SMART TALK

A Community Forum to Explore Issues Surrounding Single IRB Review

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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

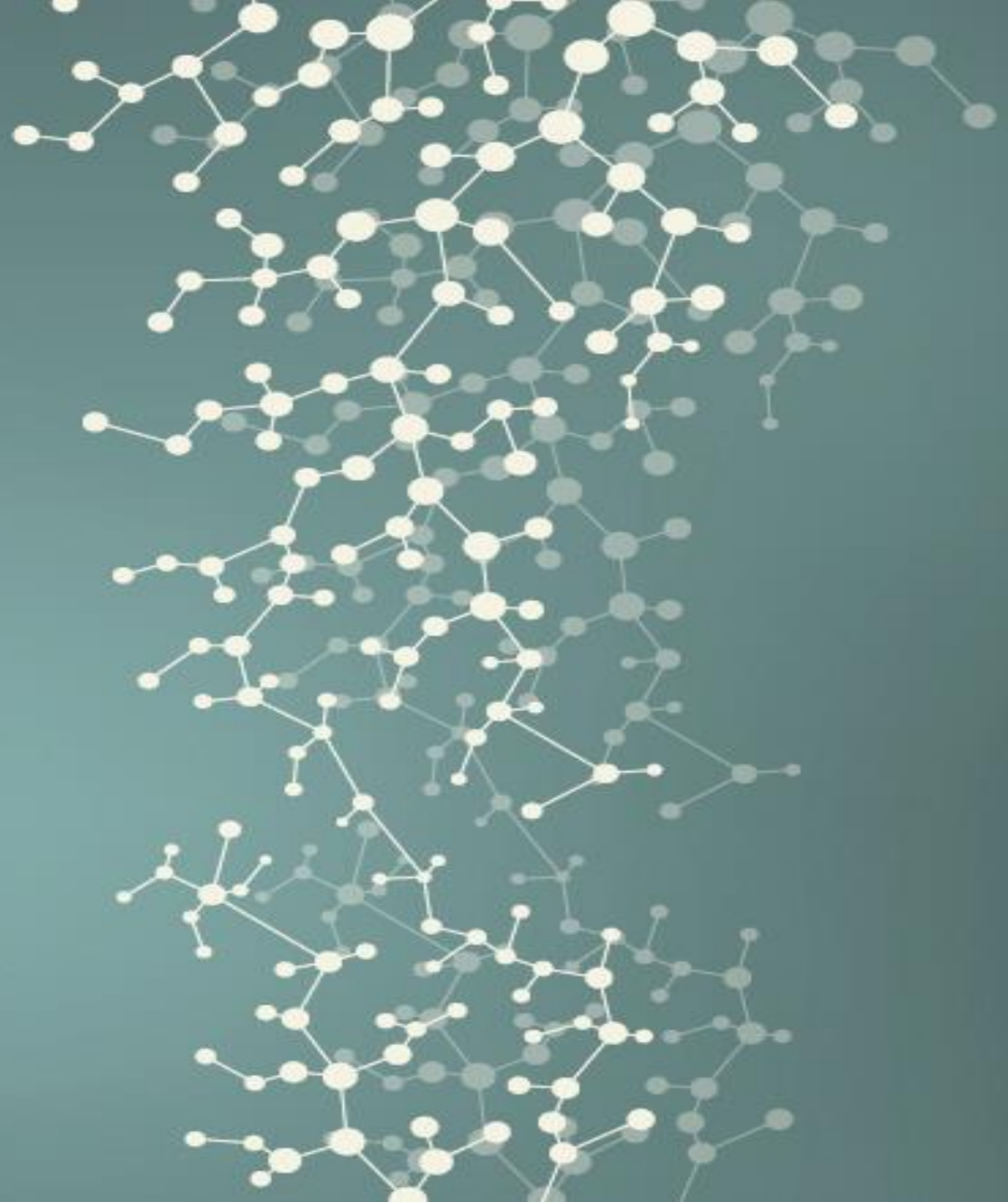
Aaron Kirby
Harvard Catalyst

Kathy Lawry
AAHRPP

Stacey Goretzka
Ind. Consultant

Carissa Minder
Washington University in St. Louis

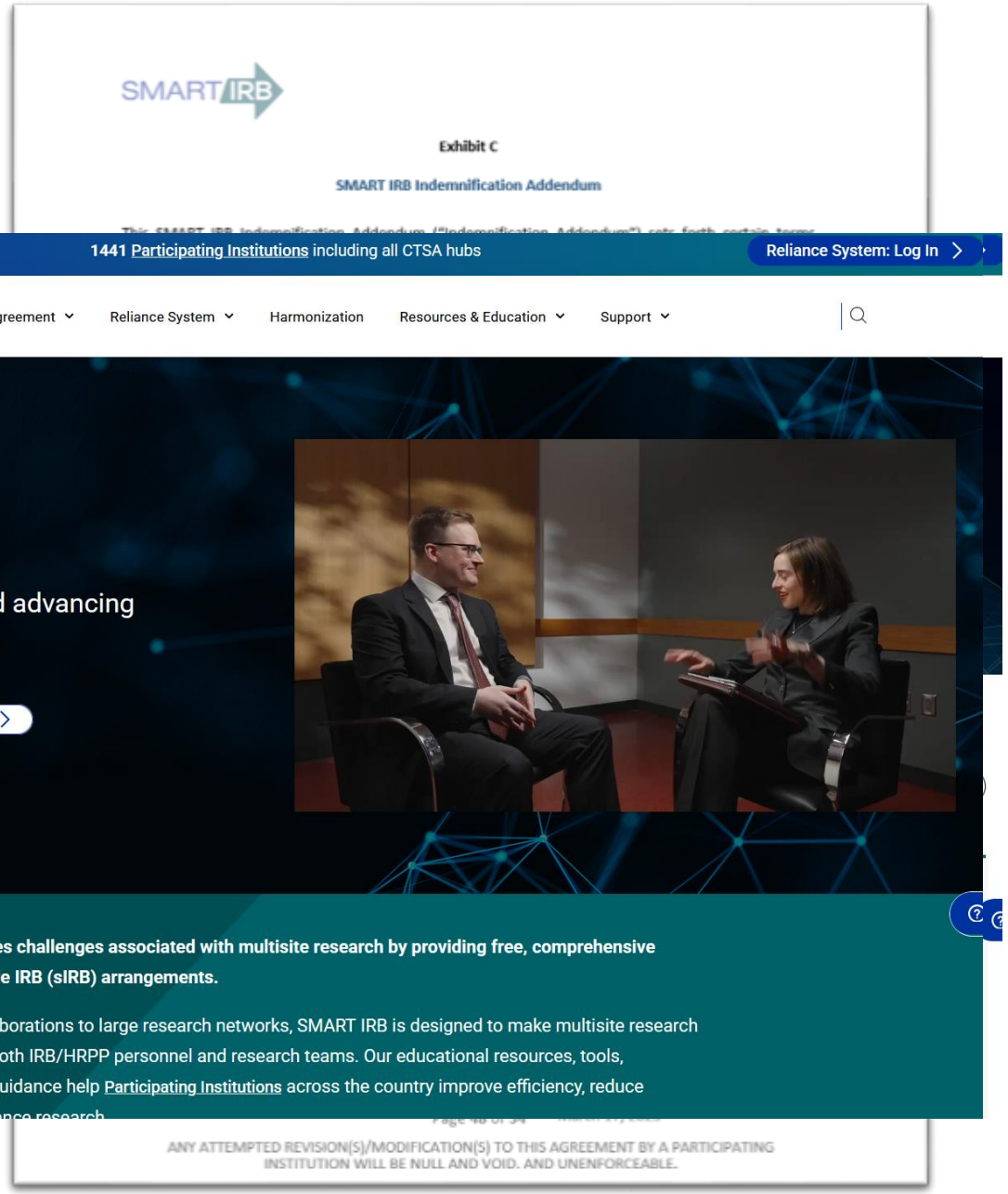
Updates!



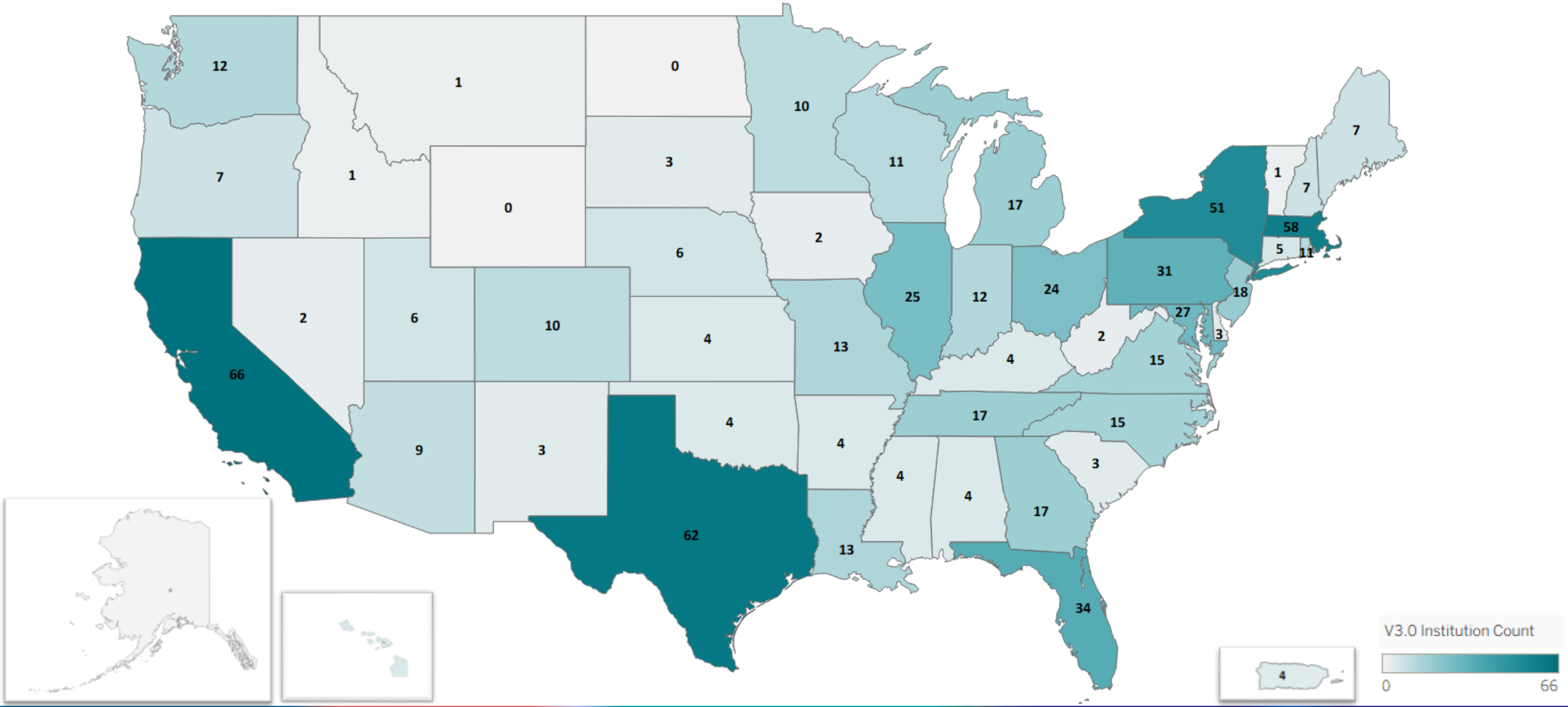
Oh, What a Year It Has Been!

THANK YOU for your ongoing support as SMART IRB celebrates the 1-year anniversary of the launch of our biggest achievements to date:

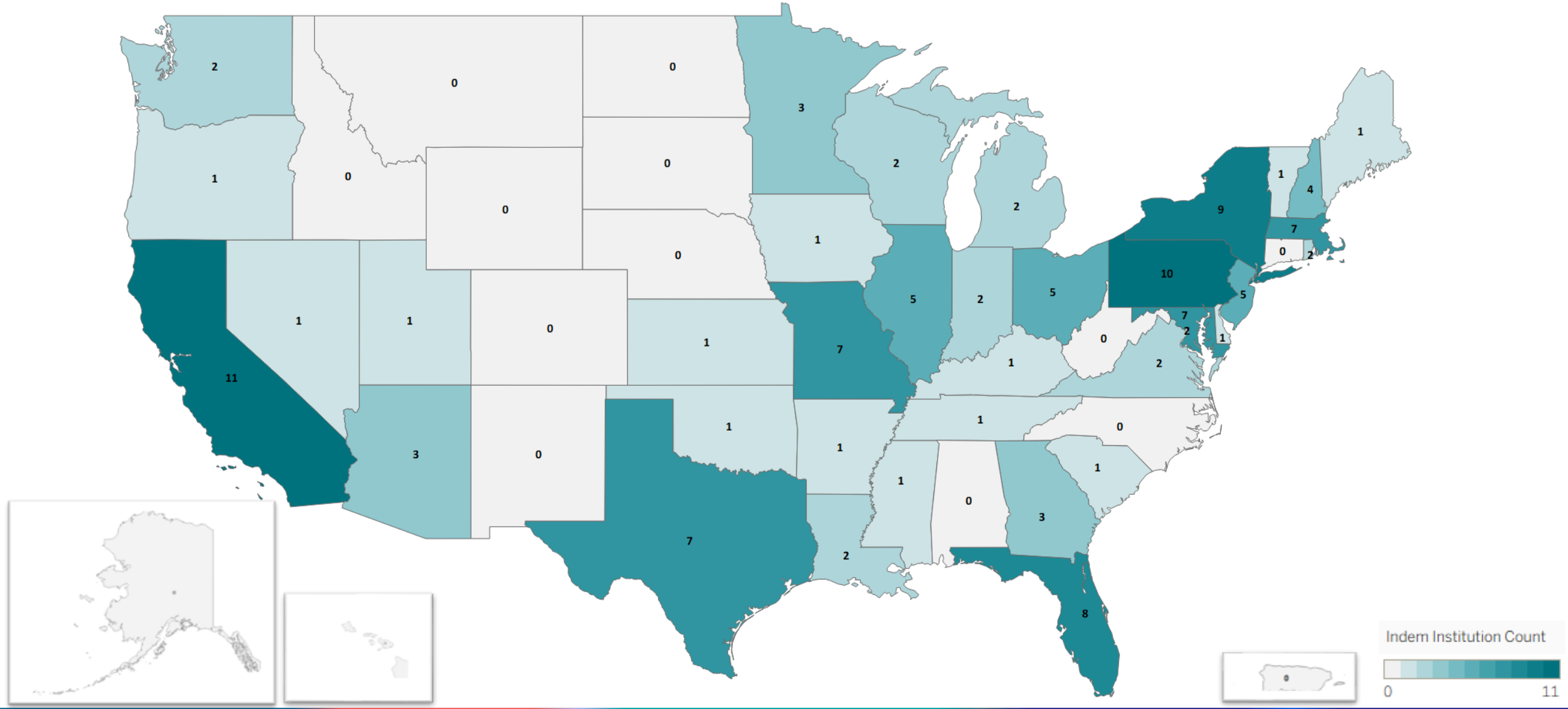
- Version 3.0 Agreement
- Optional Indemnification Addendum
- New Reliance System
- New Website
- New and Updated Resources



672 SMART IRB V3.0 Signatories Across the USA



124 Indemnification Addendum Signatories



Reliance System Patch: 2.24.26

Largest patch to date since launch of Reliance System. Key changes include:

- Editing ability expanded to include **all** PI Home institution research personnel, including research personnel added at any time
  - Editing parameters currently remain between states of ‘Draft’ through ‘Under Review’, with plans for future updates to increase flexibility further
- Fixed bug which prevented non-US institutions from requesting V3.0 signature
- Updated ‘Unauthorized’ language on login fail
- Updated Reliance System landing page language
- Other miscellaneous items

Stay tuned for additional updates to the Reliance System!

SMART IRB Survey: We Want To Hear From You!

Let us know how SMART IRB is impacting your reliance program and help influence the future of the national initiative by completing our ~20 minute survey!

Survey to launch later this week. Stay tuned for an e-mail; survey will also to be available on SMART IRB homepage under ‘News and Events’ at www.smartirb.org

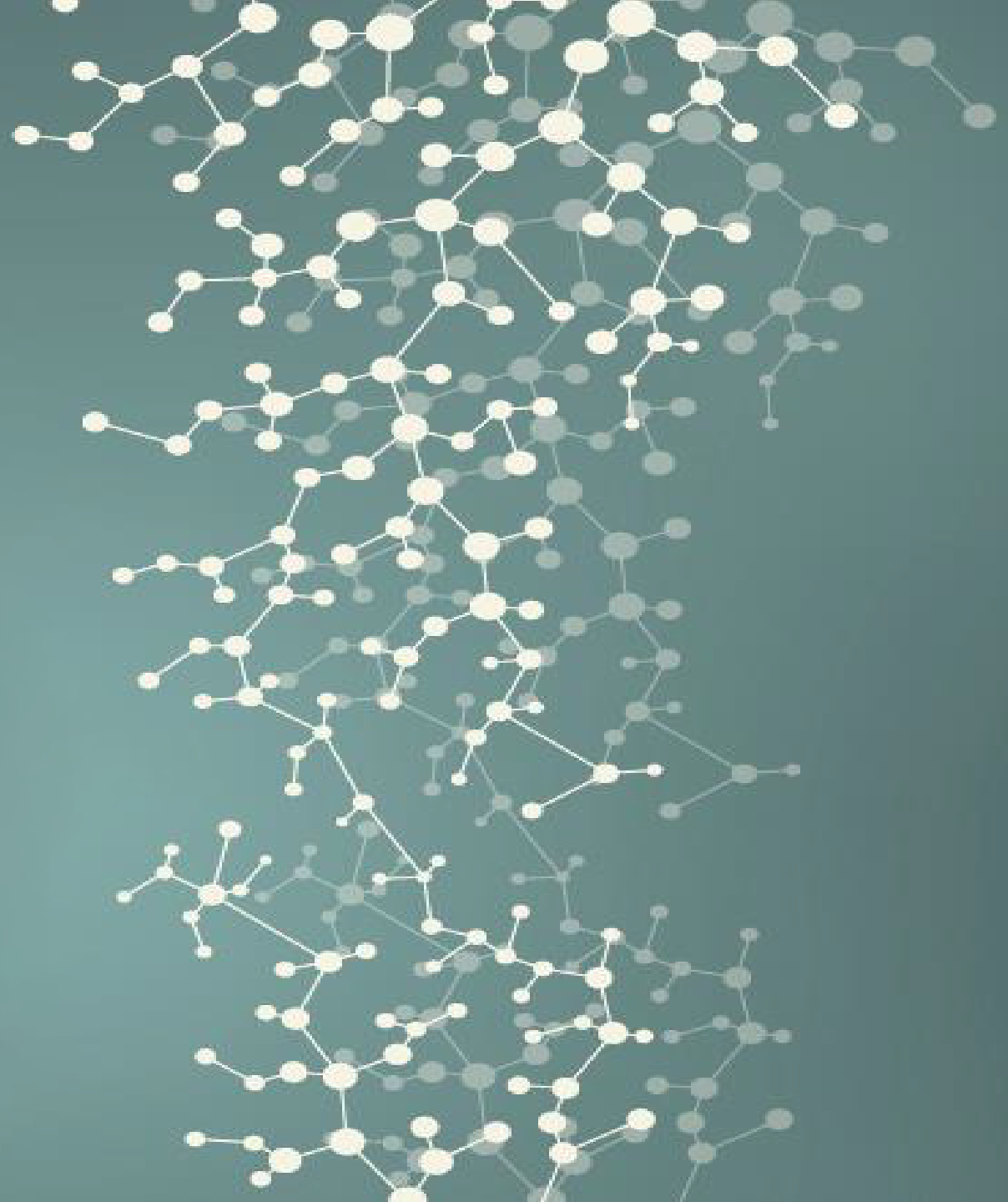
All Aboard! Helping Researchers and Research Partners Navigate Single IRB

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

Panelists:
Nadia Johnson, Assistant Director, Human Research Protections, NYU Langone Health
Janelle Maddox-Regis, Director, IRB Reliance Program, Johns Hopkins University School of Medicine
Cindy Schwarz, Associate Director, Center for Obesity Prevention and Policy Research, Washington University in St. Louis
Brittany Keown, IRB Reliance Manager, Ascension Health

SMARTIRB.org

Key Resources for Today's Session



Relying Site Investigator Checklist

This checklist helps site investigators and study teams understand and fulfill their responsibilities when a study has been ceded to an external institution.

Purpose of the form: Relying institutions can use this form to provide their local study teams with guidance regarding the investigator's responsibilities when a study is under the oversight of an IRB external to their institution, particularly when the SMART IRB Standard Operation Procedures are followed. Language in this document should be adapted to reflect local processes.

Relying Investigator Guidance and Checklist

As Principal Investigator at the **Relying Institution** for a study that may be overseen by an external IRB, you should be aware of your responsibilities. Once you have agreed to collaborate with an investigator at another institution and intend to use an external IRB for oversight of this study:

- ☐ You should contact the IRB administration or relevant Human Research Protection Program (HRPP) personnel at your institution to:
  - ☐ Discuss whether ceding IRB oversight to an external IRB is appropriate.
  - ☐ Provide them with details about the study (including your study team's role), the proposed reviewing IRB, and the lead investigator's name and institution.
    - ⇢ Obtain a copy of the studywide protocol and template consent documents(s), which will help facilitate the discussion with your local IRB/HRPP.
- ☐ If your institution agrees to cede review to an external IRB, you will be asked to:
  - ☐ Provide the IRB administration or relevant HRPP personnel at your institution with:
    - ⇢ The names and roles of all key study personnel on the local study team
    - ⇢ Any management plans for potential conflicts of interest (COI) relevant to the study that will be ceded to the external IRB, including any new or altered management plans put in place throughout the lifespan of the study.
  - ☐ Register the study at your institution according to local processes, such as creating a shell

Relying on an External Single IRB: FAQs for Relying Site Study Teams

This document provides helpful hints for investigators and study teams whose institutions are considering or have agreed to rely on an external IRB for a study. Investigators and study teams must work with their institutions to implement external IRB review for their studies.

Purpose of Form: This document provides helpful hints for investigators and study teams whose institutions are considering relying, or have agreed to rely, on an external IRB for a study. Investigators and study teams must work with their institutions to implement external IRB review for their studies.

Relying on an External Single IRB: FAQs for Relying Site Study Teams

What is SMART IRB?

SMART IRB is an IRB reliance platform designed to harmonize and streamline the IRB review process for multisite studies while ensuring high protection for research participants. SMART IRB is not an IRB; it is a platform encompassing a common IRB reliance agreement (the SMART IRB Agreement) and a suite of web-based resources to facilitate single IRB arrangements. Through smartirb.org, institutions can join the SMART IRB Agreement and manage their profiles. Investigators, study team members, IRB/HRPP staff, and administrators can request, track, and document single IRB (sIRB) arrangements for their studies. SMART IRB also provides essential education and flexible tools and resources to support the implementation of single IRB oversight, with a team of ambassadors available to assist in onboarding and implementation. More information about SMART IRB is at https://smartirb.org.

What is the SMART IRB Agreement?

The SMART IRB Agreement is a national reliance agreement that allows institutions to avoid negotiating individual agreements per study or group of studies. An IRB reliance agreement is a formal document that outlines the terms and conditions under which one institution agrees to rely on the IRB of another institution for the review and oversight of

Overall PI and Lead Study Team Checklist

This checklist helps an Overall PI (and Lead Study Team, where applicable) understand and fulfill his/her responsibilities, particularly for studies using the SMART IRB SOPs, which require identification of a Lead Study Team.

Purpose of the form: The Home Institution for the Overall Principal Investigator and/or Lead Study Team can use this form to provide them with guidance regarding the additional responsibilities accrued in assuming that role, particularly when the SMART IRB Standard Operation Procedures are followed. Language in this document should be adapted to reflect local processes

Overall Principal Investigator/Lead Study Team Guidance and Checklist

As the Overall Principal Investigator for a study for which research activities involving human subjects will be overseen by a single IRB for all or most sites, you should be aware of your additional responsibilities in assuming that role. Once you have agreed to collaborate with investigators at another institution(s) and intend to use a single IRB for oversight of this study:

- ☐ You should contact the IRB administration or relevant Human Research Protection Program (HRPP) personnel at your institution to:
  - ⇢ Discuss whether your home institution's IRB can act as the single IRB for all or some institutions participating in this study or whether another external IRB would be appropriate.
  - ⇢ Identify who will act in the role of the Lead Study Team (e.g., your own study team, a coordinating center, or both). The Lead Study Team assumes additional responsibilities when single IRB review will be used.
  - ⇢ Provide them with details about the study, including the studywide protocol and template consent document(s), which will help facilitate the discussion with your local IRB/HRPP.
  - ⇢ Identify all sites that will be engaged in human subjects' research and thus need IRB coverage.
- ☐ If your institution agrees to single IRB for the study, you will need to ensure the Lead Study Team:
  - ☐ Provides a reliance request to the Overall PI's home institution using the process required by that institution.

Single IRB Readiness Checklist for Lead Study Teams & Coordinating Centers

This checklist will help Lead Study Teams and Coordinating Centers identify the processes and resources they may need to facilitate a single IRB reliance arrangement for a multisite research study.

Purpose of Form: This checklist will help you identify the processes and resources you may need to facilitate a single IRB reliance arrangement for your multisite research study. Any item on the checklist that prompts a "no" response means that you may need to address that gap.

Single IRB Readiness Checklist for Lead Study Teams & Coordinating Centers

AREA	YES	NO	NOTES
1. Have you contacted your local IRB/HRPP regarding this study? You should contact them prior to completing this checklist.	☐	☐	*Enter additional notes*
2. Have you identified a Reviewing IRB that is willing to serve as the Reviewing IRB? Often, but not always, the Reviewing IRB is at the Overall Principal Investigator's institution. Helpful Resource for Selecting a Single IRB	☐	☐	*Enter additional notes*
3. Have you identified the reliance agreement the Reviewing IRB will use for this study?	☐	☐	*Enter additional notes*
4. Will the Reviewing IRB use the SMART IRB Agreement?	☐	☐	*Enter additional notes*
5. Are all institutions involved in the study SMART IRB Participating Institutions? If not, the Lead Study Team may need to assist the institution with joining the Agreement. To join the SMART IRB Agreement, Institutions must have a Federal Assurance, unless they are an Independent IRB. Local investigators should contact their IRB or human research protection office to ensure their institution has an Federal Assurance.	☐	☐	*Enter additional notes*

Communication Plan

Institutions can use this template to document key communication roles, such as submitting initial and continuing reviews, amendments, and reportable events to the Reviewing IRB; providing conflict of interest management plans to the Reviewing IRB; and providing IRB-approved documents and communicating Reviewing IRB determinations to relying site study teams.

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		

Reliance System User Guides

Step-by-step guidance to assist study teams, IRB/HRPP administrators and staff in using the SMART IRB Reliance System.

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**.

https://smartirb.org/user-guides/

Next SMART Talk

TBD – another fabulous topic

June 17, 2026, 2-3:30 pm EST