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.

Before we begin

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.

SMART IRB: Your Roadmap to Single IRB Review

Agreement

Providing a common, comprehensive framework reliance agreement with 1420+ signatories across the United States

Reliance System

Your home to request, document, and track reliance requests with fellow Participating Institutions in one centralized place

Harmonization

Strategically align your institution's policies and procedures with industry best practices

Resources & Education

Explore an ever-growing portfolio of customizable resources for your institution's reliance program

Support

Need assistance? Check out our Support Center, Ambassadors, and Helpdesk

Meet Your SMART IRB Ambassadors!

Polly Goodman
Harvard Catalyst

Nichelle Cobb
AAHRPP

Jeremy Lavigne
Harvard Catalyst

Ada Sue Selwitz
University of Kentucky

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

Aaron Kirby
Harvard Catalyst

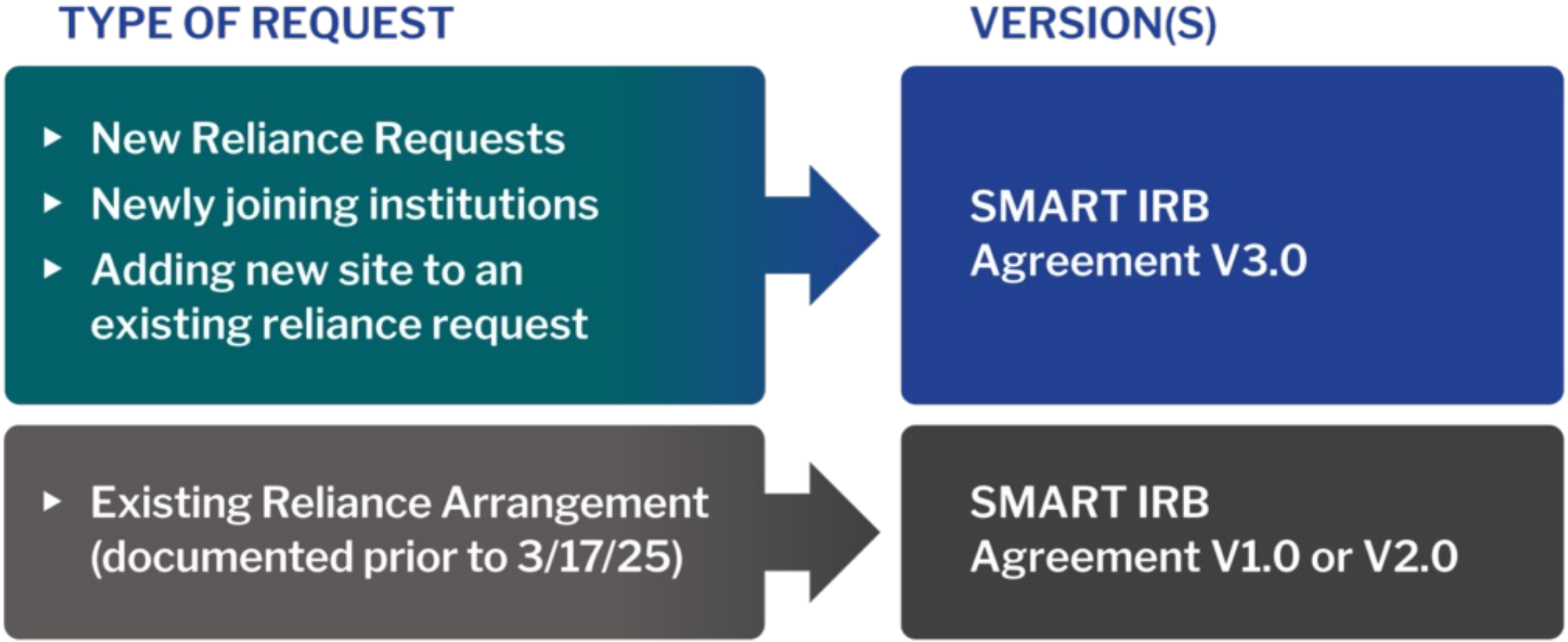
Kathy Lawry
AAHRPP

Stacey Goretzka
Ind. Consultant

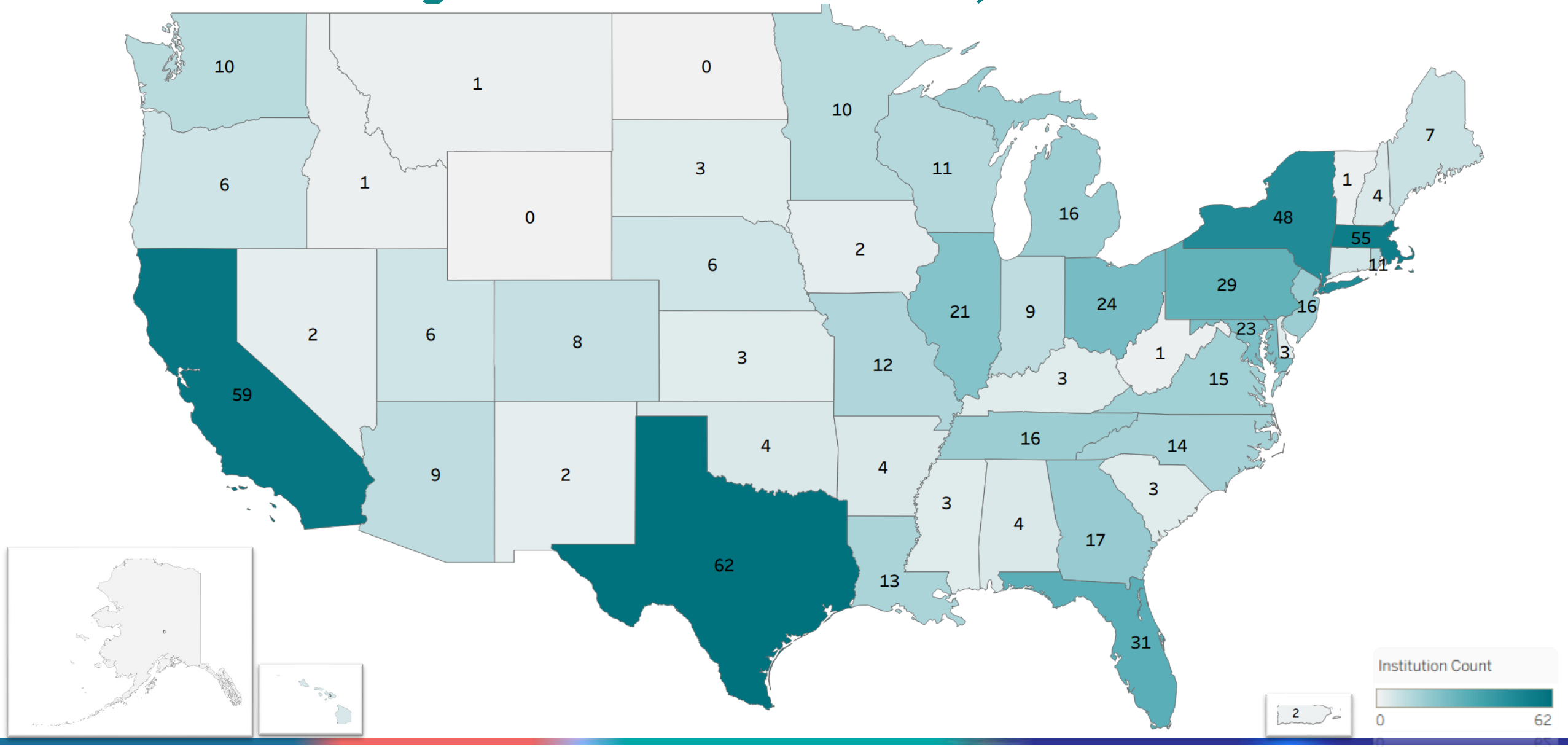
Carissa Minder
Washington University in St. Louis

SMART IRB: Versions and New Reliance Requests

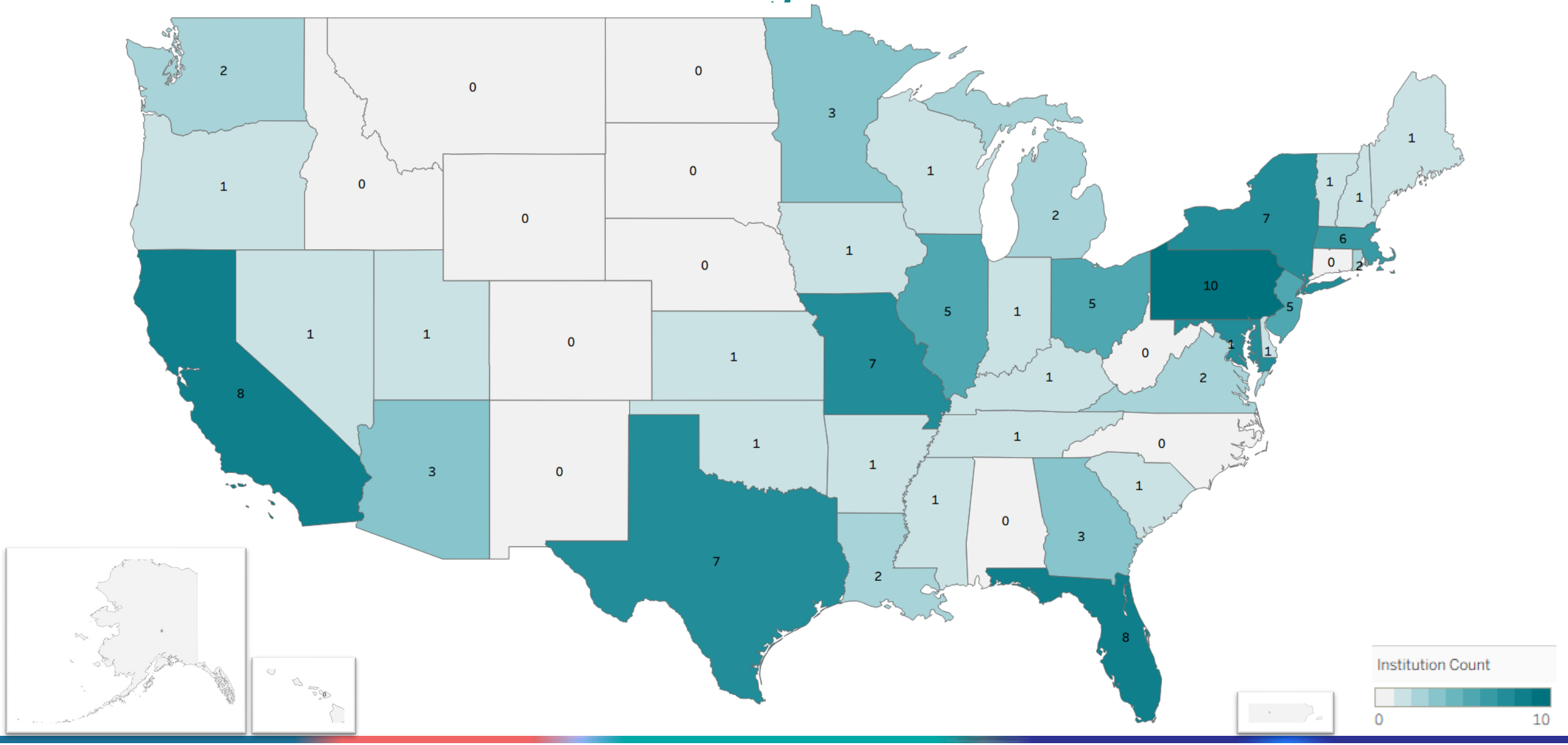
- Version 3.0 is the only option to join and use for new reliance arrangements
- Check the Participating Institutions list for updated list of V3.0 institutions



623 Version 3.0 Signatories across 47 states, DC + Puerto Rico!



111 Indemnification Addendum Signatories across 36 states + DC!



New SMART IRB Resources!

Recent publications include:

- Relying on an External Single IRB: FAQs for Relying Site Study Teams
- Guidelines for Relying Site Study Teams: Enhancing sIRB Process Standardization
- SMART IRB Reliance System: New Institution Onboarding Checklist

Stay tuned for:

- Harmonization: Exemptions – Public Comment Period
- Harmonization: Local Considerations - Publication

SMART IRB Reliance System Patch, 12.11.25

Primary focus on e-mail correspondence

- Broadened ‘cc’ recipients on most e-mails, including research personnel, institutional group e-mails (from ‘institutions’ tab), etc
- Fixed bug where other sites would be included on site-specific correspondence (e.g. site-specific determinations)
- Fixed bug where ‘site willing to rely’ e-mail was not being sent
- Fixed bug where ‘site reminder’ e-mail was not being sent
- ‘Request Revisions’ e-mail will now include the specific revisions requested
- ‘Accept Determination’ bug fixed (no need to select ‘additional comments’)

Next Reliance System patch anticipated for January 2026, stay tuned!

Upcoming Events

Next SMART Talk

You Say Non-Compliance, I Say Noncompliance: Exploring Reportable Event Harmonization in a Single IRB World

January 21, 2026, 2-3:30 pm EST

Venturing into Version 3.0: Tips for Successfully Implementing the Revised SMART IRB Agreement

Moderator:
Nichelle Cobb, SMART IRB Ambassador At Large + Senior Advisor

Panelists:
Jeremy Lavigne, Senior Officer, SMART IRB + SMART IRB Ambassador
Carissa Minder, Associate Director, HRPO, Washington University in St. Louis + SMART IRB Ambassador
Sarah Shade, IRB Analyst III - Reliance Specialist, Children's Hospital of Philadelphia
Jamie Wunderle, Assistant Director, IRB Reliance, University of Chicago Medicine

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Version 3.0 Changes

SMART IRB Version 3.0: Four Core Aims

Version 3.0 was developed to:

- Address feedback from current and potential Participating Institutions
- Fully reflect changes to IRB review requirements in the 2018 Common Rule
- Enable additional federal departments/agencies to participate in the Agreement
- Establish an optional common Indemnification addendum

Version 3.0 vs. Legacy (V1.0/V2.0)

Version 3.0

- Federal Assurance required (from any US governmental agency/dept)
- SMART IRB SOPs apply unless specifically documented otherwise
- HIPAA: Relying institution in driver's seat for their own HIPAA decisions
- Common Indemnification Addendum

Legacy

- Federalwide Assurance required (HHS); no other assurances accepted
- No specific requirement to document; SMART IRB SOPs encouraged
- HIPAA: Reviewing IRB in driver's seat for relying site HIPAA decisions
- No indemnification model

Version 3.0 vs. Legacy, continued

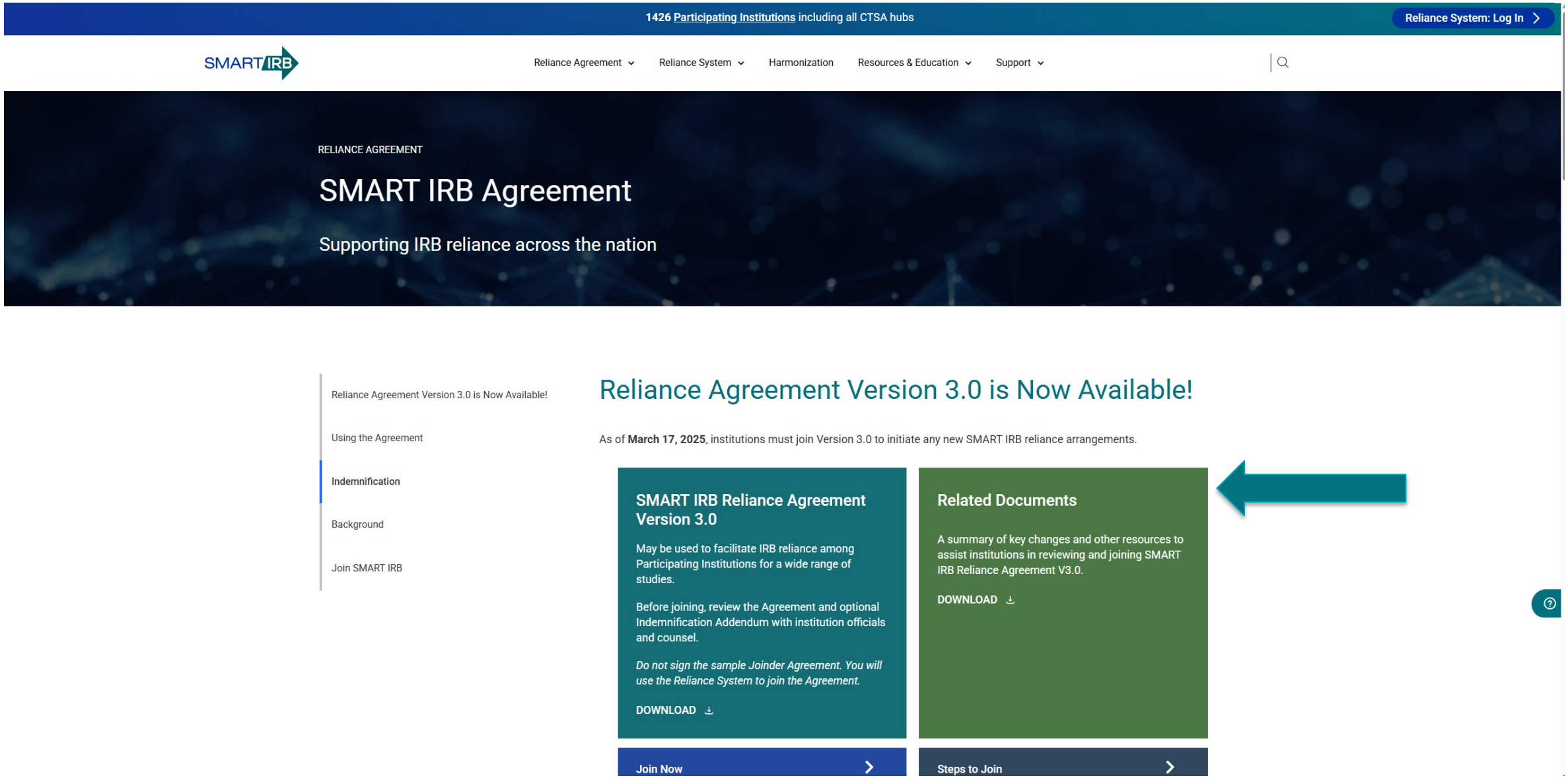
Version 3.0

- Must document when federally mandated policies/processes apply
- Reviewing IRB must consider relying institution requests for ICF changes to address institutional/legal/regulatory
- 'Good faith' provision on resolution prior to withdrawal of ceded review
- Reviewing IRB Withdrawal from Ceded Review mechanism present

Legacy

- No specific requirement to document when policies/processes apply
- Reviewing IRB controls what sections of ICF are customizable by Relying Institution.
- No specified 'good faith' provision; SMART IRB encourages cooperation
- No designated Reviewing IRB Withdrawal mechanism; SMART IRB encourages cooperation

Comprehensive List of Changes

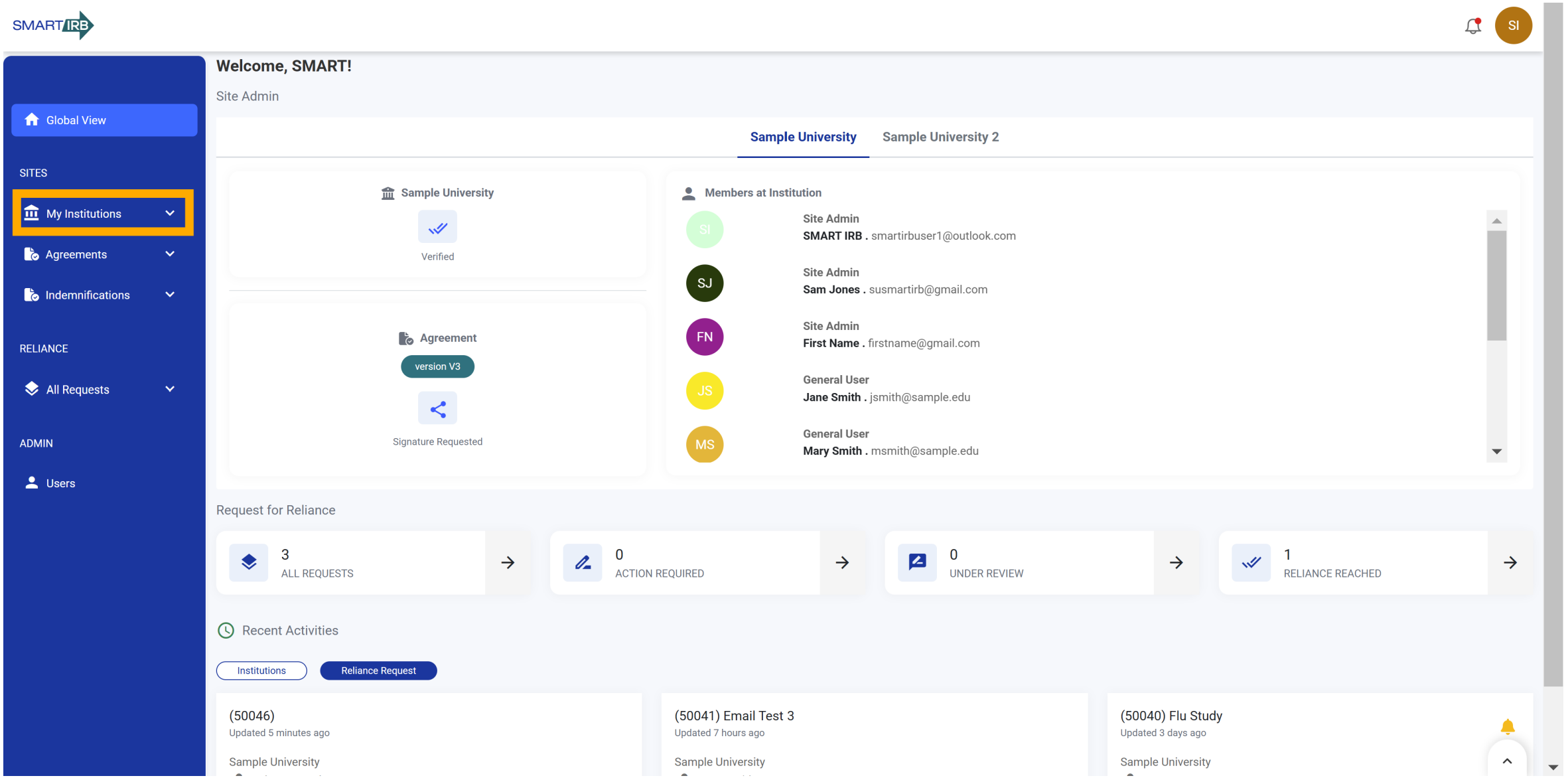


Joining SMART IRB Has Never Been Easier

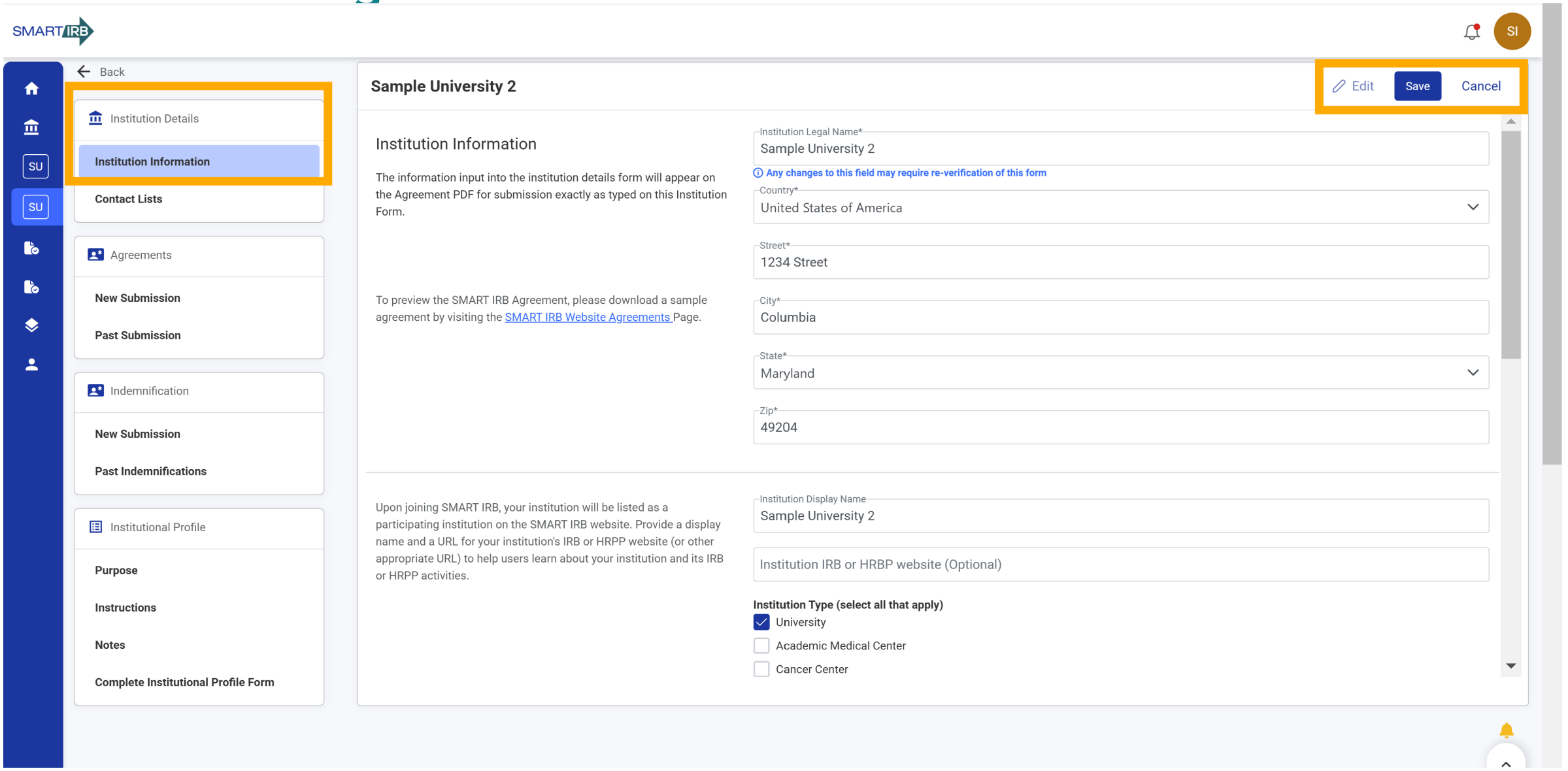
Requirements to Join SMART IRB Version 3.0:

- Active Federal Assurance (e.g. FWA)
- Designate a Point of Contact (POC)
- If institution has an IRB, initiating or completing an HRPP Quality Assessment
  - Note: This is a one-time requirement; legacy institutions do *not* need to complete this assessment again to join V3.0
  - HRPP QA Assessment does *not* require accreditation; free options include the DHHS HRPP Self-Assessment Tool

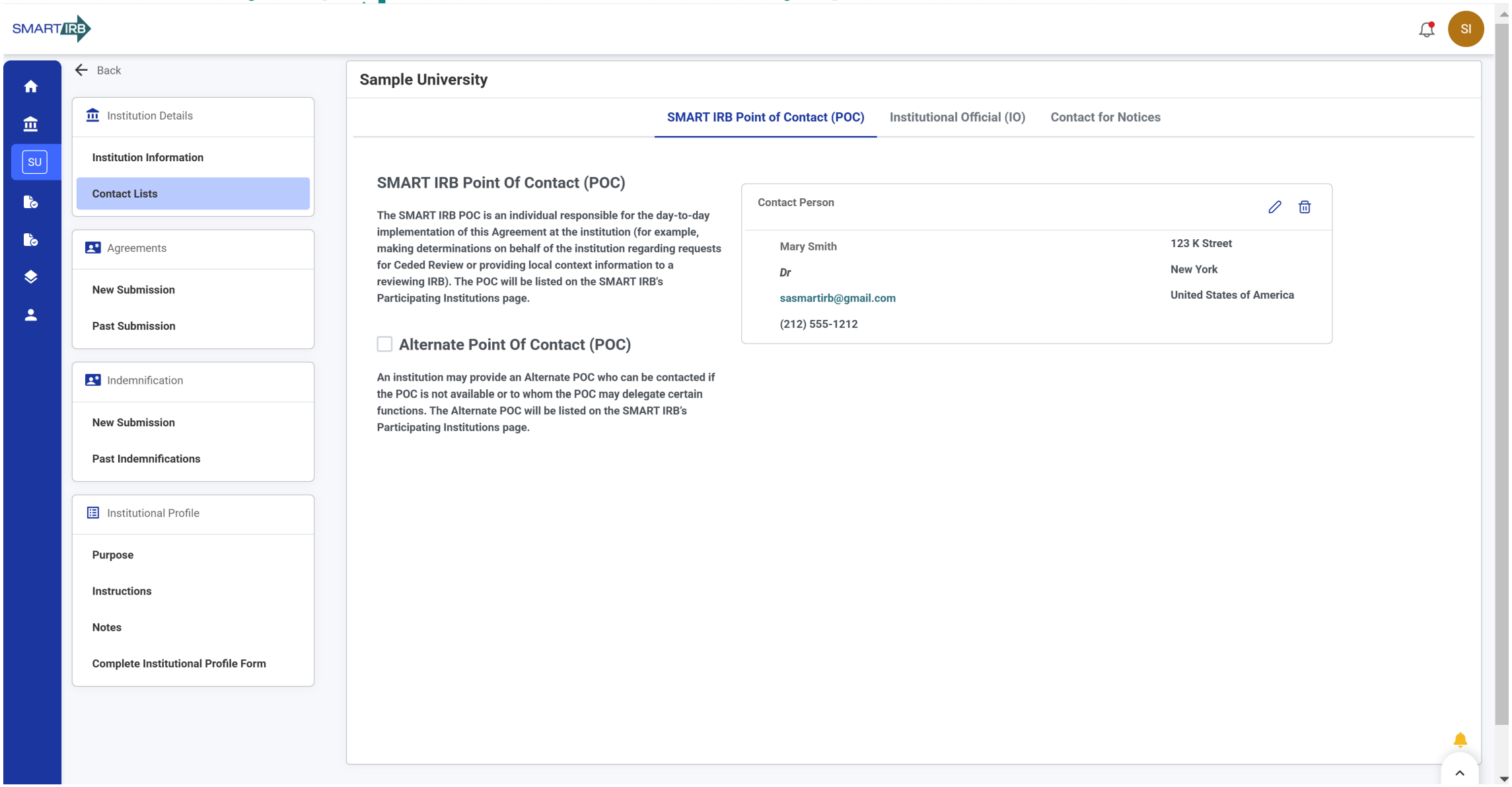
Version 3.0 Signature Process: Reliance Dashboard



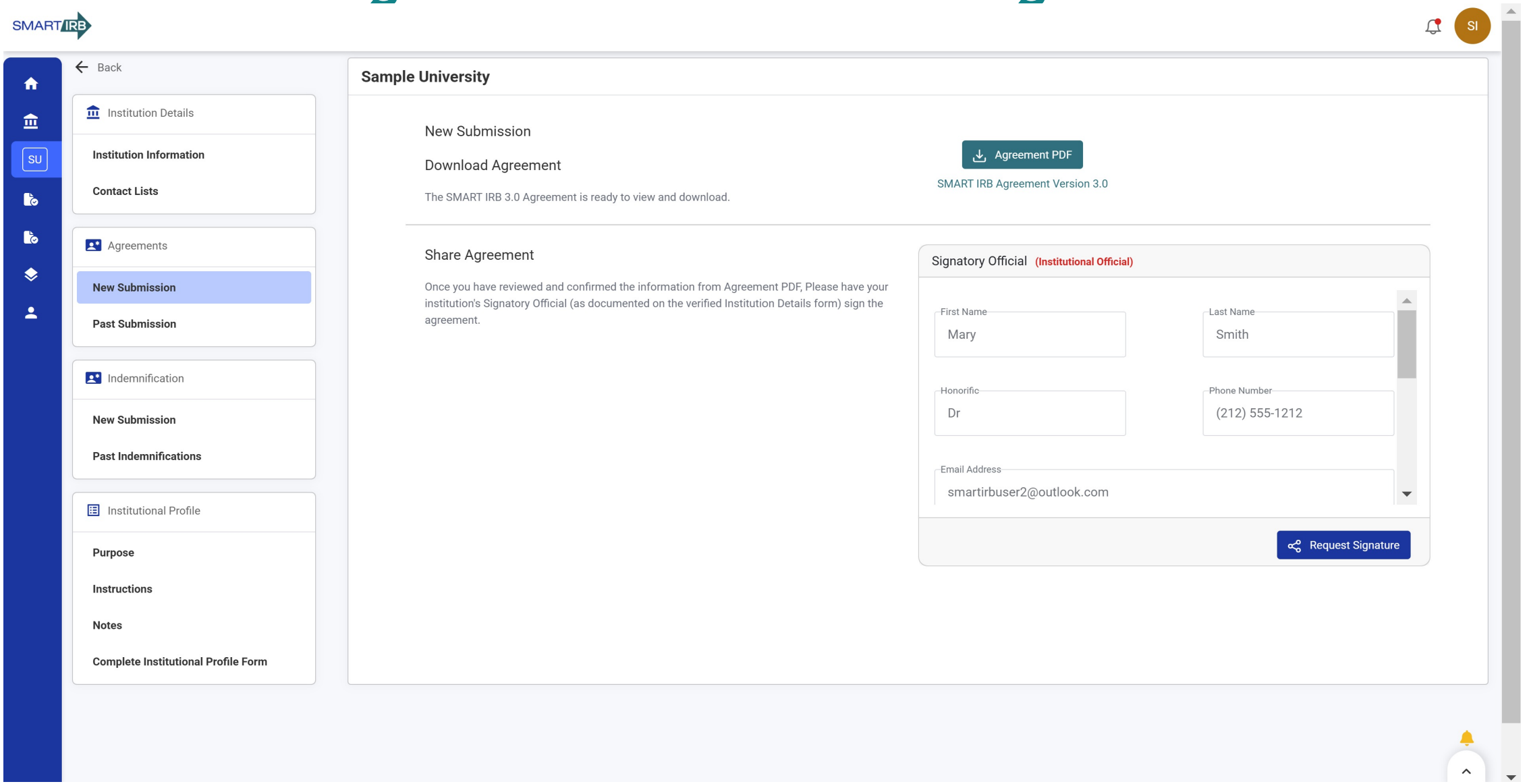
Version 3.0 Signature Process: Institutional Information



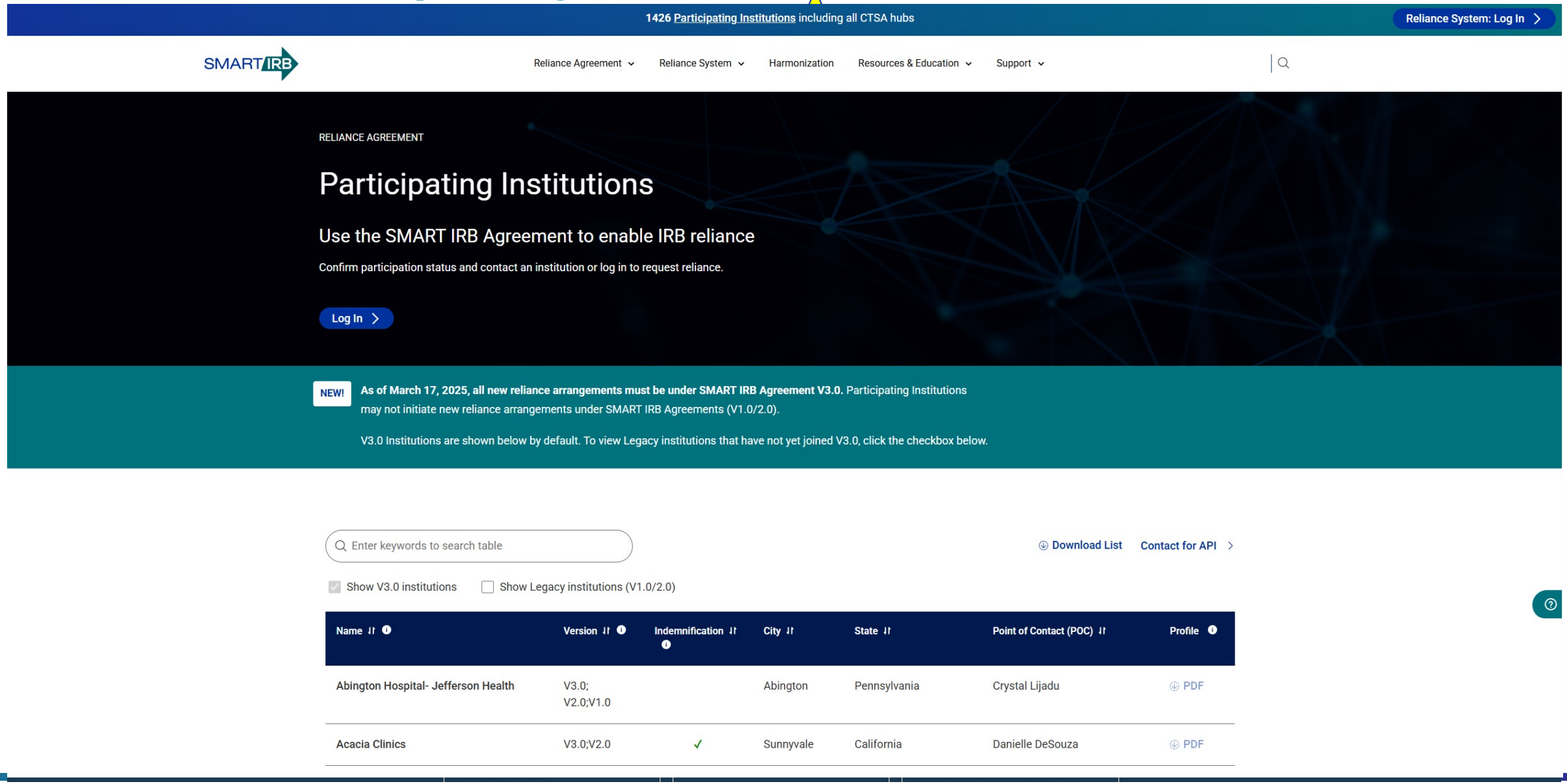
Version 3.0 Signature Process: Contact List



Version 3.0 Signature Process: Sending to IO

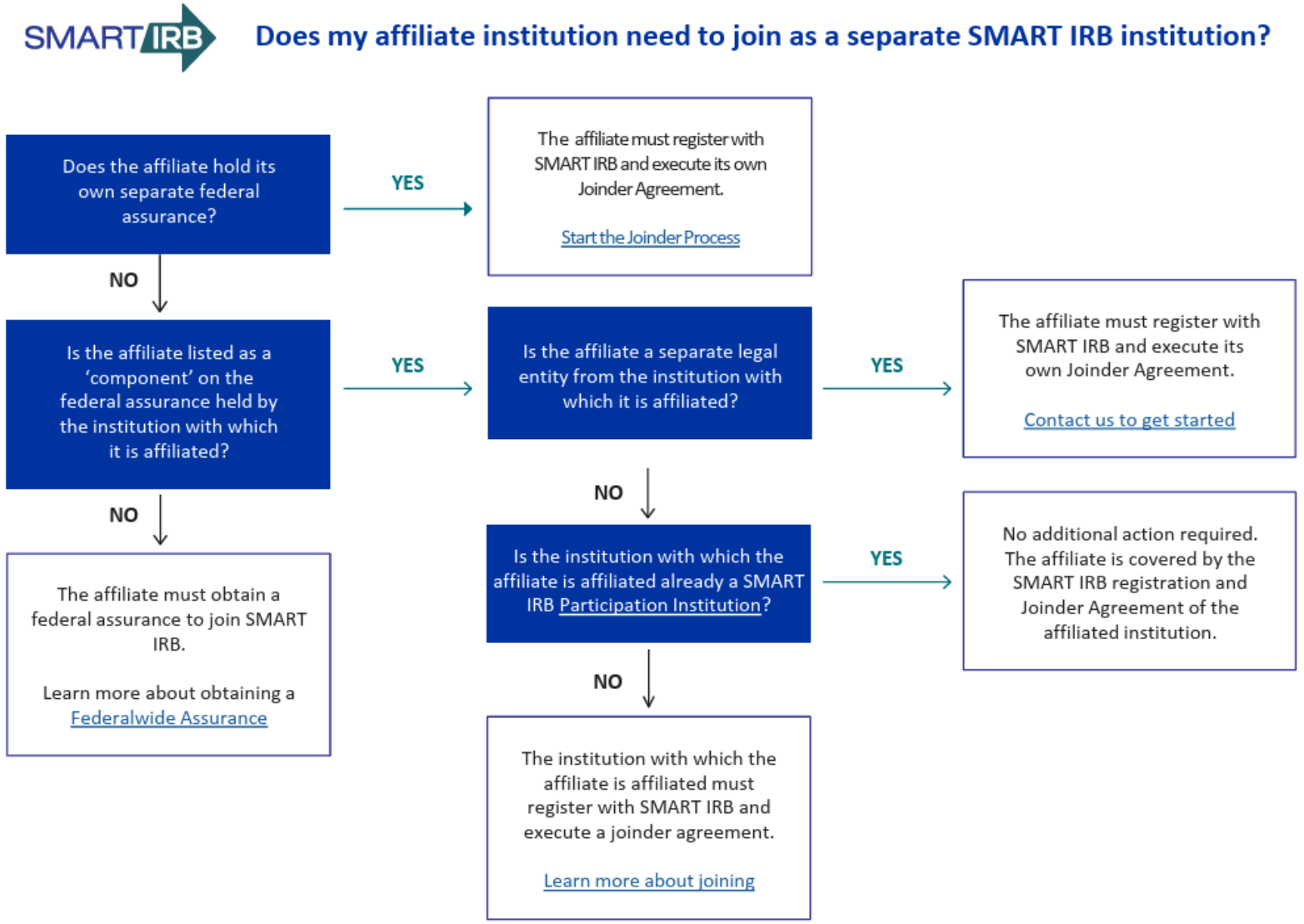


SMART IRB Participating Institutions



V3.0 and Affiliates

- "Does my affiliate institution need to sign a separate Joinder?"
  - It depends!
- Decision tree available in the SMART IRB Resources Library, "Joining SMART IRB Guidance for Affiliates"



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Letters of Acknowledgment (LOA) and V3.0: “Basic”

Purpose of Form: *If not using the SMART IRB Online Reliance System to coordinate and document study-specific reliance arrangements, institutions may use this template to document the Reviewing IRB and Relying Institutions for a study.*

Template Letter: Acknowledgement of Site Agreement to Cede IRB Review and Reviewing IRB to Provide Oversight

This form documents that:

1) [NAME OF REVIEWING IRB INSTITUTION] will serve as the Reviewing IRB for [NAME OF RELYING INSTITUTION] for the study noted below;

and

2) [NAME OF RELYING INSTITUTION] has agreed to cede IRB review to [NAME OF REVIEWING IRB INSTITUTION] for the study noted below.

Study Title:	
Overall PI:	
Relying Site Investigator:	

IRB review will be ceded under the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement.

Questions about the IRB review process or study status should be directed to [POINT OF CONTACT EMAIL AND TELEPHONE].

cc: *<Overall PI>*

<Relying Site Investigator>

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Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, through grant number 3UL1TR002541-01S1.

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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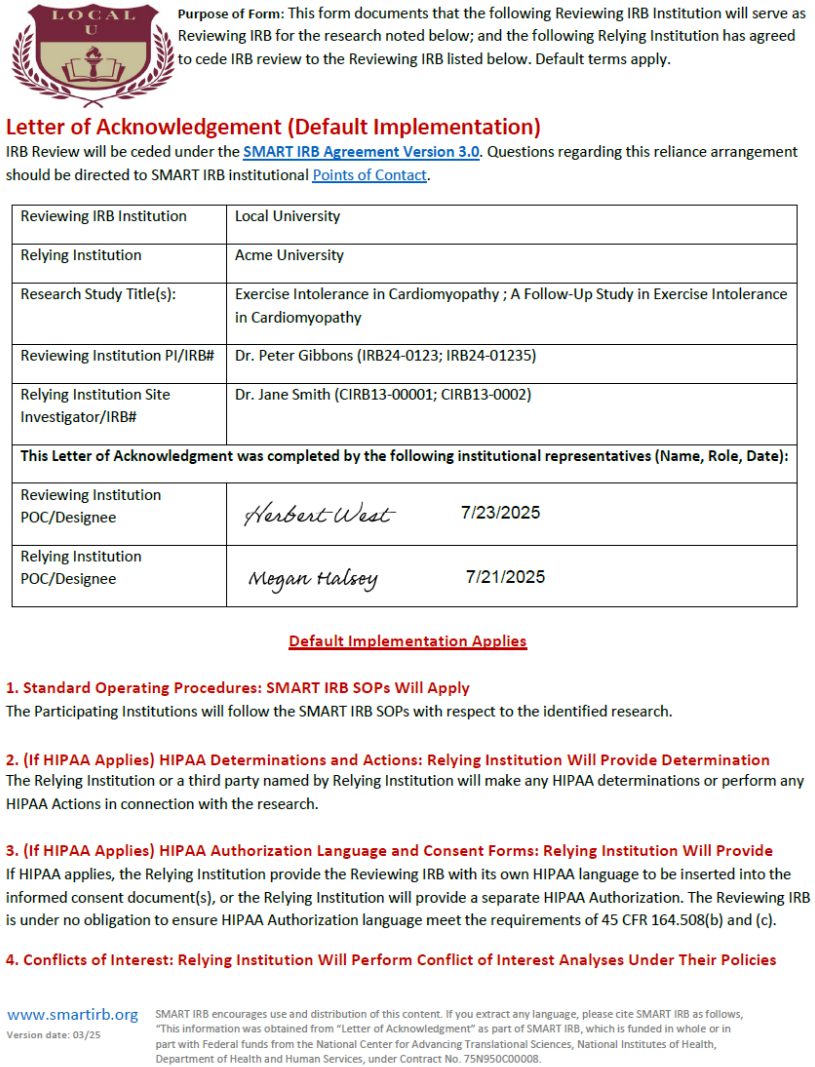
Version date: 03/25

‘Default’ vs ‘Flexible’ Implementation

SMART has *always* allowed flexibility.

- During Legacy period, focus on documenting flexibility via Implementation Checklist Tool
- Industry practice led to increasing use of ‘Flexible Terms Addendums’ tacked on to LOAs
- SMART increased versatile options for documenting flexibility on the LOA itself (see next slide for example ‘default’ vs ‘flexible’)
- Version 3.0 materials continue to be customizable to meet your institutional needs



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	Local University
Relying Institution	Acme University
Research Study Title(s):	Exercise Intolerance in Cardiomyopathy ; A Follow-Up Study in Exercise Intolerance in Cardiomyopathy
Reviewing Institution PI/IRB#	Dr. Peter Gibbons (IRB24-0123; IRB24-01235)
Relying Institution Site Investigator/IRB#	Dr. Jane Smith (CIRB13-00001; CIRB13-0002)
This Letter of Acknowledgment was completed by the following institutional representatives (Name, Role, Date):	
Reviewing Institution POC/Designee	Herbert West 7/23/2025
Relying Institution POC/Designee	Megan Halsey 7/21/2025

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

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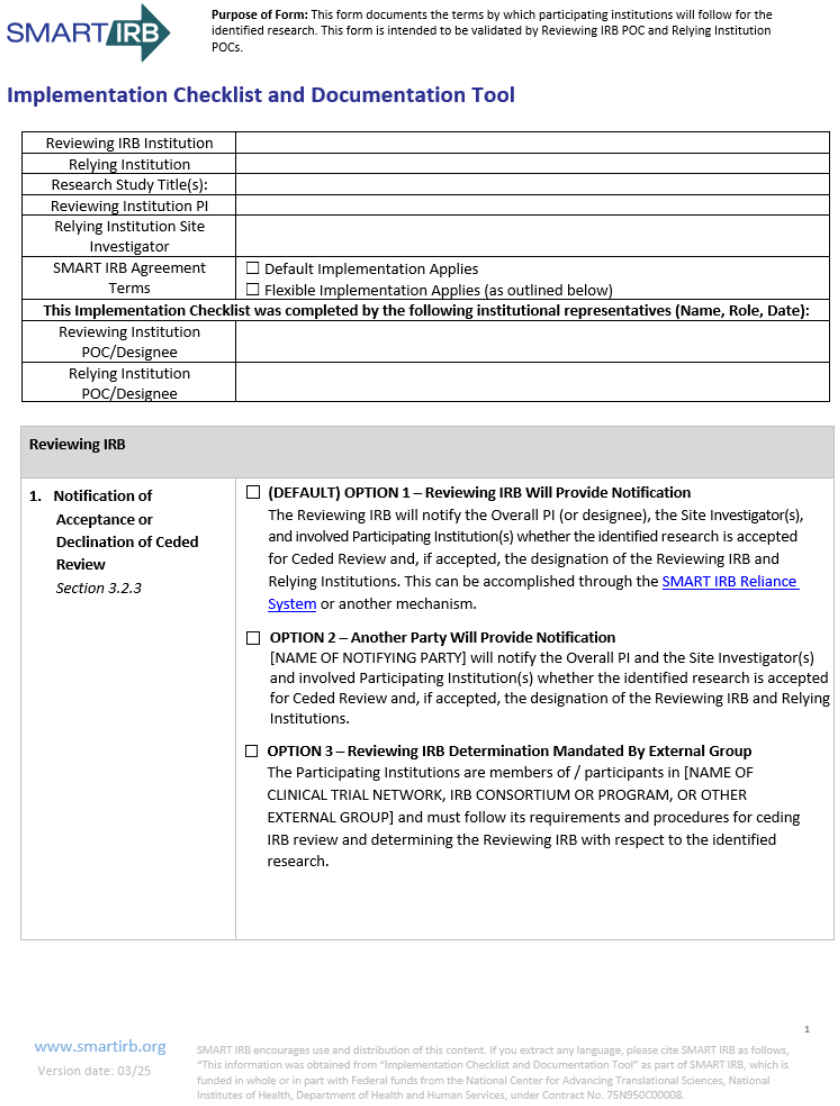
Version date: 03/25

LOA and V3.0: “Default” and “Flexible”

- Letter of Acknowledgment (Default Implementation) outlines the specific default Agreement implementation
  - Sites may additionally use the Letter of Acknowledgment (Basic) to reflect this
- Letter of Acknowledgment (Flexible Implementation) includes all options; sites should designate which apply and delete those that do not
- Implementation Checklist continues to be used and remains common particularly when documenting reliance via the SMART IRB Reliance System



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.