



## 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  
SMART IRB 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

# SMART IRB Ambassadors



Aaron Kirby  
*Harvard Catalyst*



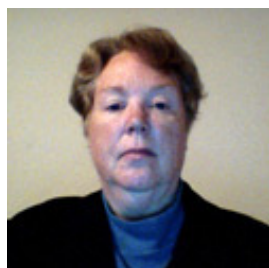
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*Harvard Catalyst*



Jeremy Lavigne  
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*AAHRPP*



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Stacey Goretzka

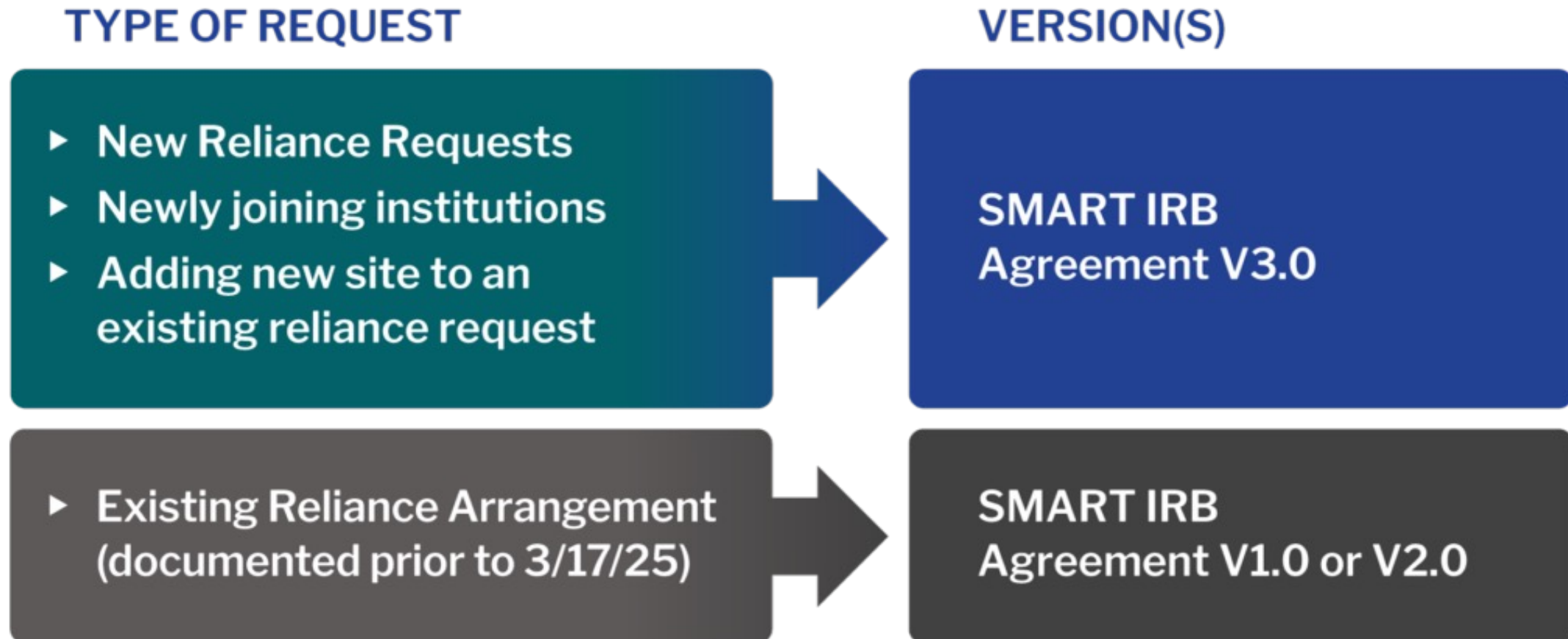


Carissa Minder  
*Washington University in St. Louis*

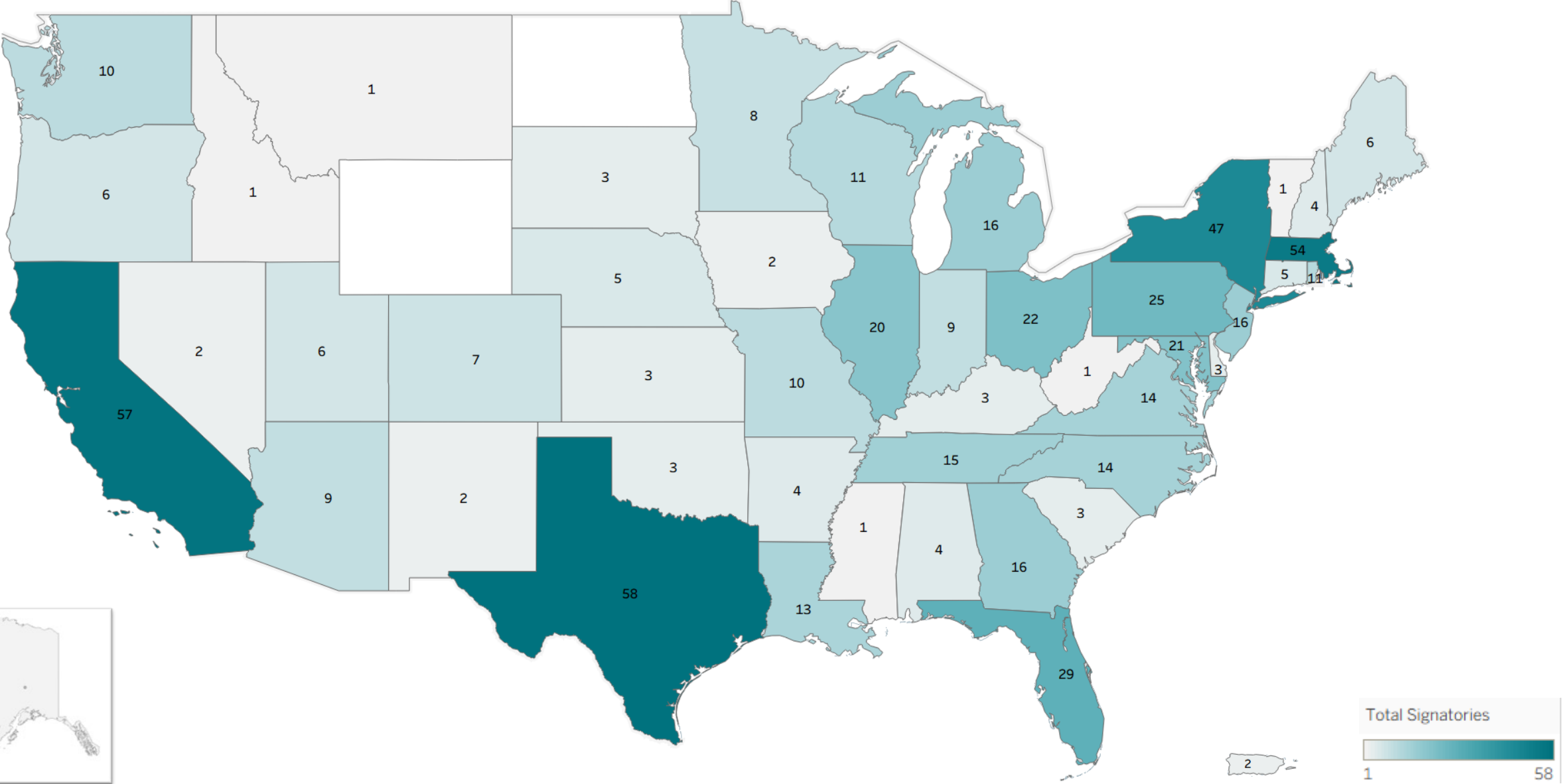
Find your SMART IRB  
Ambassador Today:  
[www.smartirb.org](http://www.smartirb.org)

# SMART IRB: Versions and New Reliance Requests

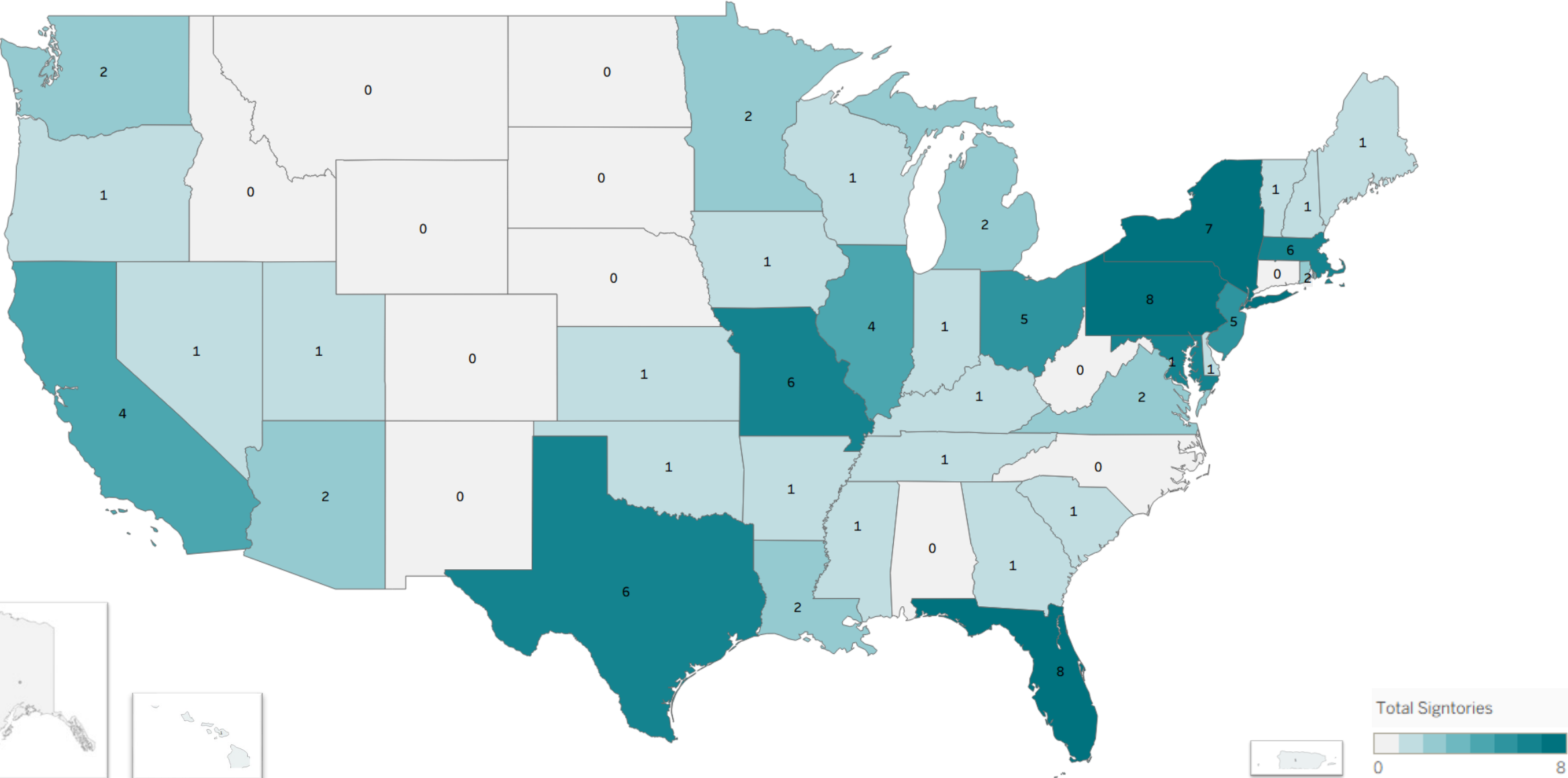
- Version 3.0 is the only option to join and use for new reliance arrangements
- Check the [Participating Institutions](#) list for updated list of V3.0 institutions



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



# 98 Indemnification Addendum Signatories across 36 states + DC!





## Ready to join the optional Indemnification Addendum?

- The indemnification addendum is easy to join!
- Process is nearly identical to joining Version 3.0
- Check out our Point of Contact User guide on this [topic](https://smartirb.org/user-guides/points-of-contact/)
  - <https://smartirb.org/user-guides/points-of-contact/>

1414 Participating Institutions including all CTSA hubs

Reliance System: Log In

SMARTIRB

Reliance Agreement

Reliance System

Harmonization

Resources & Education

Support

Q

User Guides

Sending V3.0 to Institutional Official

Q

Search by keyword

Home » User Guides » Points of Contact » Sending V3.0 to Institutional Official

Step by Step Instructions

Video with Voiceover

1. Click "My Institutions" from the left-hand navigation to show all institutions associated with your account.

2. You can also select "Agreement" from the left hand navigation.

3. Click "New Submission".

4. To view what the Signatory Official will see in the agreement, use the download agreement PDF button.

5. Open the downloaded PDF to see a copy of the agreement.

1. Click "My Institutions" from the left-hand navigation to show all institutions associated with your account.



# Upcoming Events



# October 22-24: Fall CTSA Program Annual Meeting, DC

- Join Jeremy and Polly in DC next week to discuss the success of Version 3.0, key highlights of the SMART IRB national reliance initiative, and more!
- Registration is now live!

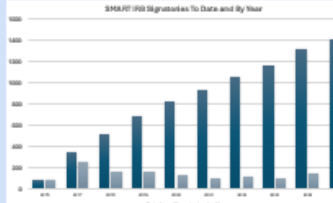
## SMART IRB Version 3.0: America's Gold Standard Approach to Single IRB

Jeremy Lavigne, MA, CIP<sup>1</sup>; Polly Goodman, CIP<sup>2</sup>; Aaron Kirby, MSc<sup>3</sup>; Barbara E. Bierer, MD<sup>1\*</sup>

<sup>1</sup>SMART IRB | <sup>2</sup>Harvard University, <sup>3</sup>Brigham and Women's Hospital

### Background

With over **1,410 Participating Institutions** (including all CTSA hubs) across 49 states, DC and Puerto Rico, SMART IRB has revolutionized single IRB (sIRB) domestic multisite human participant research by providing a common comprehensive model to eliminate inefficient and redundant processes, promote harmonization, and improve transparency in human research protection program review and oversight of sIRB research.

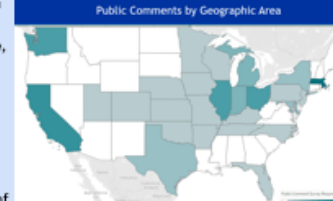
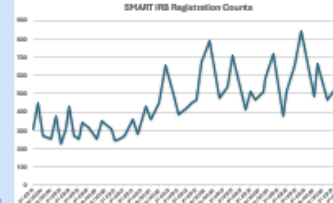
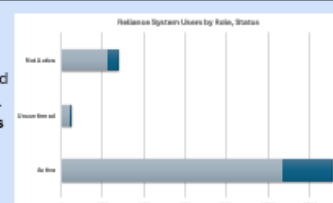


### Methods and Discussion

Using proven data-driven, dynamic and responsive approaches to single IRB, SMART IRB rapidly grew to be the largest reliance network in the US, with over **12,000 studies** and **18,000 researchers and IRB/HRPP personnel** in the Reliance System, and **tens of thousands more** via alternative mechanisms.

Alongside the meteoric rise of the SMART IRB platform, SMART IRB established educational initiatives to tackle hot button regulatory issues, including monthly SMART Talks, Boot Camps, Symposium, Office Hours, and more. Frequently **exceeding 500+ attendees per month**, these initiatives also serve as opportunities to network, harmonize sIRB processes and policies, and discuss resource implementation.

Following implementation of the SMART IRB Agreement Version 2.0 in 2020, which included NIH's participation, SMART IRB began work on V3.0 of the Agreement. SMART IRB worked with federal agencies, community experts at the SMART IRB Harmonization Steering Committee, and more to create Version 3.0. SMART IRB sought public feedback which yielded **250 unique comments** and suggested revisions from **54 institutions**. A subsequent round of comments yielded **20 unique comments** from **12 institutions**, providing SMART IRB with pivotal feedback necessary to craft the future of reliance across the country.



### The Road to V3.0 and Beyond

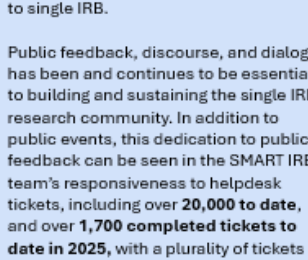


Version 3.0 is the culmination of a decade of dedication to forge a national consensus framework agreement capable of covering institutions and human subjects research of all sizes and types. Engineered to transform the federal research regulatory landscape, SMART IRB celebrated the **NIH as the #1 signatory of V3.0**. Less than 6 months after launch, the first Department of Defense institution [US Army Institute of Surgical Research (USAISR)] joined V3.0. SMART IRB looks forward to additional federal signatories and deepening federal engagement with SMART IRB, including the US Department of Energy, US Department of Veterans Affairs, and more!

### Key Takeaways and Lessons Learned

Version 3.0 of the Agreement launched on **March 17, 2025** to tremendous success, with **over 580+ institutions joining** in the first 6 months. The rapid onboarding of institutions across the United States allowed for a seamless transition from V2.0/V1.0 to V3.0. The demonstrable success is attributable to the tremendous efforts of the research community, SMART IRB team and ambassadors, and the support of NCATS which has been critical to ensuring a smooth operational transition to what is now America's gold standard approach to single IRB.

Public feedback, discourse, and dialogue has been and continues to be essential to building and sustaining the single IRB research community. In addition to public events, this dedication to public feedback can be seen in the SMART IRB team's responsiveness to helpdesk tickets, including over **20,000 to date**, and over **1,700 completed tickets to date in 2025**, with a plurality of tickets touched within 1 business hour.



### Funding and Support for SMART IRB



The SMART IRB national reliance initiative 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. 75N550C00008. **Learn more about the national SMART IRB initiative by using the QR code to the left or visiting us at [www.smartirb.org](http://www.smartirb.org).** Questions? Contact us at [Help@smartirb.org](mailto:Help@smartirb.org)!

# October 29-30: Single IRB Boot Camp Returns!

- **When:** 12-3pm EST, 10/29 and 10/30
- **Who:** IRB/HRPP personnel who have beginner-to-intermediate level experience with the Single IRB review process. Experienced personnel interested in learning more about integrating changes in SMART IRB Agreement V3.0 into your reliance process may also wish to attend.
- **Registration** is now live at [www.smartirb.org](http://www.smartirb.org) !



# November 6-8: 2025 Annual PRIM&R Conference, Baltimore

- **Exhibitor Booth:** Say hello to Polly and Jeremy (and get yourself the SMARTest swag to date)
- **Friday, Nov 7<sup>th</sup>; 10:30 AM - 11:45 AM ETA04 - *Local Context Review: Why It's Essential and How to Do It Well***  
Speakers: Nichelle Cobb, PhD, CIP - AAHRPP, SMART IRB; Megan Kasimatis Singleton, JD, MBE, CIP - Johns Hopkins University School of Medicine
- **Saturday, Nov 8<sup>th</sup>; 12:30 PM - 1:30 PM ET N20 - *Everything You Wanted to Know About SMART IRB Agreement Version 3.0***  
Speakers: Jeremy Lavigne, MA, CIP - SMART IRB, Harvard University; Polly Goodman, BS, CIP- SMART IRB, Harvard University; Barbara E. Bierer, MD - SMART IRB; Multi-Regional Clinical Trials Center

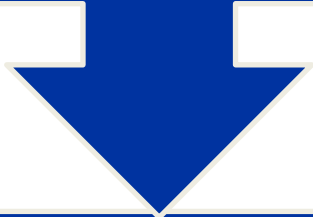


# The Indemnification Dilemma & Single IRB: What? Why? Why Not?



## Next SMART Talk

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



December 17, 2025, 2-3:30 pm ET





# Agenda

- What is indemnification?
- What are the parts of an indemnification provision?
- Why/when might a party want to include indemnification in a contract?
- Why/when might a party not want to do so or be unable to do so?
- Indemnification in the context of IRB reliance
- SMART IRB Indemnification Addendum

# What is indemnification?

Indemnification = a party's promise to pay another party's financial losses



# Indemnify vs. hold harmless vs. defend

## Indemnify

- Promise to pay financial losses (most states)  
-----
- Reimbursement after the fact (some states)

## Hold Harmless

- Promise to pay financial losses (most states)  
-----
- Relief from paying in the first instance, like a release (some states)

## Defend

- Promise to defend a party in a legal proceeding
- Typically includes providing and paying for legal counsel
- May be implied by “indemnify” or may need to be explicit (depending on the state)

# What are the parts of an indemnification provision?

1. Specification of the indemnifying party - the contracting party promising to pay
2. Specification of the indemnified party(ies) - the parties protected by the promise:
  - The other contracting party
  - Its employees/agents
  - Its directors/trustees/officers
  - Its students/volunteers
  - Its subcontractors?
  - Its corporate affiliates?
  - Others?

# What are the parts of an indemnification provision?

## 3. Definition of covered financial loss

- *Types of losses:* damages and judgments; fines and penalties; costs and expenses including attorneys' fees
- *Losses resulting from:* claims by third parties (most common); first-party claims (less common)
- *Losses attributable to what and whose fault:*
  - Negligence; recklessness; willful misconduct; breach of the contract; violation of laws or regulations
  - By the indemnifying party; by its employees/agents; by its directors/trustees/officers; by its subcontractors?; by its affiliates?



# What are the parts of an indemnification provision?

## 4. Identification of any carveouts/exclusions

- *Implicit*: losses are only covered in the first instance “to the extent” they are attributable to the indemnifying party’s fault
- *Explicit*: losses attributable to the indemnified party’s(ies’) fault (negligence; recklessness; willful misconduct; breach of contract; violation of law/regulation) are excluded

# What are the parts of an indemnification provision?

## 5. Notification obligation

- Timely notification to indemnifying party of a covered loss
- Consequences of failure to timely notify, including potentially relief of the indemnifying party from the indemnification obligation

## 6. Defense obligation

- Indemnifying party's rights to control the defense; select legal counsel; negotiate a settlement
- Cooperation of the indemnified party(ies) in the defense (availability of documents, representatives)
- Indemnified party's(ies') rights to approve certain (usually non-financial) settlements; to take back the defense (opt out of indemnification)

# What are the parts of an indemnification provision?

7. Survival: How long will the provision survive after the expiration or termination of the contract?

- Considerations include applicable statutes of limitation for underlying claims

# Why/when might a party want to include indemnification in a contract?

- Protection from potential financial losses associated with liability to a third party and increased certainty as to magnitude of financial risk associated with the contract
- Activities under the contract are high-risk (e.g., could result in injury to people or significant property damage)
- Likely that the other party's activities under the contract will be the cause of any financial loss
- Causes of action/theories of liability available to the third party are well-established
- Assurance of a source of funds available to the third party
- Insurance policies require obtaining indemnification as a condition of coverage (e.g., indemnification for financial losses resulting from third-party product liability claims)

# Why/when might a party not want to or be unable to include indemnification in a contract?

- Activities under the contract are low-risk (e.g., no or low risk of harm to people, property, or privacy)
- Likely that the party's own activities under the contract will be the cause of any financial loss
- Causes of action/theories of liability available to the third party are not well-established
- Lack of funds/resources to make good on indemnification obligation and/or insurance policies do not cover indemnification obligations
  - Potential role of charitable immunity statutes
- Government entities and public institutions may be prohibited under state law, constitution, or charter from indemnifying due to sovereign immunity and/or other legal limitations

# Indemnification in the context of IRB reliance

- An indemnification provision in an IRB reliance agreement may be more likely to benefit the party that is serving as the Reviewing IRB than the Relying Institution(s)
  - Well-established state law causes of action/theories of liability are available to third party against the Relying Institution(s) (e.g., medical negligence, lack of informed consent, breach of confidentiality)
  - In contrast, little precedent for causes of action/theories of liability against IRBs (no private right of action under federal IRB regulations; no established duty for negligence claims; cases tend to settle)



# History of the SMART IRB Indemnification Addendum

- Introduced with Version 3.0 of the SMART IRB Agreement
- Developed by the SMART IRB Indemnification Work Group (2019), which included representatives from both private and public institutions and their legal counsel
- Modeled on indemnification agreements already in wide circulation among the community (e.g., TIN LOI)
- Received input from federal agency counsel as part of their review of Version 3.0

# Transition to the SMART IRB Indemnification Addendum

The SMART IRB Indemnification Addendum is optional and does not supersede existing indemnification agreements or preclude new separate indemnification agreements.

| Type of Indemnification Agreement       | Scope                                                                                                                                                                                                                  |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Existing Indemnification Agreements     | Remain applicable to reliance requests initiated under the existing agreement                                                                                                                                          |
| SMART IRB Indemnification Addendum      | If signed, applies to any new reliance requests entered into by two (or more) institutions as of the date they sign it, unless a more limited scope (e.g., only certain new requests) is agreed to by the institutions |
| New Separate Indemnification Agreements | Continue to be permitted for any new reliance requests outside the scope institutions defined for the Addendum                                                                                                         |

# Questions and Discussion

