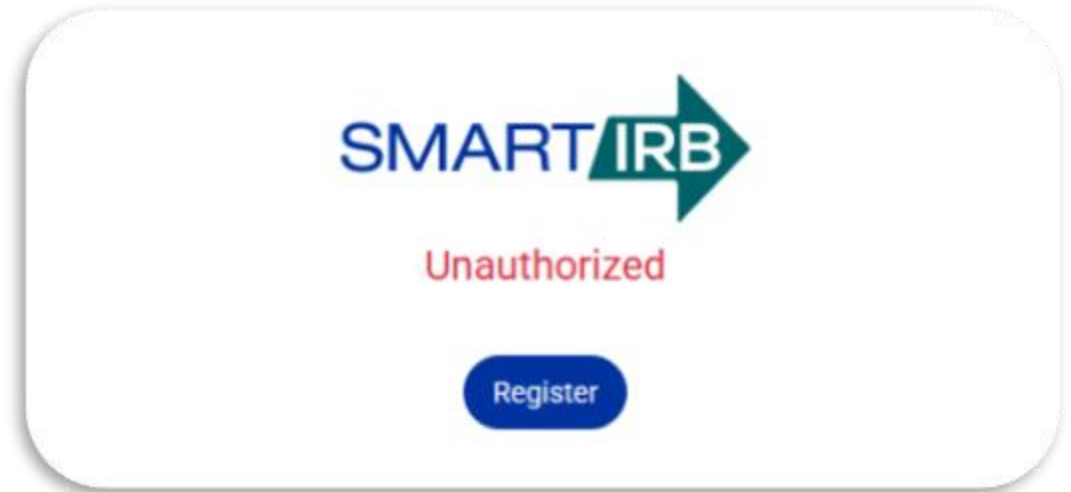
# Troubleshooting: Common Problems and Solutions

- SSO Institution not on list
  - Sign in via Login.gov
- SSO e-mail doesn't match e-mail in SMART IRB Reliance System
  - Email [Help@SMARTIRB.org](mailto:Help@SMARTIRB.org)
- Unauthorized Message when attempting to Log In
  - Email address not matching with email in Reliance System
  - Account not active
  - Authorization Error on the backend of the system
    - Email [Help@SMARTIRB.org](mailto:Help@SMARTIRB.org) for assistance

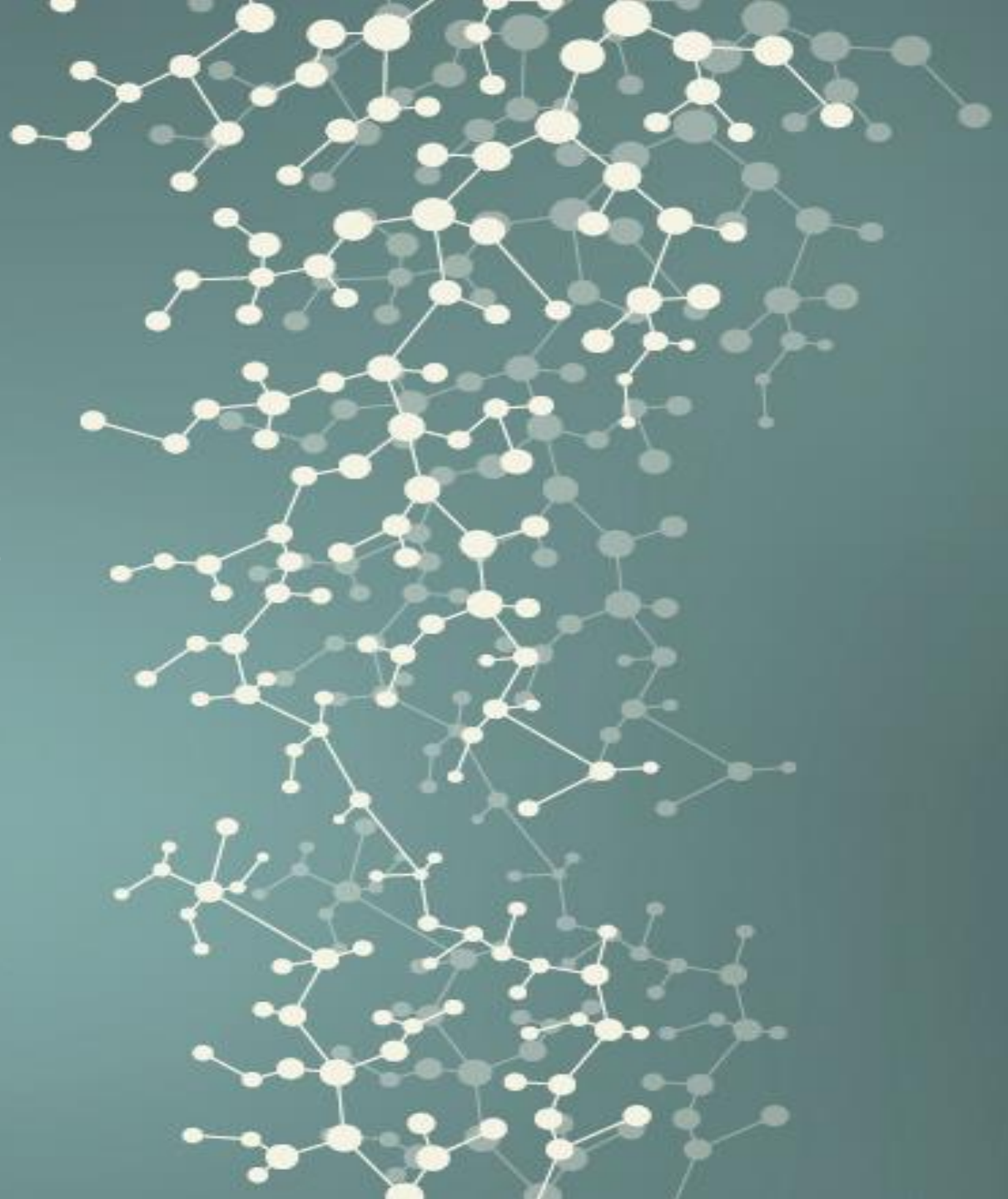


## Troubleshooting: Why Is My Account “Unauthorized”?

- Unauthorized errors are occurring when there is a mismatch between how a user is logging into the system and how the system assumed they would log in.
- These issues are being documented and the informatics team is rapidly correcting these items.
- We will push an update to the system soon to resolve the majority of these issues.



# Questions from the Single IRB Community



## Questions During Registration

- Are participating institutions required to use the electronic system or will the Reliance Acknowledgement Doc still be used
- Will the document-based version of SMART IRB [Letter of Acknowledgment] be changed?
- Will reliance agreements negotiated using the old SMART IRB reliance platform automatically carry over to the new platform?
- I would like some clarifications on the use of the indemnifications section/addendum.
- How is flexible implementation of the SMART IRB agreement documented in the Online Reliance System?
- Estimated length of time to complete required paperwork? Summarize what is new/different from previous versions.

# Questions and Discussion

