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

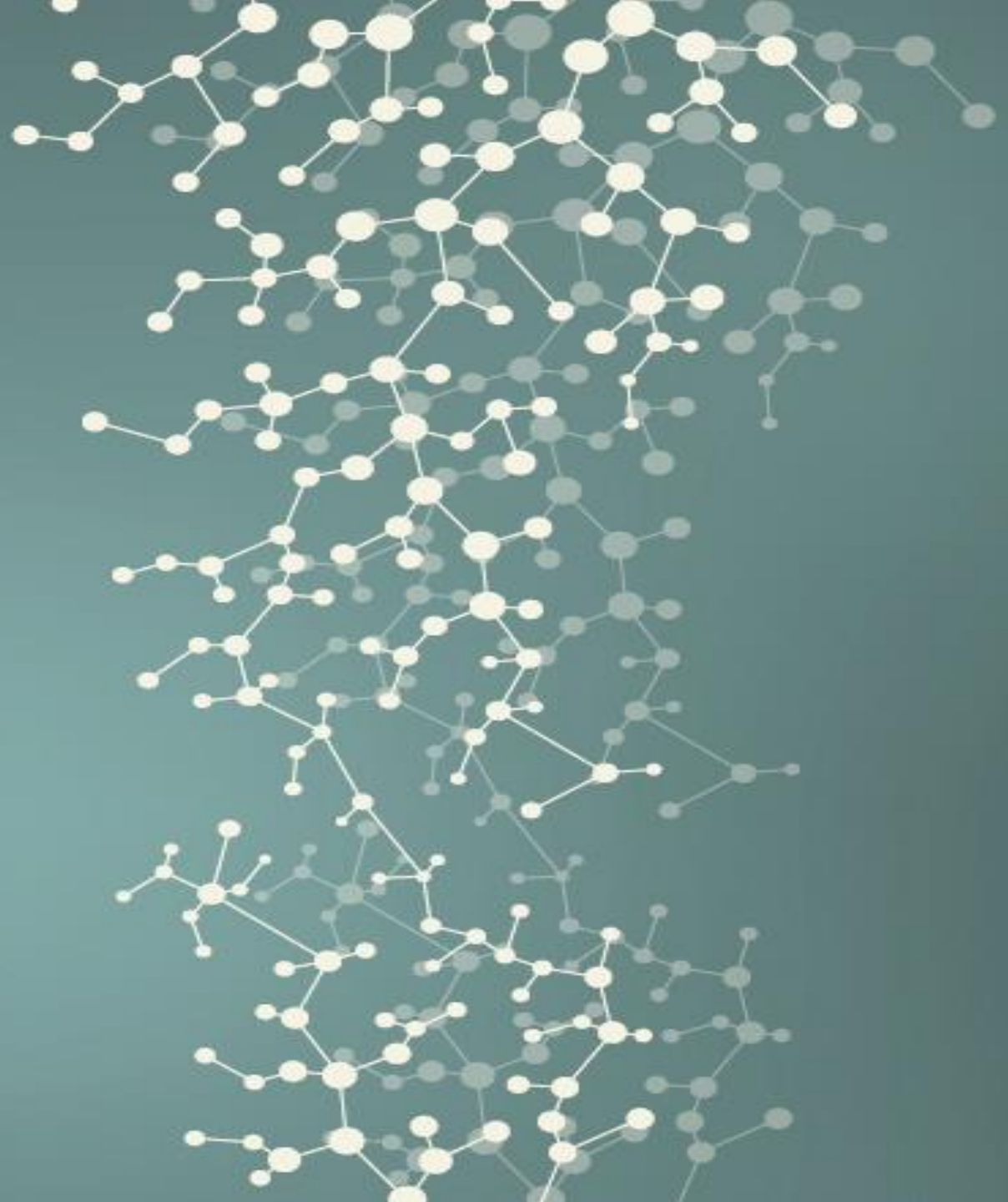
Nichelle Cobb
AAHRPP

Stacey Goretzka

Lubabah Helwani

Find your SMART IRB Ambassador Today: www.smartirb.org

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

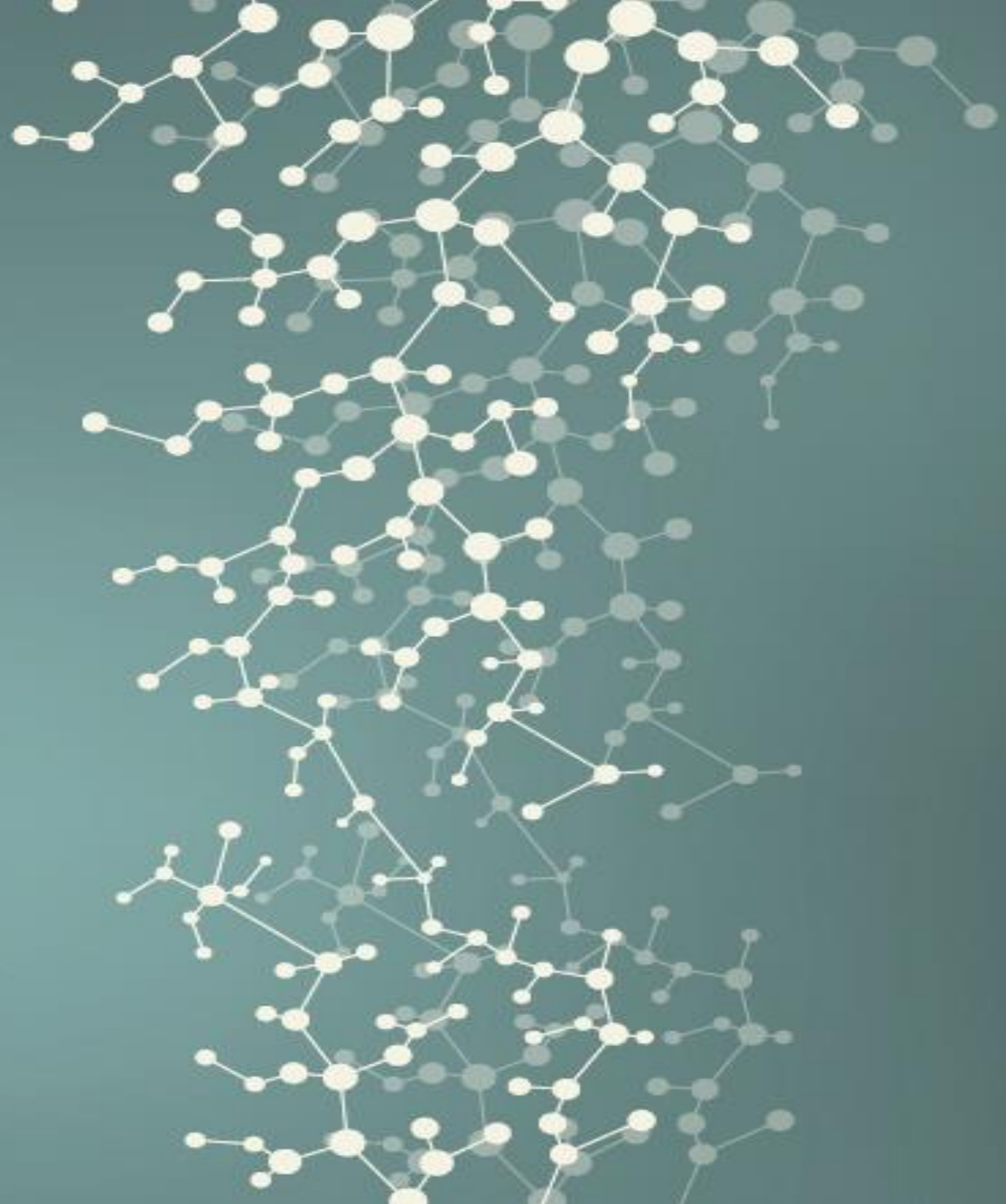
SMARTIRB.org

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

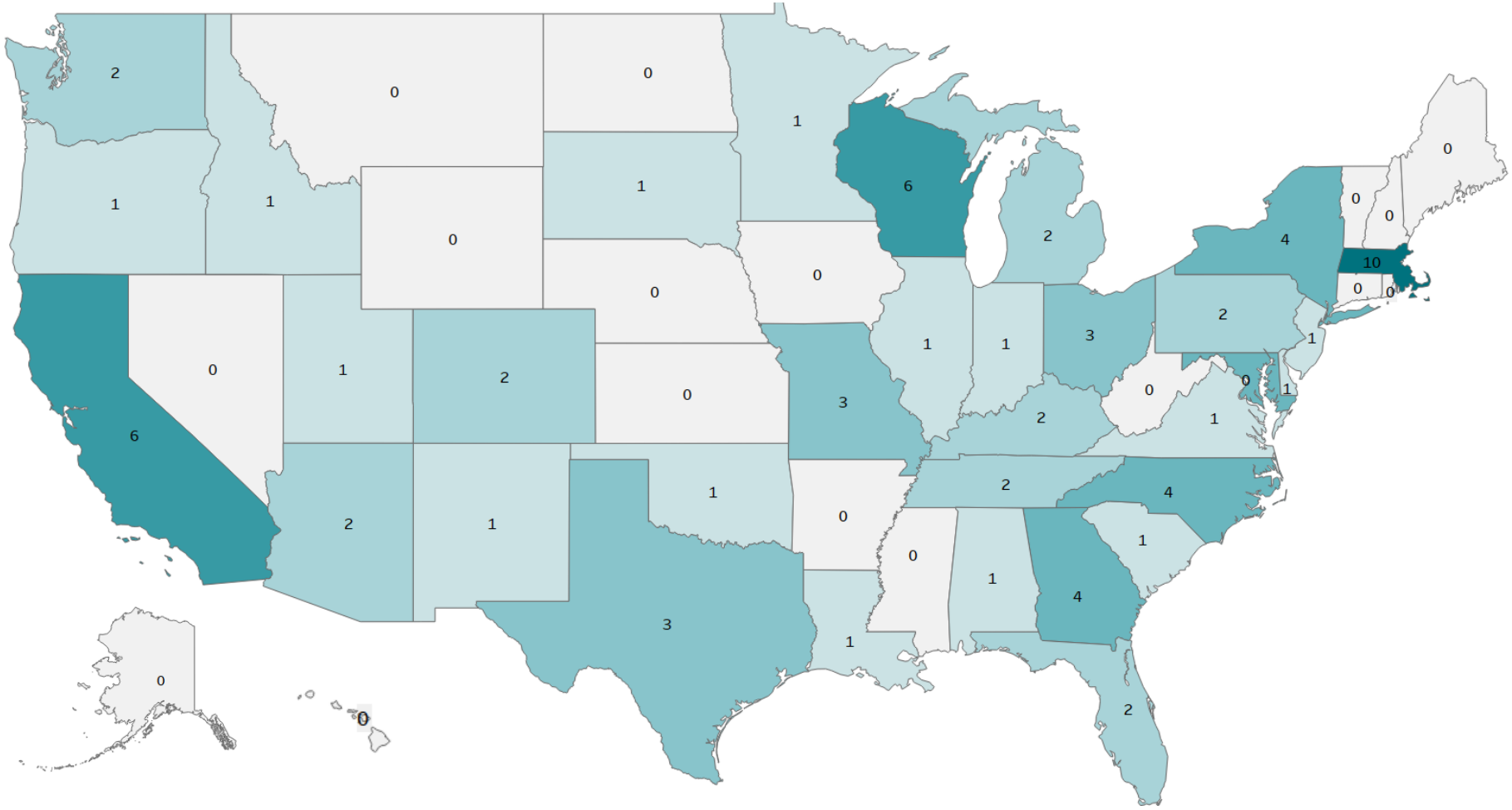
Your single IRB home, where institutions can:

- 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.

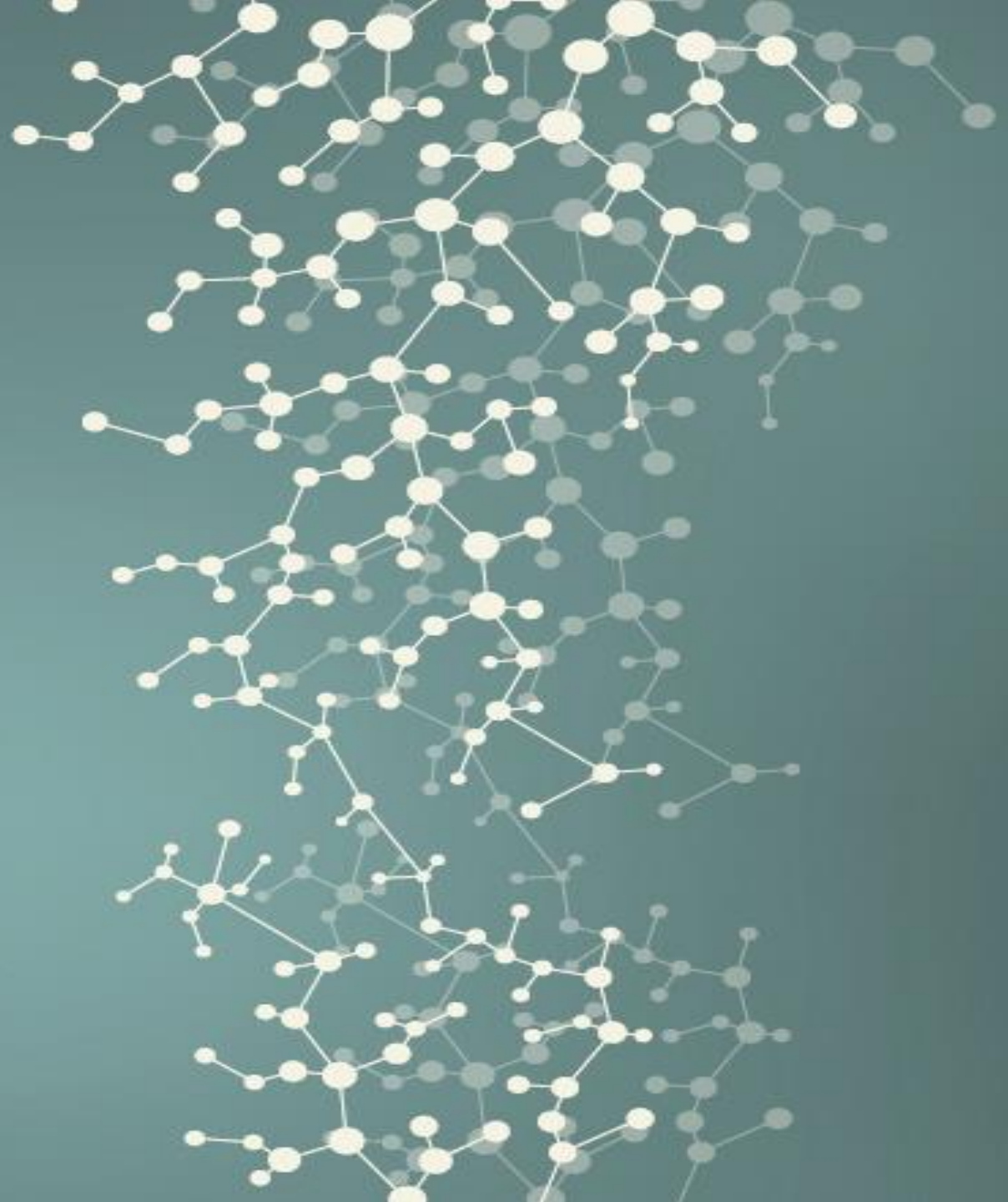
Ready to Launch: Week 1 Retrospective (3/17-3/21)

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

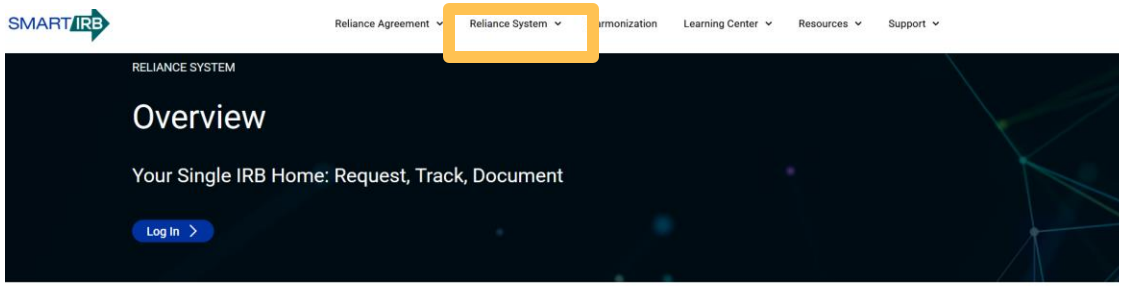
- NIH: the 1st signatory
- 27 CTSA Hubs
- 50 Universities/AMCs
- 18 Hospital Systems
- 5 Commercial IRBs
- 30 Institutions awaiting signature
- **109 Signatories to date (as of 03/25)!**



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

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)

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.

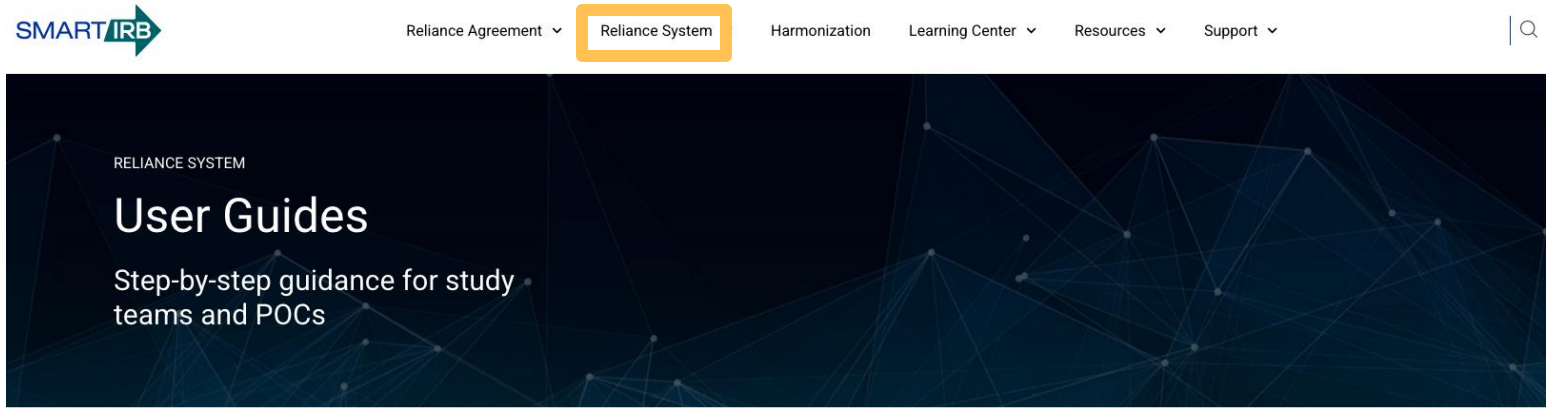
View Guides >

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 >

User Guides



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.

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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 >

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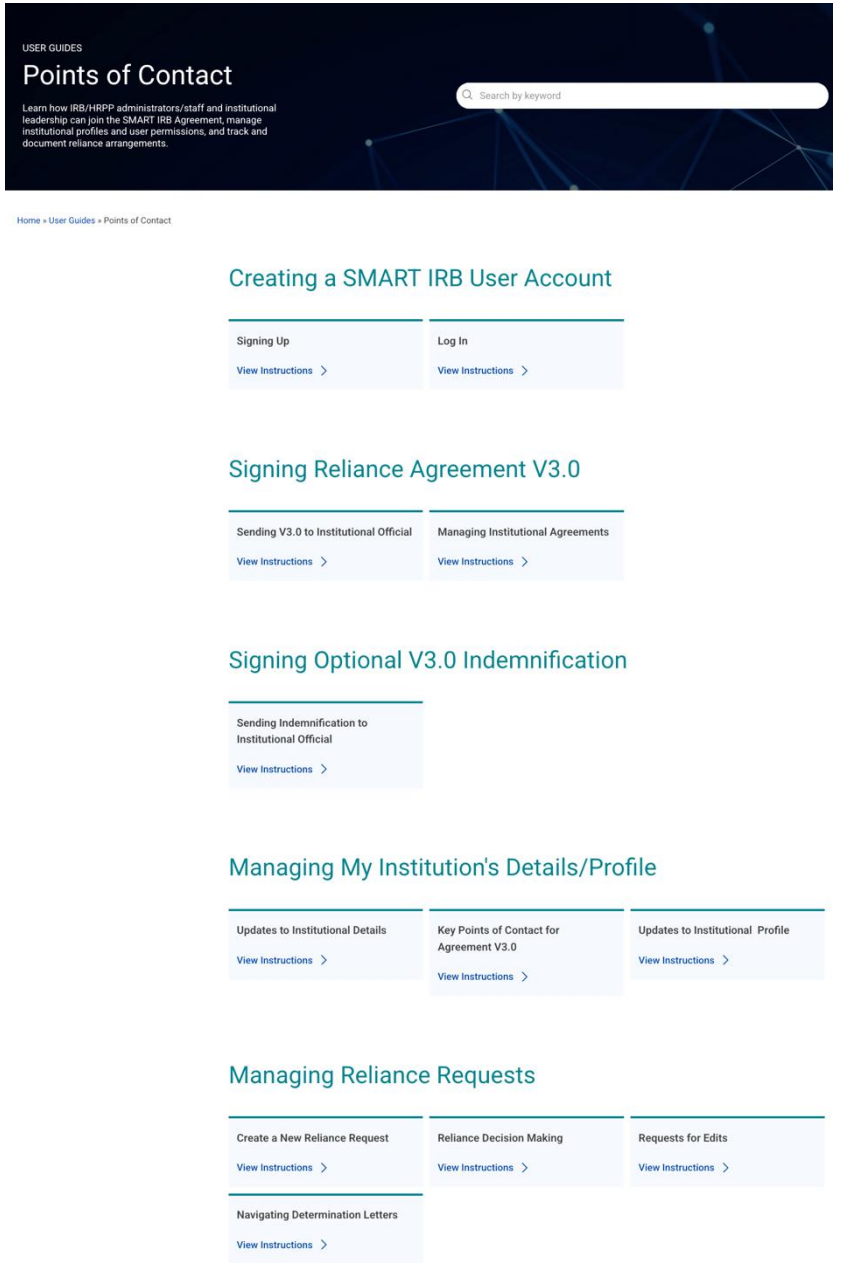
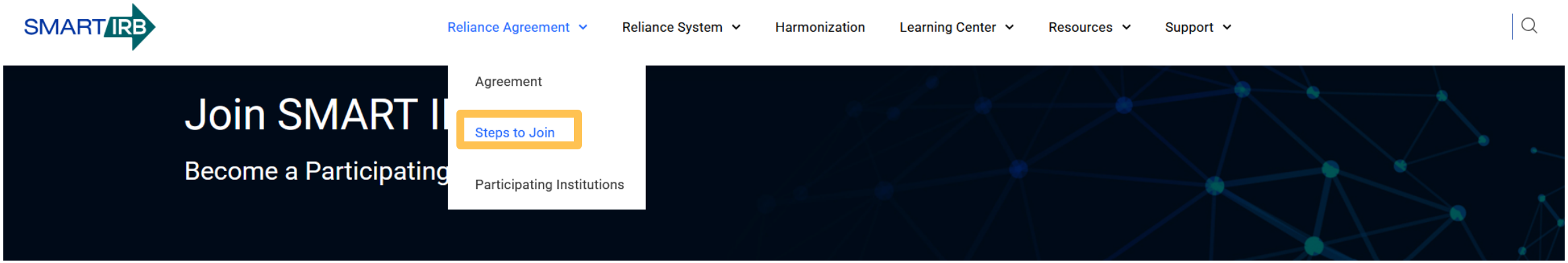


Has your institution joined V3.0?

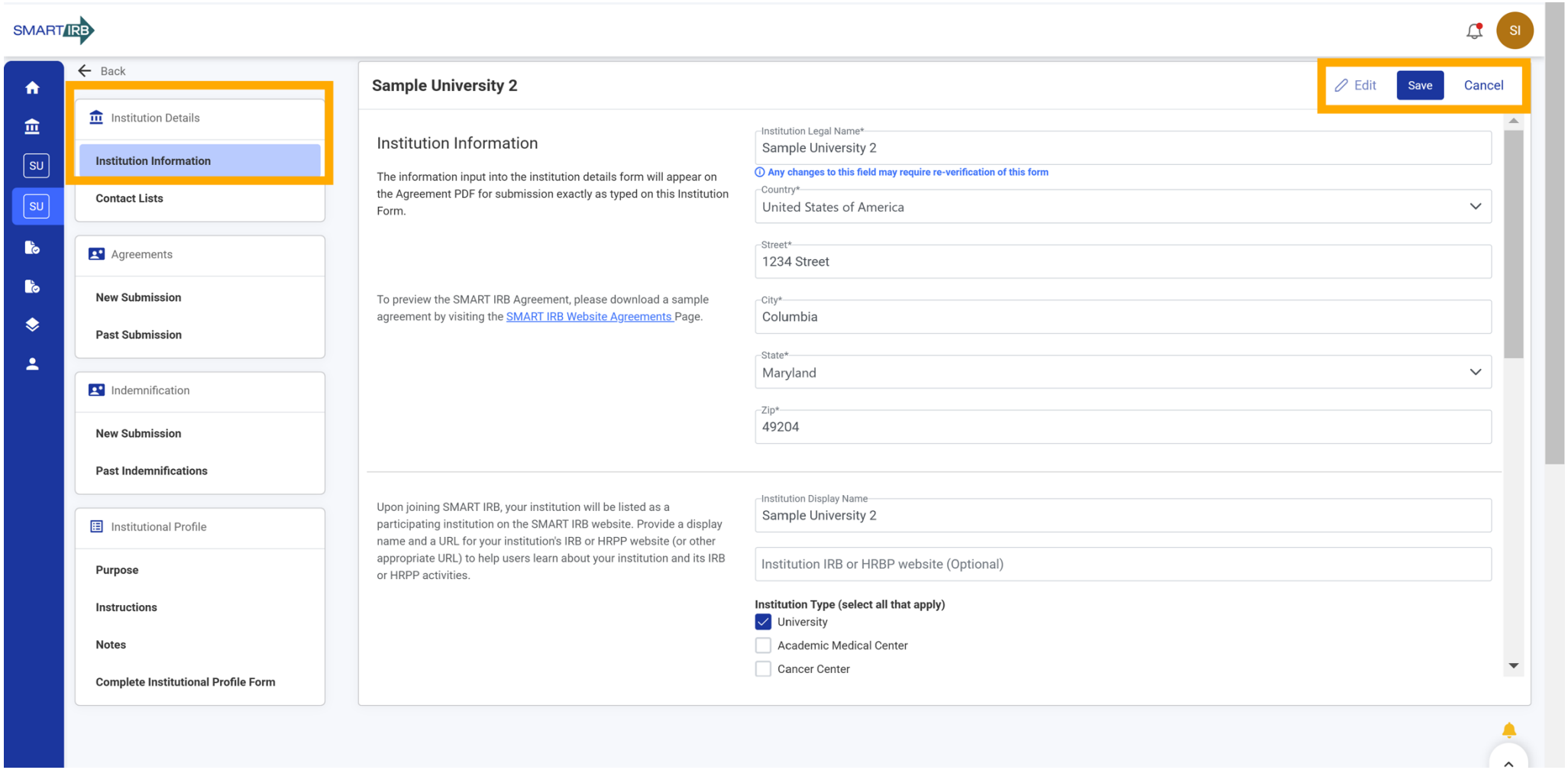


Five Steps to Join

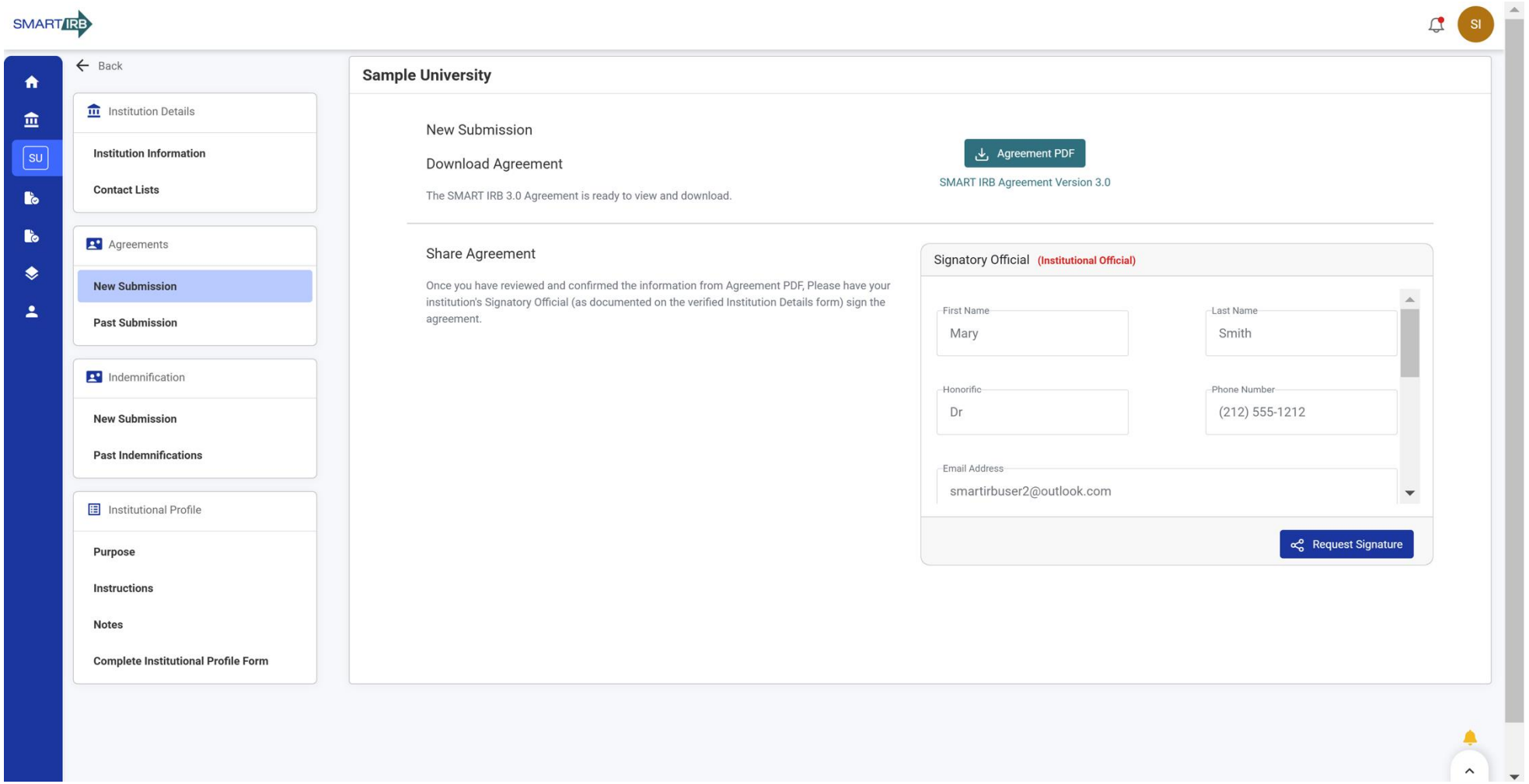
The SMART IRB Reliance Agreement (V3.0) becomes available on March 17, 2025. **As of this date, signatory institutions will need to join SMART IRB Reliance Agreement V3.0 to initiate any new reliance arrangements under the SMART IRB Agreement**. Participating Institutions may also choose to join the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

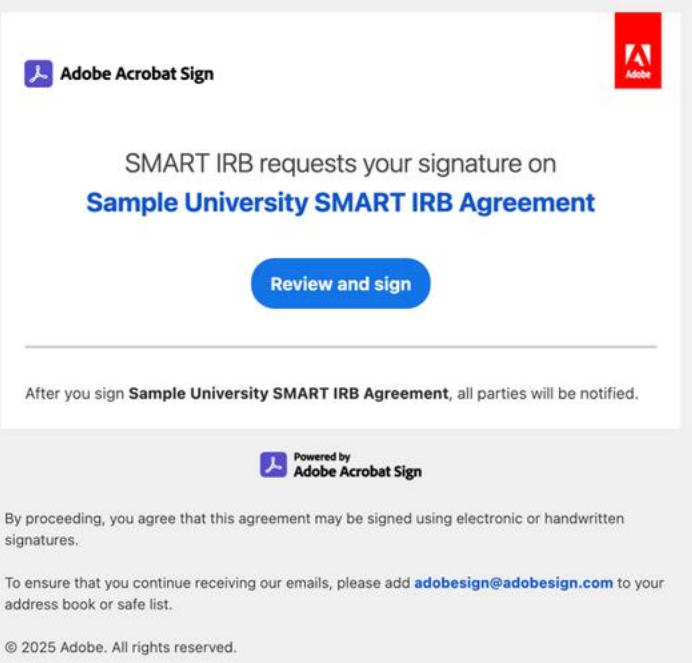
Reviewing & Updating Institution Information

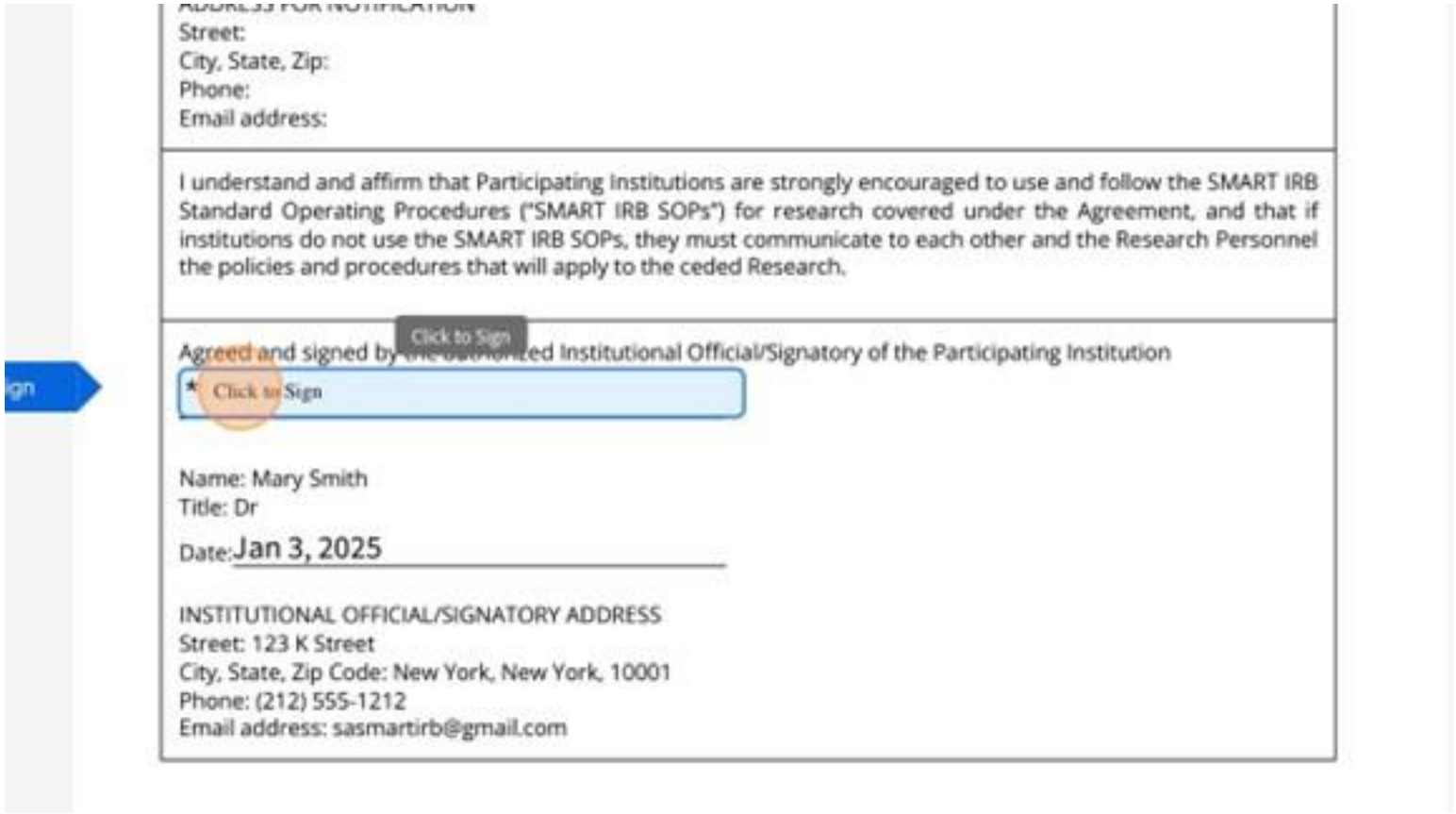


Sending Agreement to IO for Signature

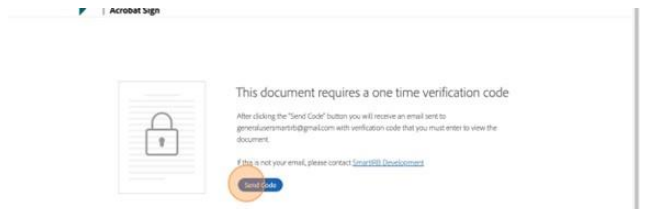


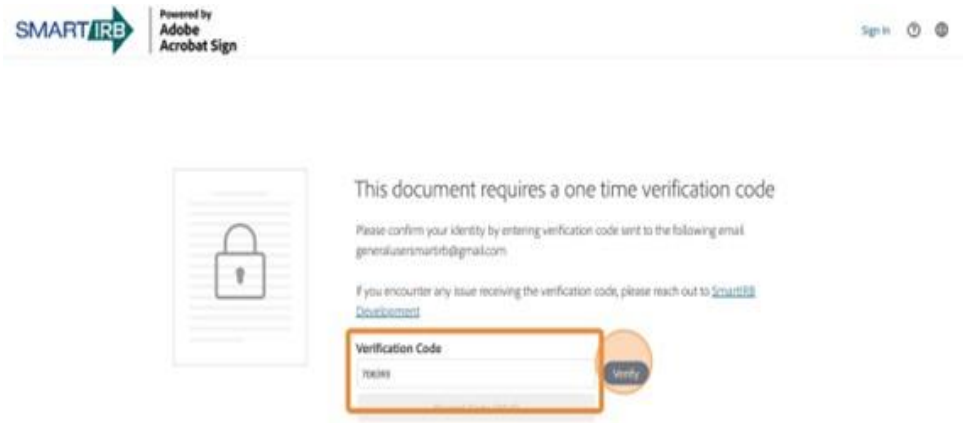
Signature Request Process





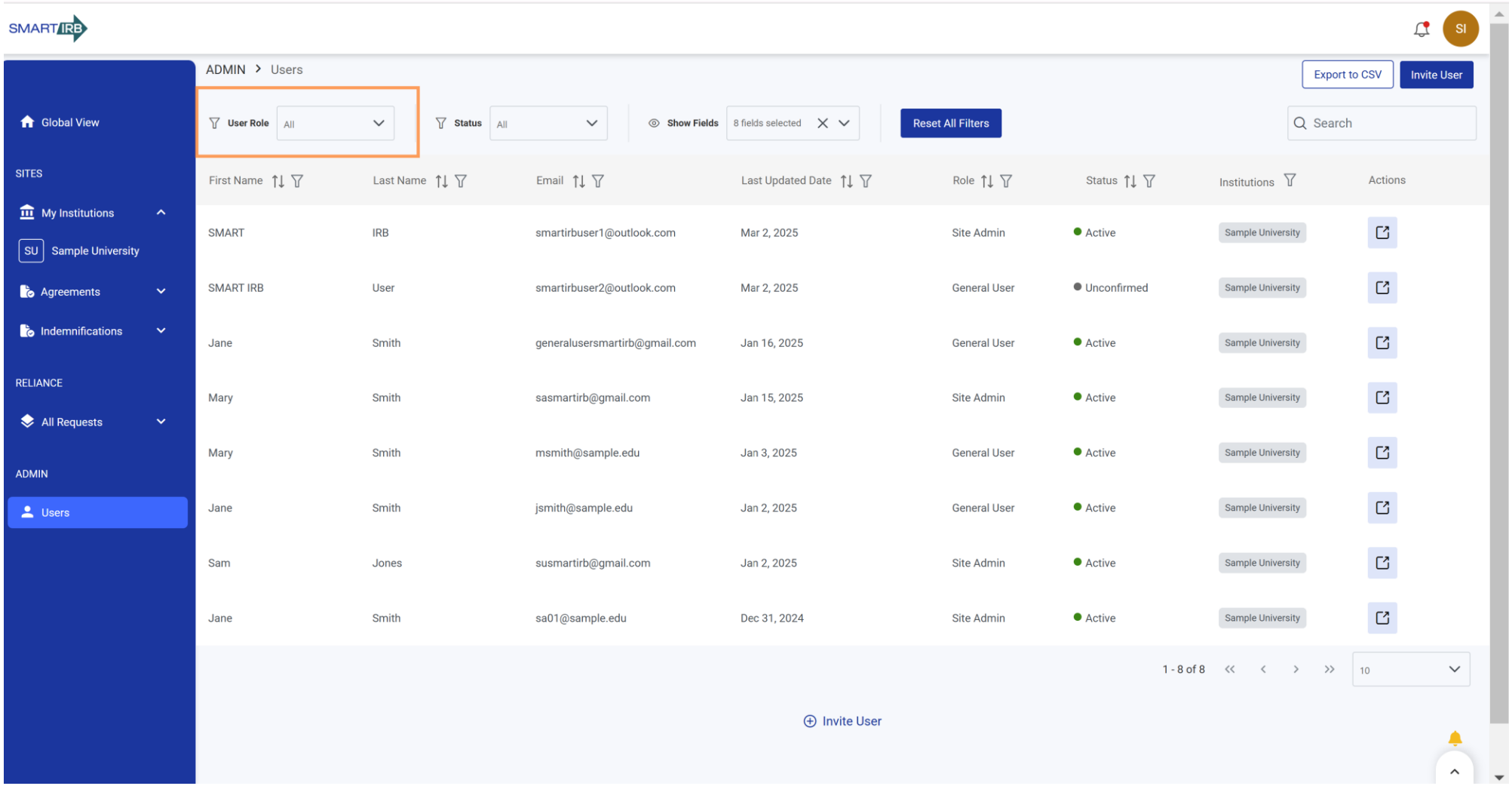
Signature Request Process, continued



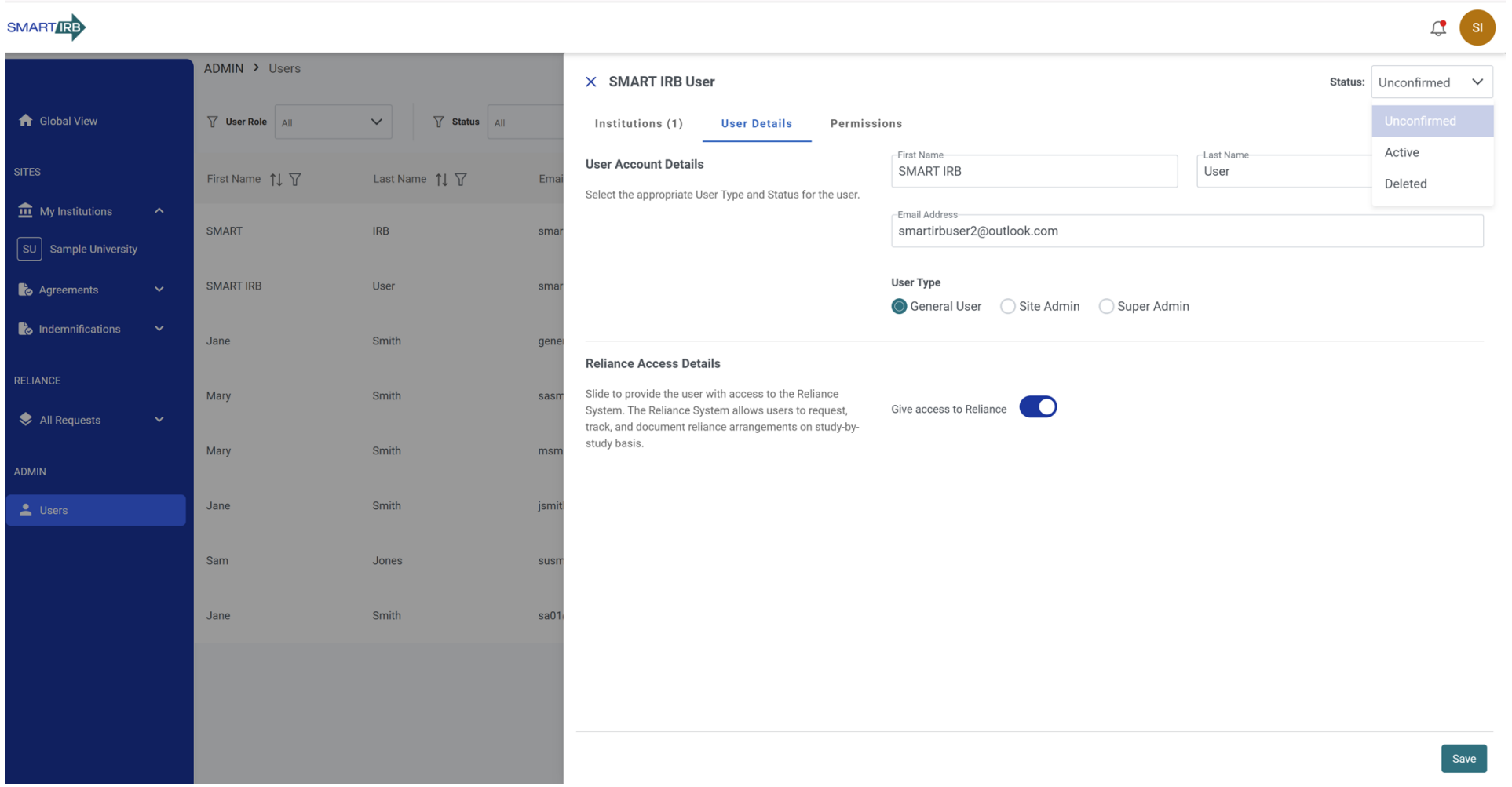


SMART IRB Reliance System: User Dashboard & Permissions

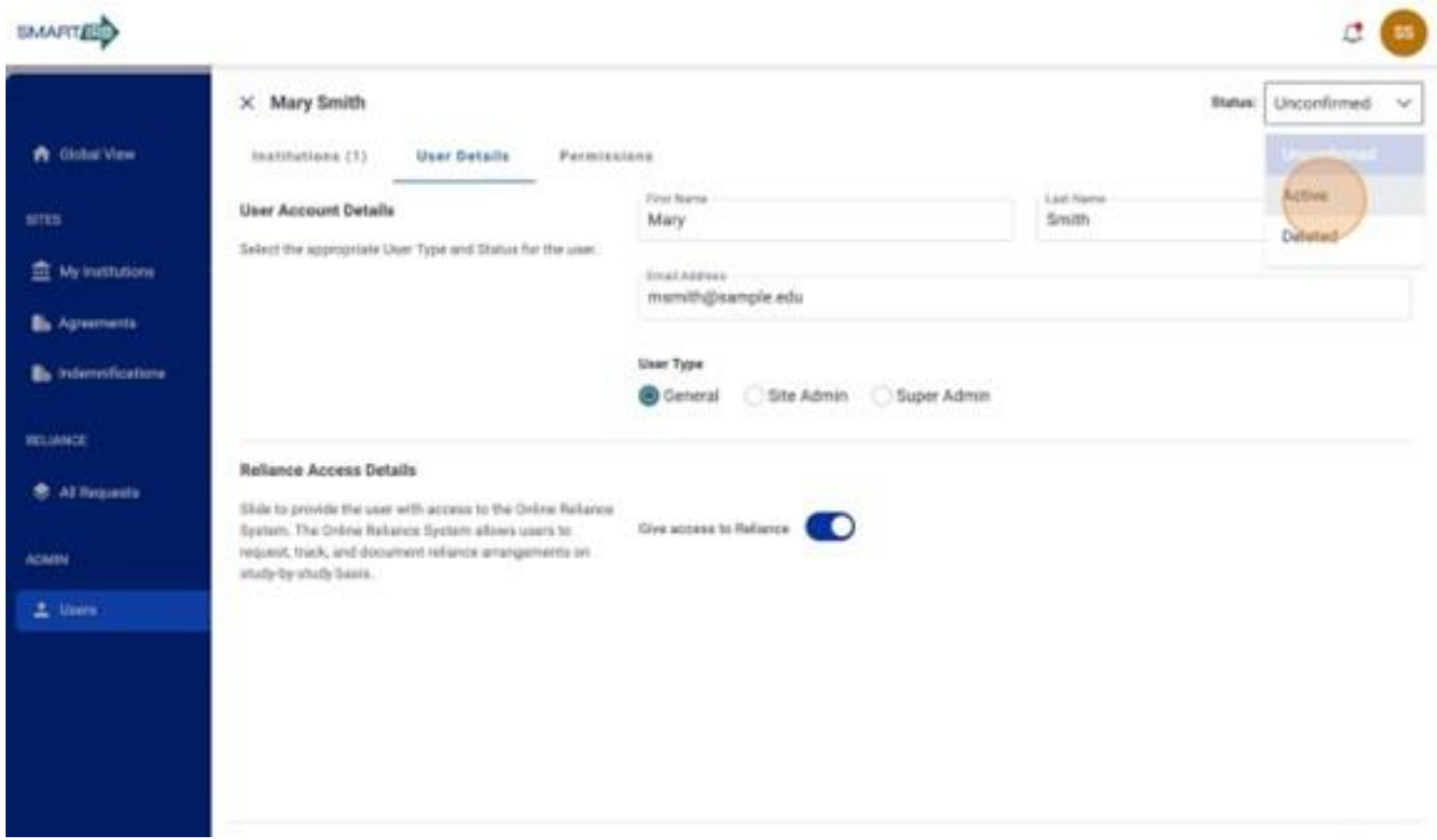
User Dashboard



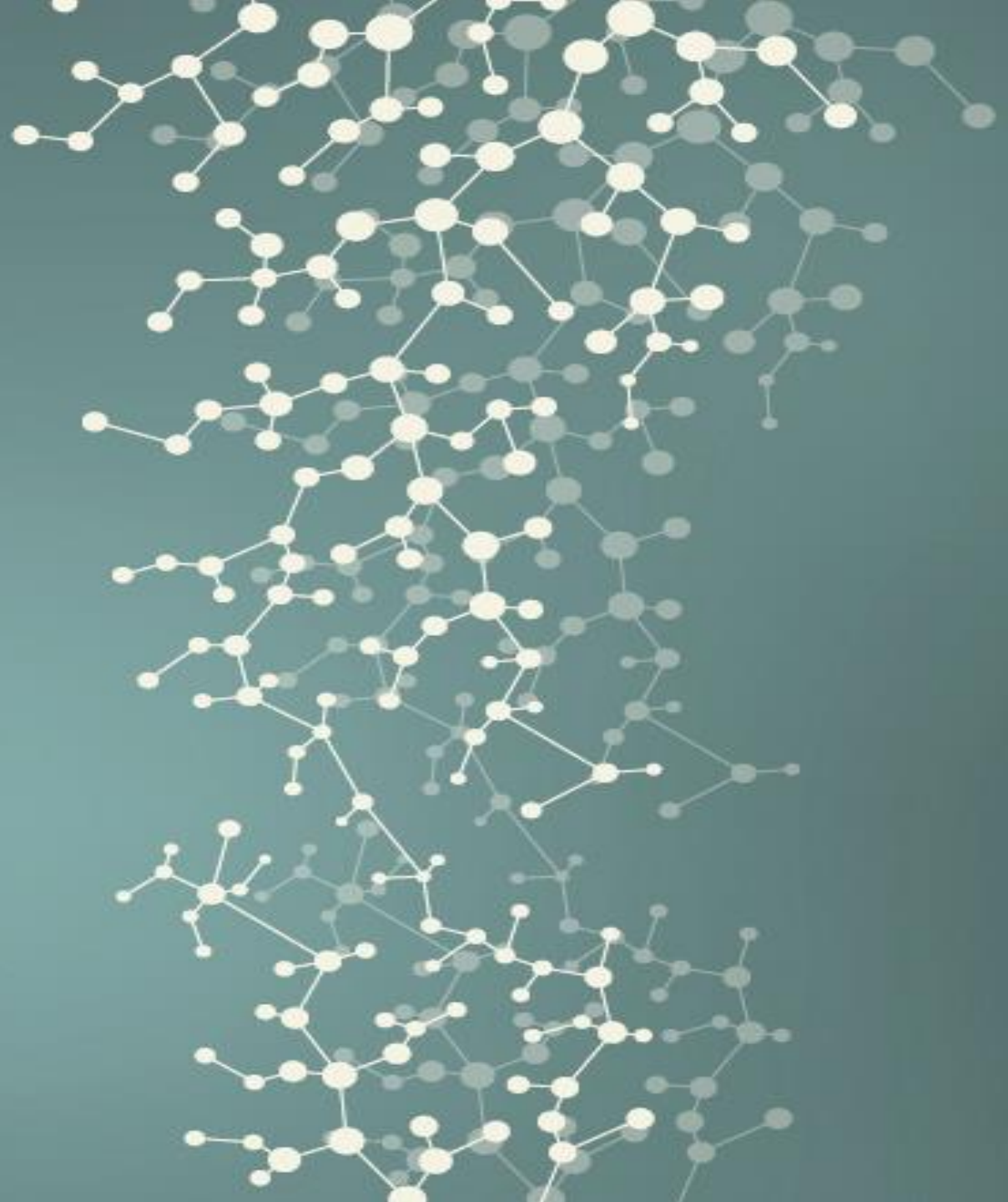
User Profiles



Activating Users

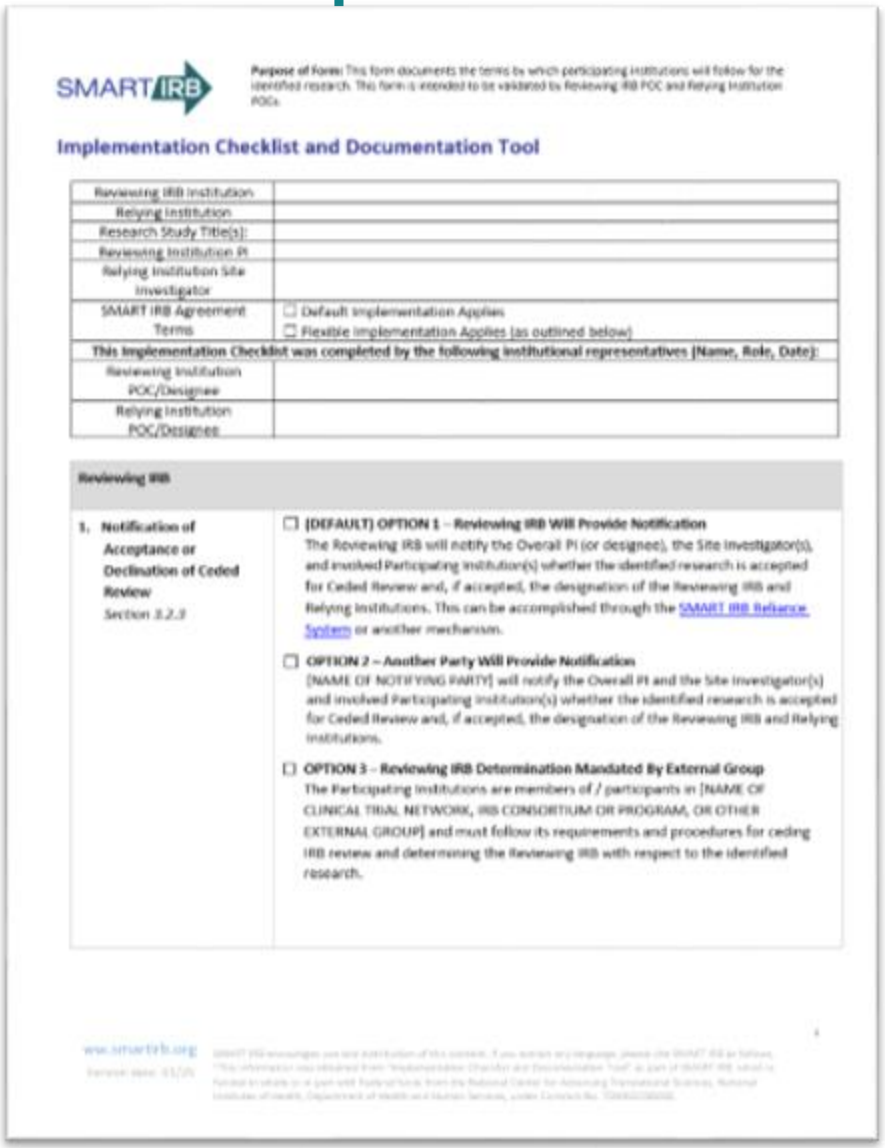


SMART IRB Checklists & Templates



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	☐ Default Implementation Applies ☐ 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	

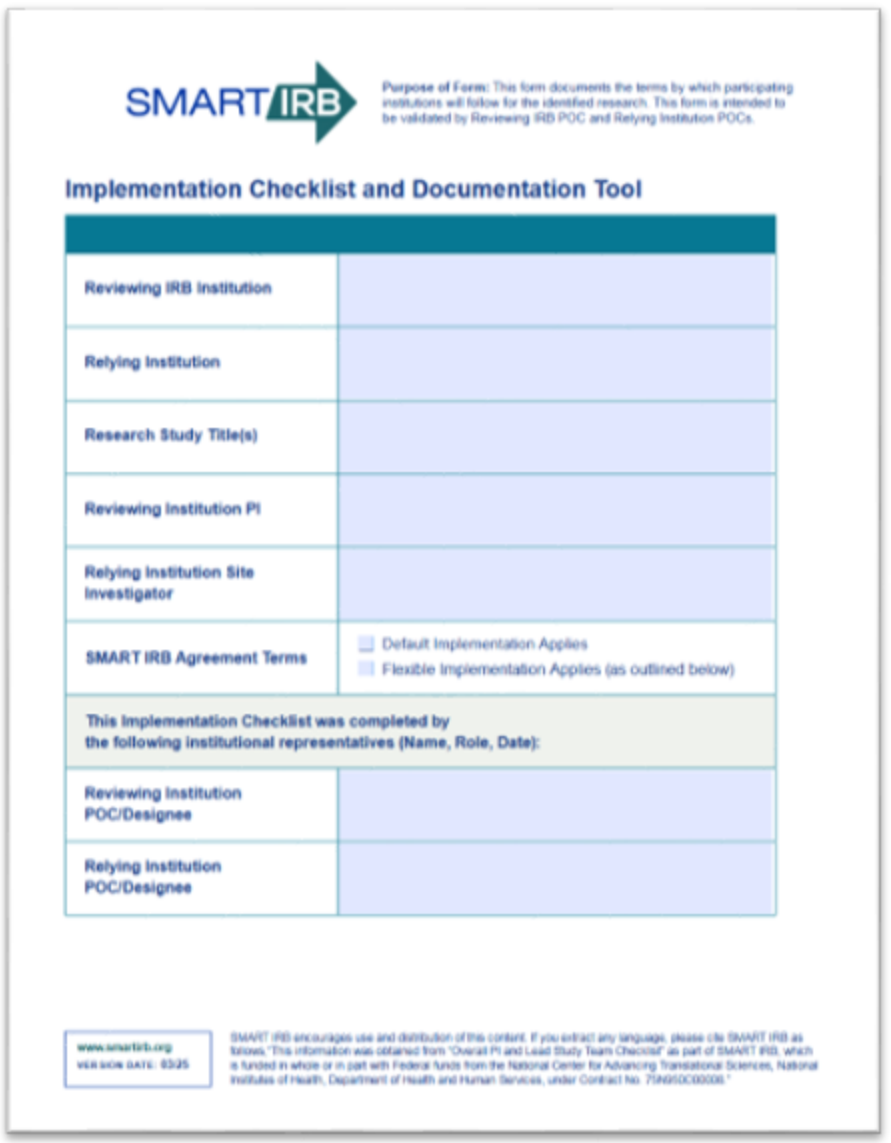
Reviewing IRB

1. **Notification of Acceptance or Declination of Ceded 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 Ceded Review and, if accepted, the designation of the Reviewing IRB and Relying Institutions. This can be accomplished through the SMART IRB Reliance 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 Ceded 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 ceding IRB review and determining the Reviewing IRB with respect to the identified research.



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	☐ Default Implementation Applies ☐ 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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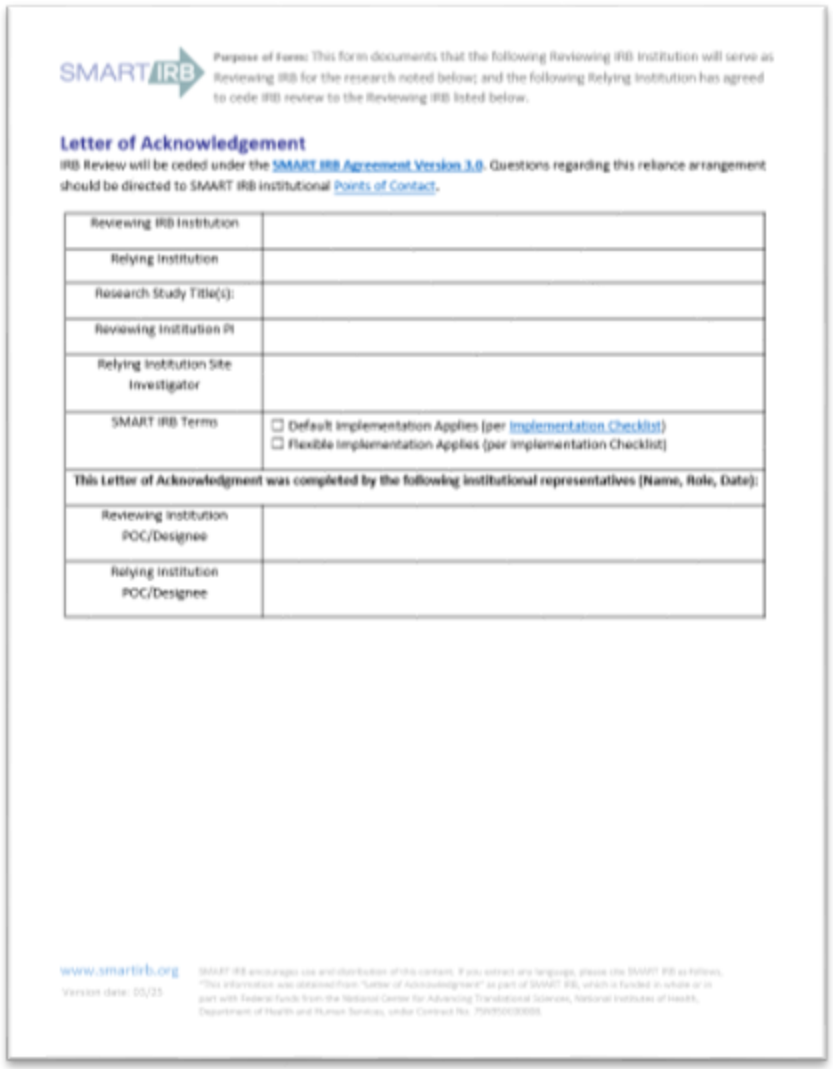
VERSION DATE: 03/25

SMART IRB encourages use and distribution of this content. If you extract any language, please cite SMART IRB as follows: "This information was obtained from "Overall PI and Lead Study Team Checklist" as part of SMART IRB, which is 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. 75N95019C00006."

Resources: Letter of Acknowledgment (3 options)



SMART IRB

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	☐ Default Implementation Applies (per Implementation Checklist) ☐ Flexible Implementation Applies (per Implementation Checklist)
This Letter of Acknowledgment was completed by the following institutional representatives (Name, Role, Date):	
Reviewing Institution POC/Designee	
Relying Institution POC/Designee	

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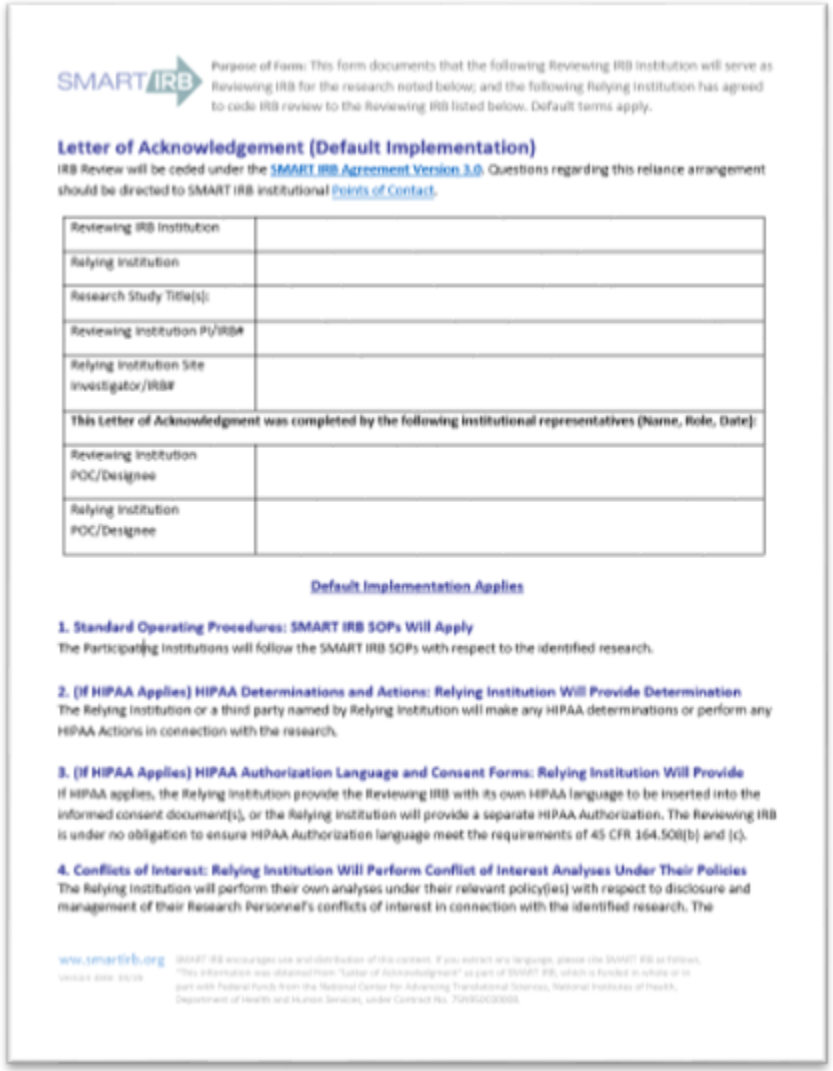

SMART IRB

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#	
This Letter of Acknowledgment was completed by the following institutional representatives (Name, Role, Date):	
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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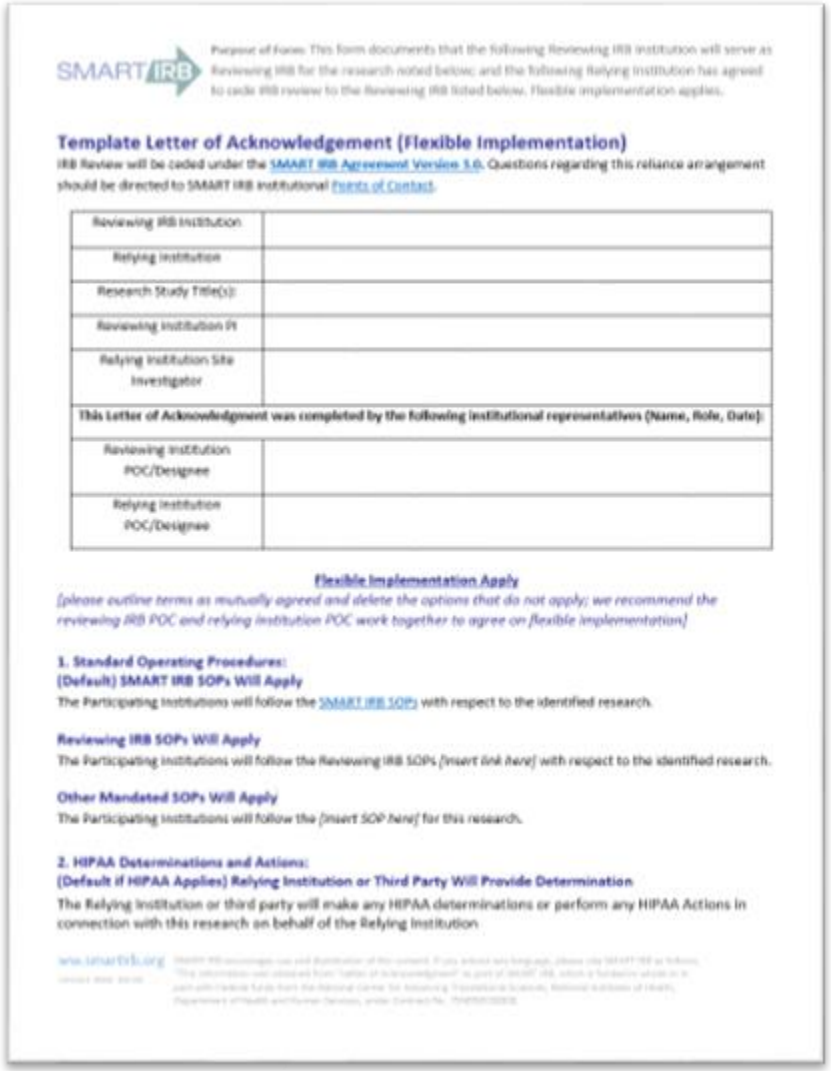

SMART IRB

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	
This Letter of Acknowledgment was completed by the following institutional representatives (Name, Role, Date):	
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.

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Resources: Communication Plan

SMART IRB

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.*

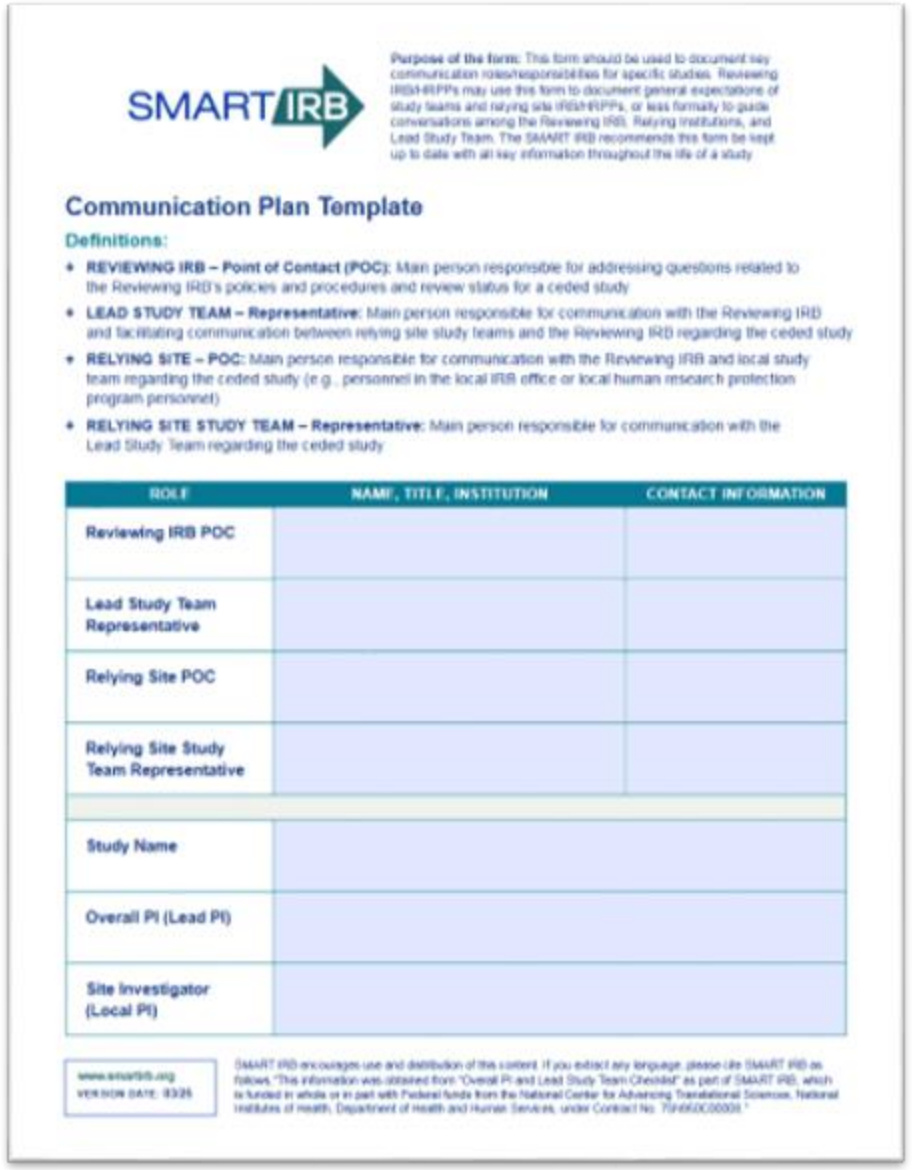
Communication Plan Template

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
CONFLICT OF INTEREST: Providing applicable Relying Site Conflict of Interest management plans to the Reviewing IRB	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
STUDY TEAM TRAINING & QUALIFICATIONS: Providing confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
LOCAL CONSIDERATIONS: 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	☐ Relying Site Study Team* ☐ Relying Site POC* ☒ Lead Study Team ☐ Other, specify:	

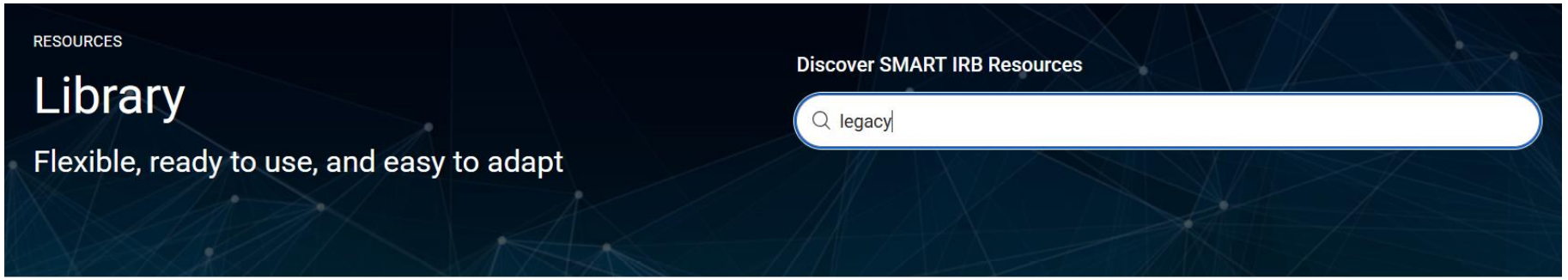


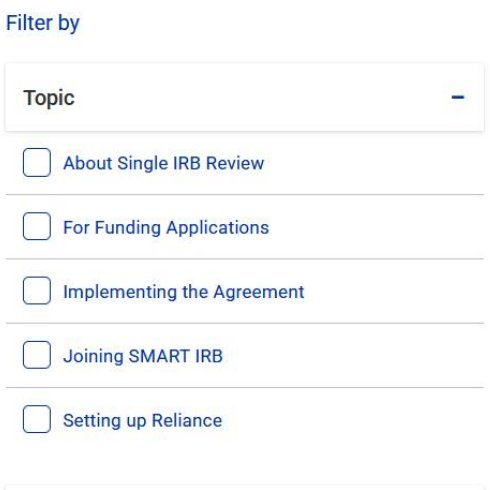
SMART IRB Standard Operating Procedures

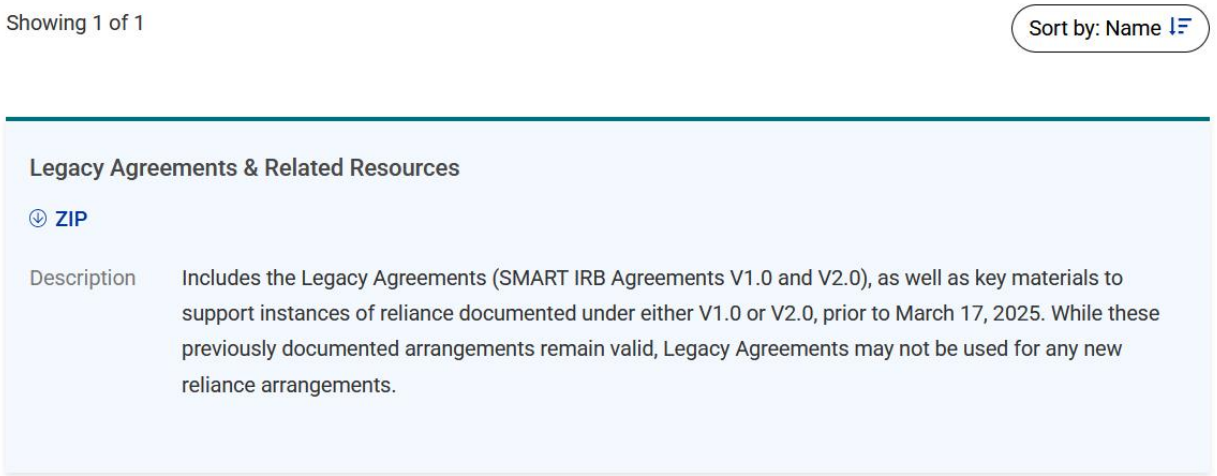
- SMART IRB SOPs updated for V3.0
- SOPs apply unless alternative SOPs are specifically documented
- Available via ‘Resources’ -> ‘Resource Library’ on www.smartirb.org

“Legacy” and Legacy Documents

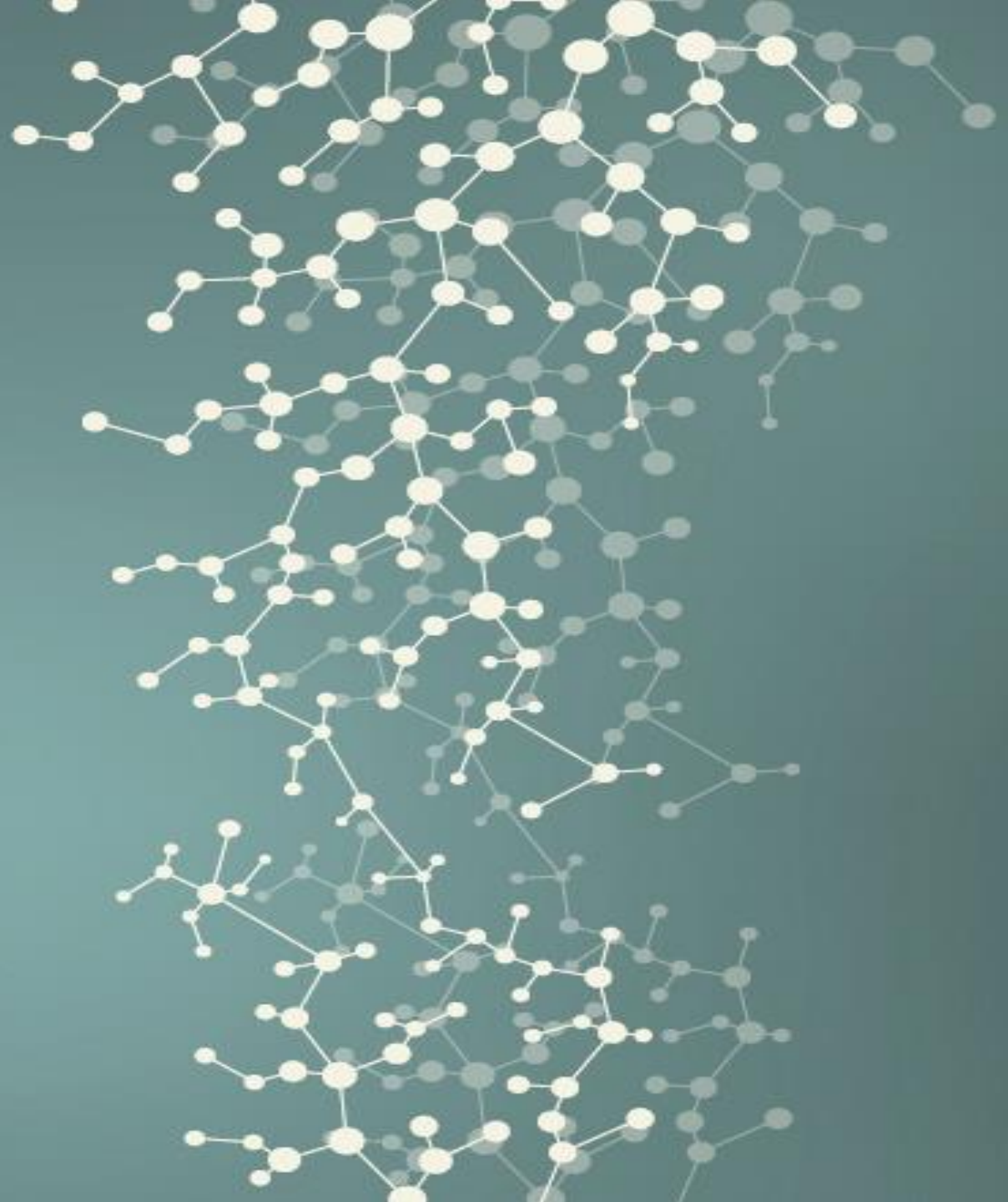
- “Legacy” refers to V2.0 or V1.0 institutions and materials
- Key documents kept for these arrangements including SOP, FAQ, checklists, and more!
- Additional materials available upon request







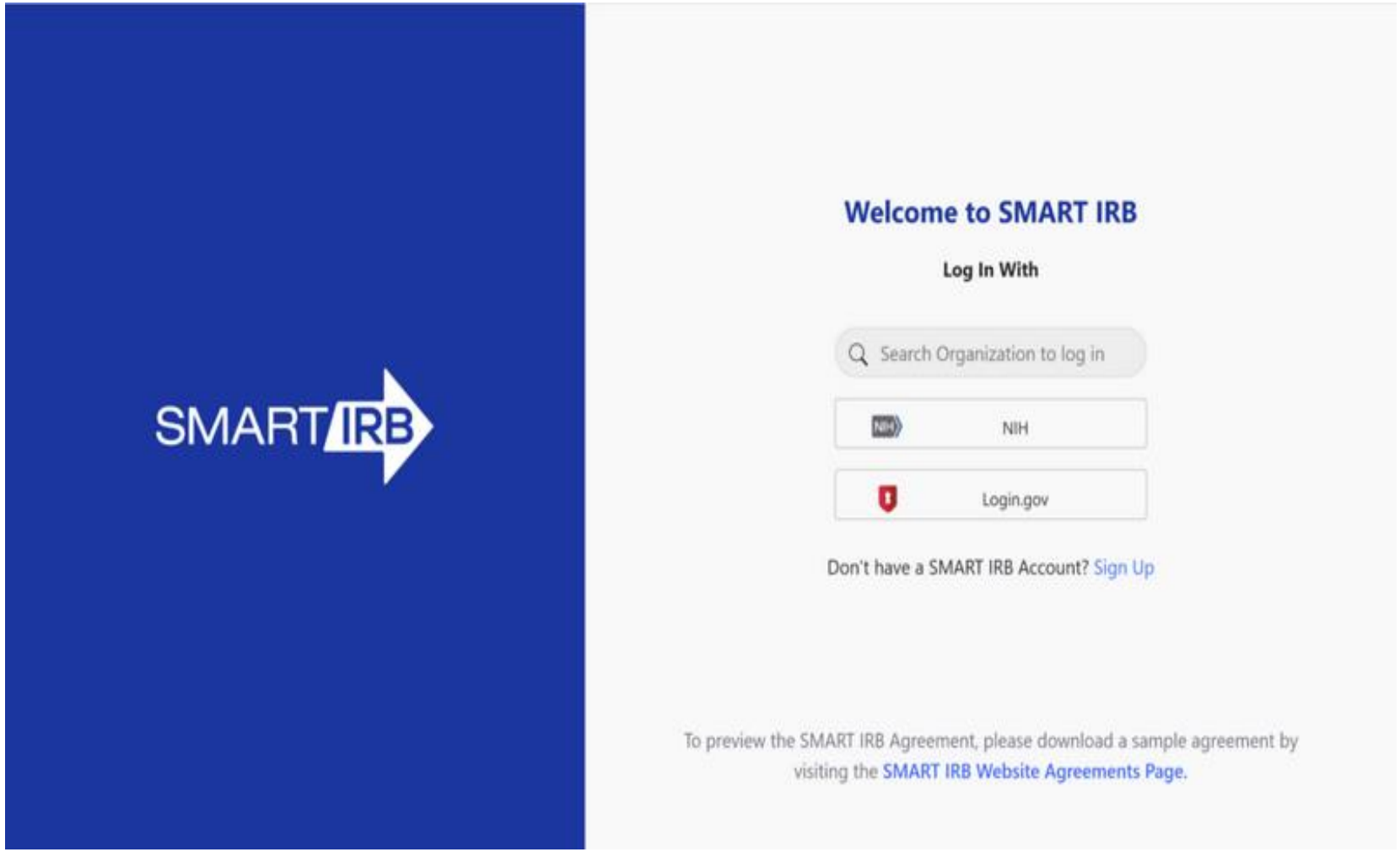
Troubleshooting: Reliance System



- **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

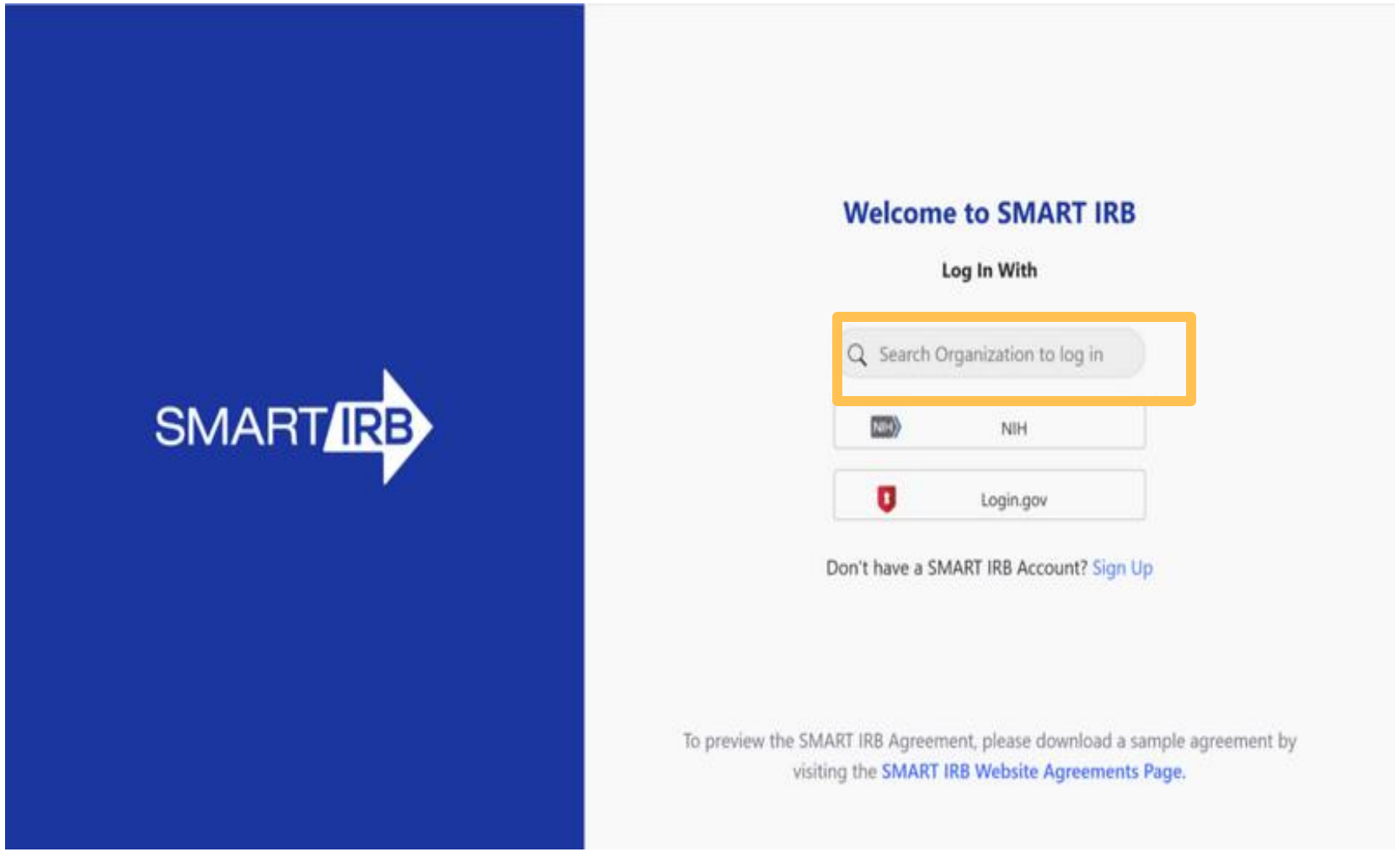


SMART IRB Reliance System has 3 Options to Log In

- **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.

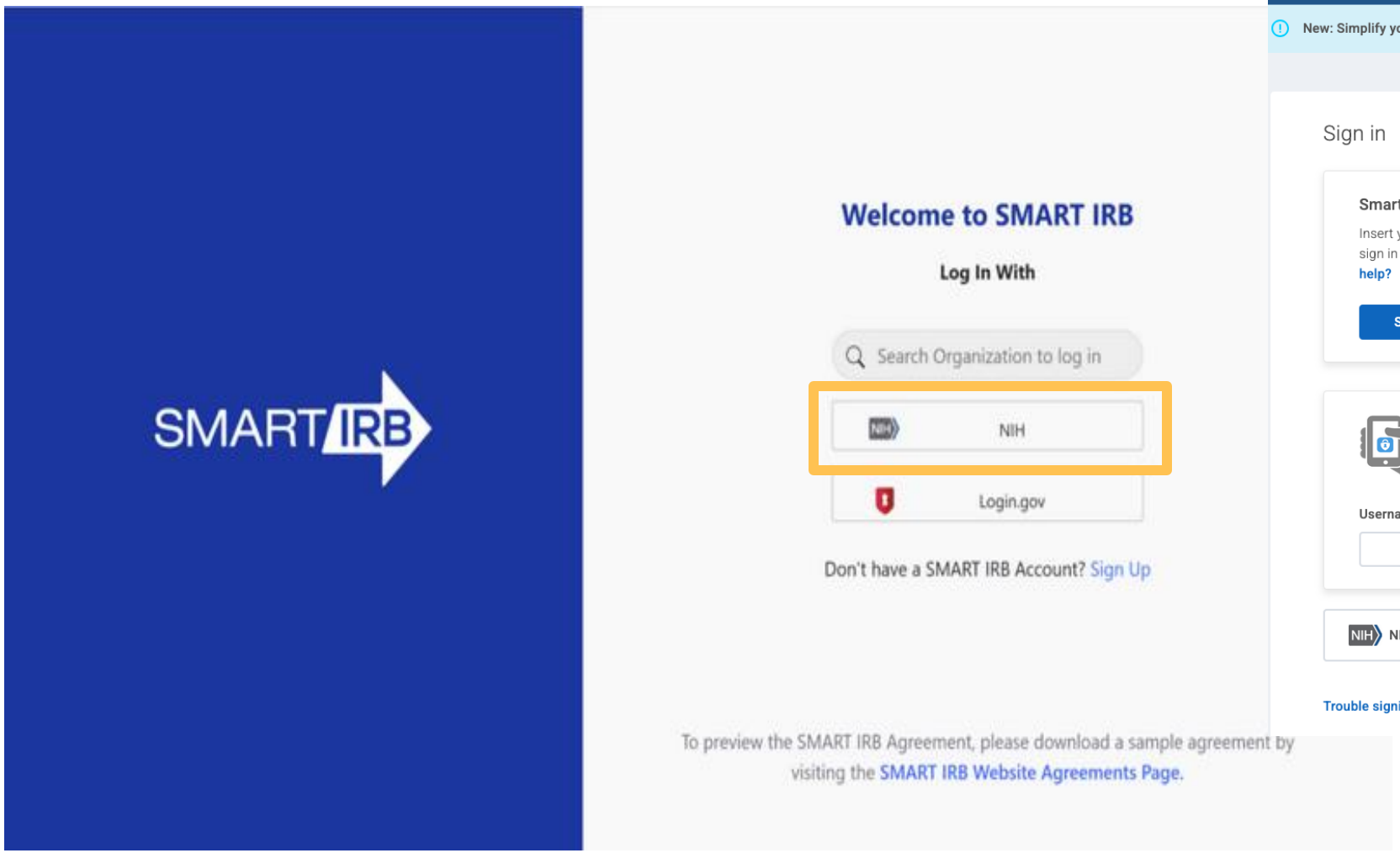
Registration and Login: SSO

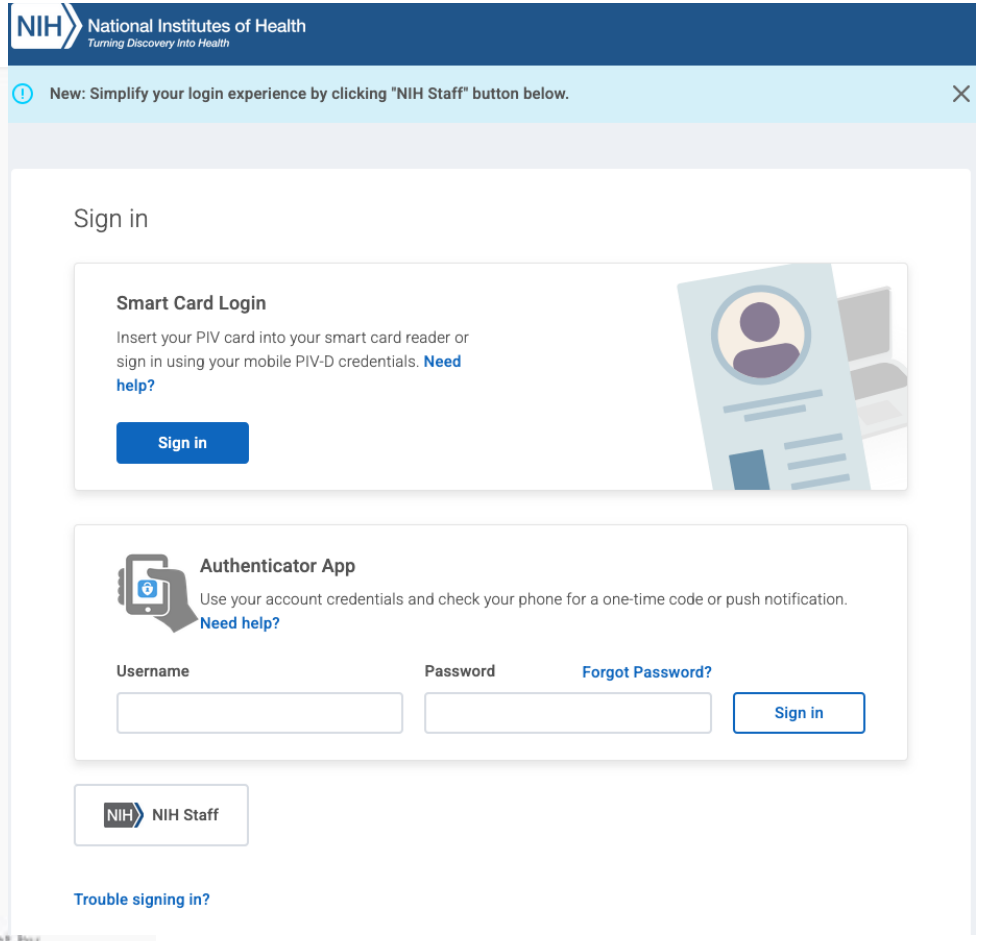


Log In with SSO

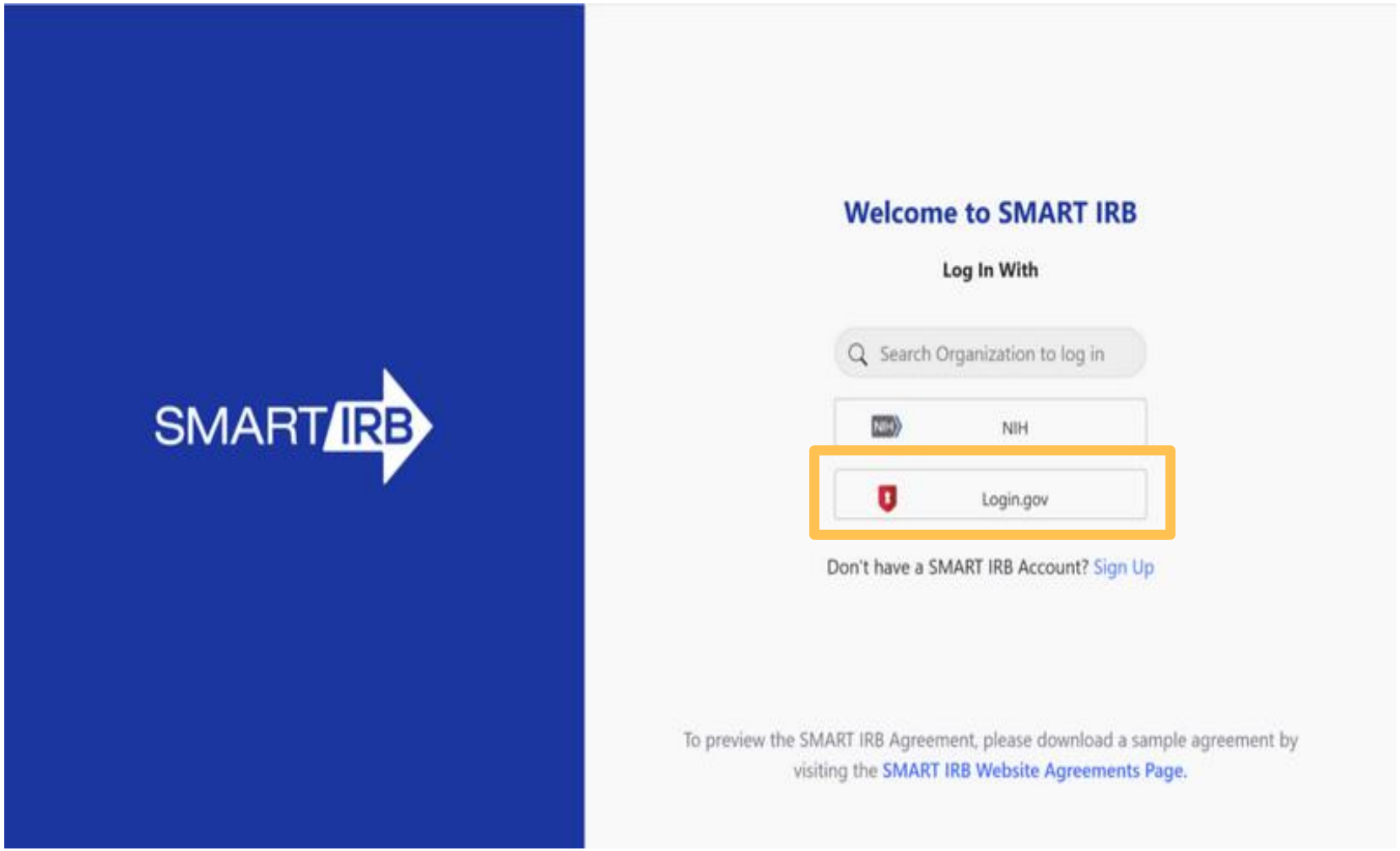
- Find Institution in search box
- List is generated from InCommon Federation network database
- All SSO may be not available
- If SSO email does *not* match your SMART IRB system email, please contact the Help desk for assistance.

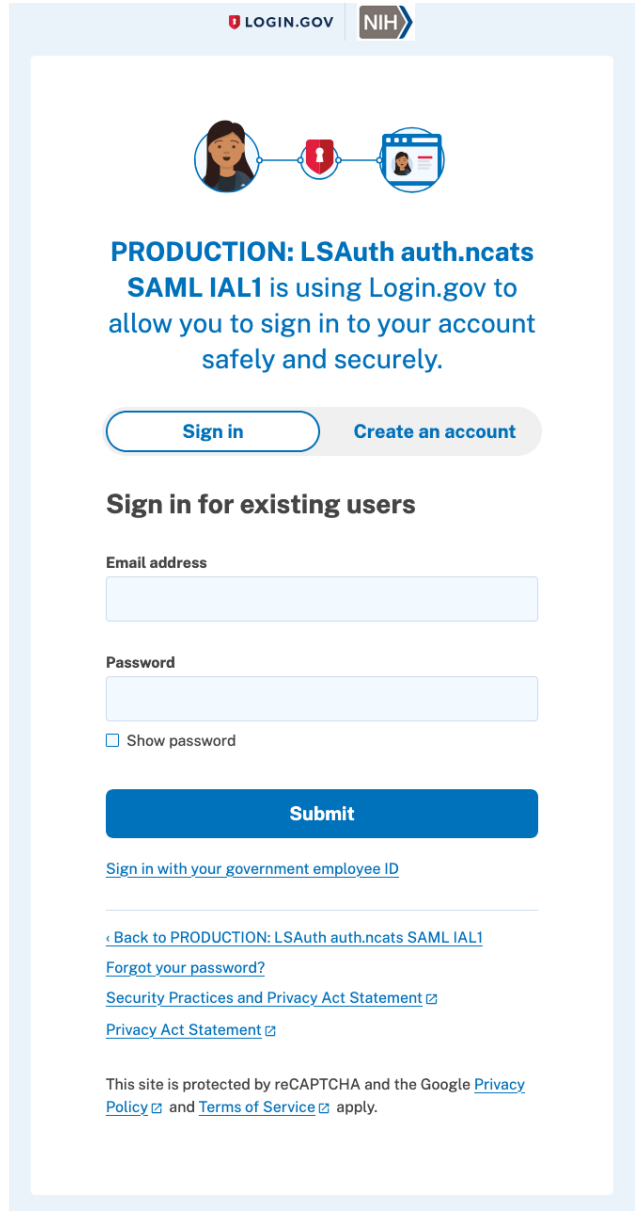
Registration and Login (NIH)





Registration and Login (Login.gov)





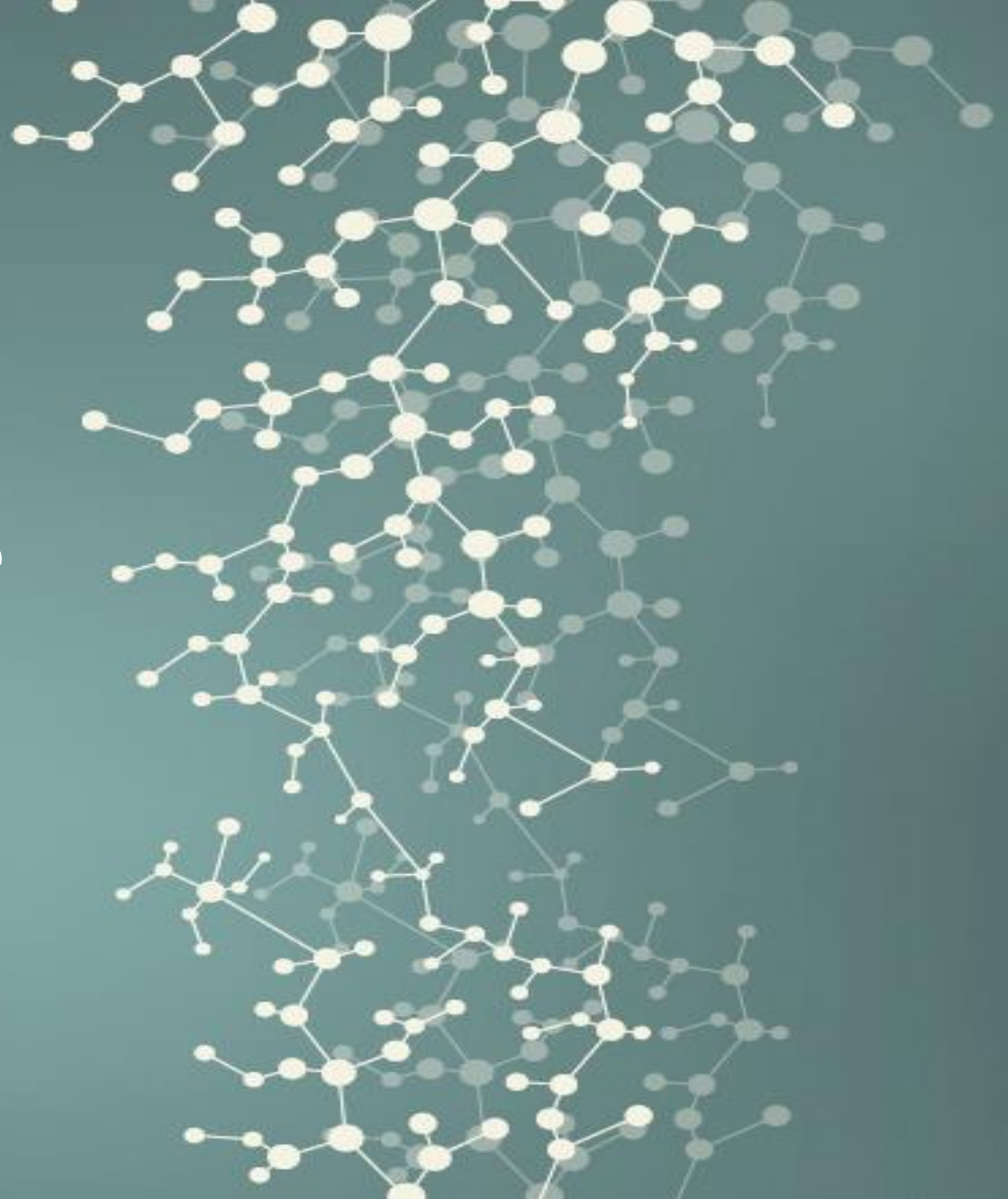
Troubleshooting: Common Problems and Solutions

- 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
- 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 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