



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

Harmonization

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

Support

Need assistance? Check out our [Support Center](#), [Ambassadors](#), and [Helpdesk](#)

Reliance System

Your home to request, document, and track reliance requests with fellow [Participating Institutions](#) in one centralized place

Resources & Education

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

Meet Your SMART IRB Ambassadors!



Polly Goodman
Harvard Catalyst



Nichelle Cobb
AAHRPP



Jeremy Lavigne
Harvard Catalyst



Ada Sue Selwitz
University of Kentucky



Aaron Kirby
Harvard Catalyst



Kathy Lawry
AAHRPP



Stacey Goretzka
Ind. Consultant

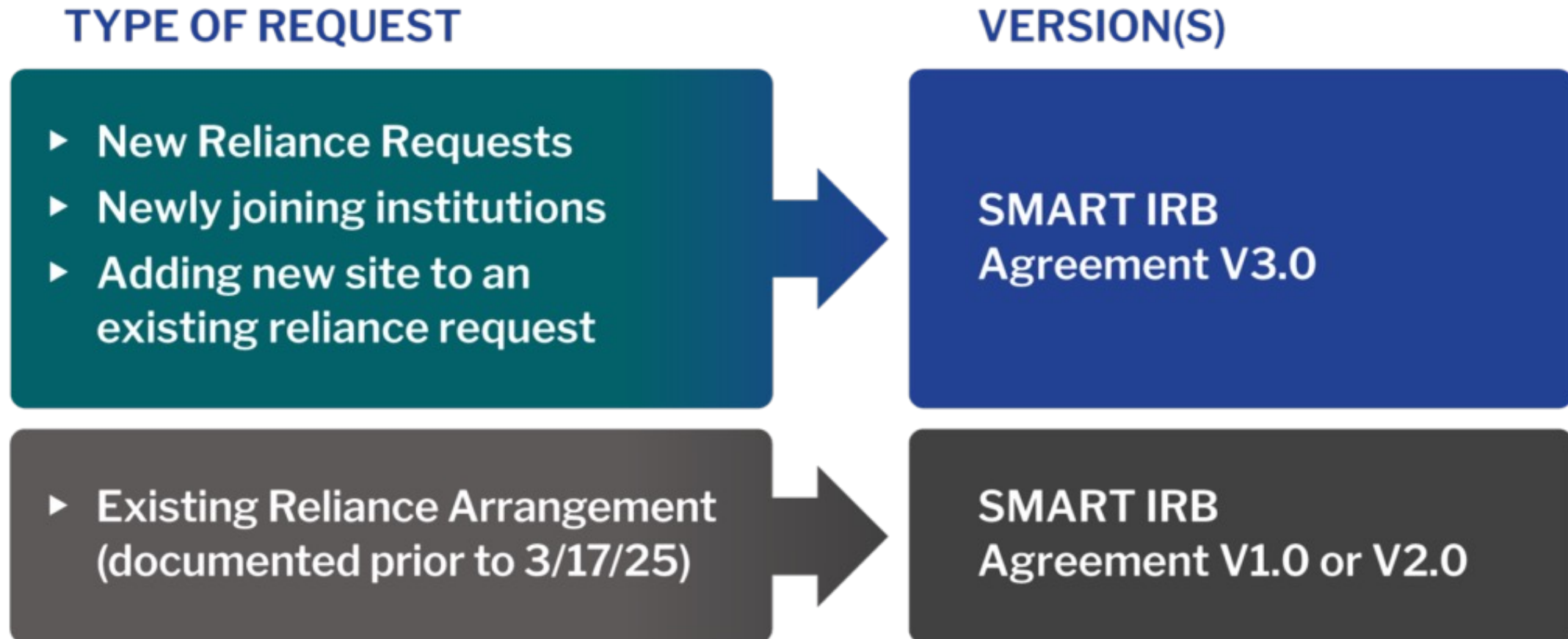


Carissa Minder
Washington University in St. Louis

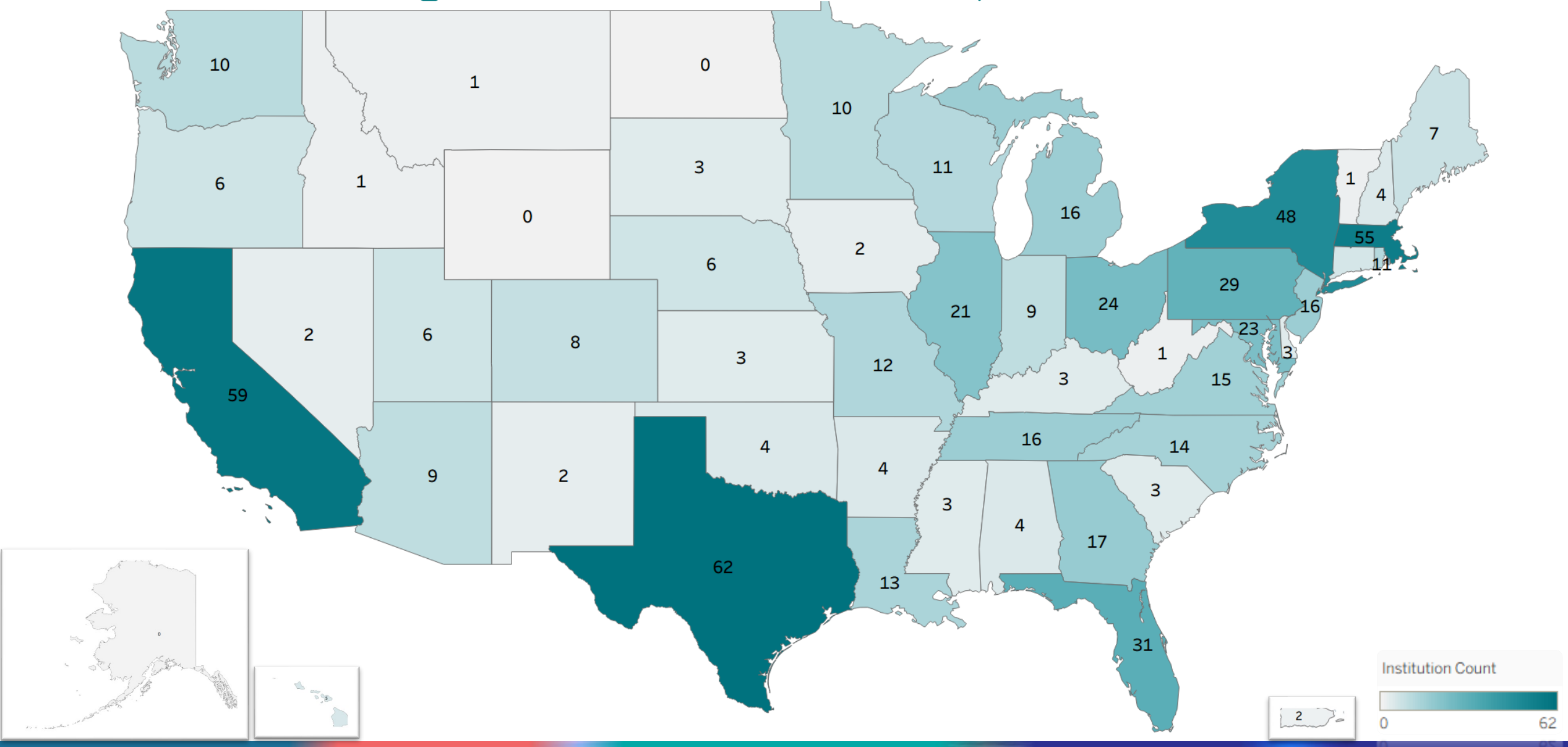
Find your SMART IRB
Ambassador Today:
www.smartirb.org

SMART IRB: Versions and New Reliance Requests

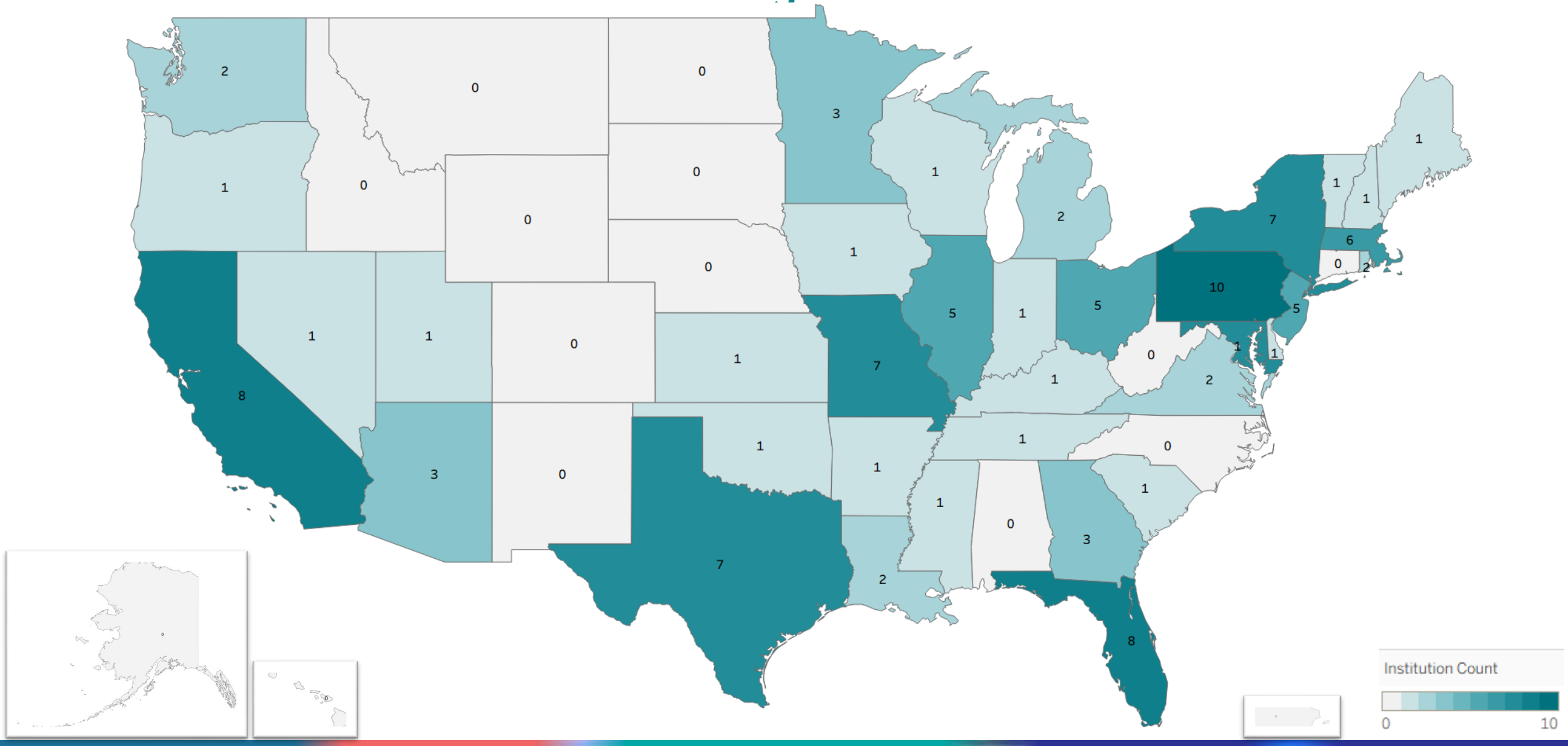
- Version 3.0 is the only option to join and use for new reliance arrangements
- Check the [Participating Institutions](#) list for updated list of V3.0 institutions



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

SMARTIRB.org

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

1426 Participating Institutions including all CTSA hubs

Reliance System: Log In >



Reliance Agreement ▾ Reliance System ▾ Harmonization Resources & Education ▾ Support ▾



RELIANCE AGREEMENT

SMART IRB Agreement

Supporting IRB reliance across the nation

Reliance Agreement Version 3.0 is Now Available!

Using the Agreement

Indemnification

Background

Join SMART IRB

Reliance Agreement Version 3.0 is Now Available!

As of **March 17, 2025**, institutions must join Version 3.0 to initiate any new SMART IRB reliance arrangements.

SMART IRB Reliance Agreement Version 3.0

May be used to facilitate IRB reliance among Participating Institutions for a wide range of studies.

Before joining, review the Agreement and optional Indemnification Addendum with institution officials and counsel.

Do not sign the sample Joinder Agreement. You will use the Reliance System to join the Agreement.

DOWNLOAD ↴

Join Now

Related Documents

A summary of key changes and other resources to assist institutions in reviewing and joining SMART IRB Reliance Agreement V3.0.

DOWNLOAD ↴

Steps to Join



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

SMARTIRB

Global View

SITES

My Institutions

Agreements

Indemnifications

RELIANCE

All Requests

ADMIN

Users

Welcome, SMART!

Site Admin

Sample University

Sample University 2

Sample University

Verified

Agreement

version V3

Signature Requested

Members at Institution

SI

Site Admin

SMART IRB . smartirbuser1@outlook.com

SJ

Site Admin

Sam Jones . susmartirb@gmail.com

FN

Site Admin

First Name . firstname@gmail.com

JS

General User

Jane Smith . jsmith@sample.edu

MS

General User

Mary Smith . msmith@sample.edu

Request for Reliance

3

ALL REQUESTS

→

0

ACTION REQUIRED

→

0

UNDER REVIEW

→

1

RELIANCE REACHED

→

Recent Activities

Institutions

Reliance Request

(50046)

Updated 5 minutes ago

Sample University

(50041) Email Test 3

Updated 7 hours ago

Sample University

(50040) Flu Study

Updated 3 days ago

Sample University

SI

Version 3.0 Signature Process: Institutional Information

SMARTIRB

Back

Institution Details

Institution Information

Contact Lists

Agreements

New Submission

Past Submission

Indemnification

New Submission

Past Indemnifications

Institutional Profile

Purpose

Instructions

Notes

Complete Institutional Profile Form

Sample University 2

Edit

Save

Cancel

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

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.

smartirb.org 20

Version 3.0 Signature Process: Contact List



SU



Complete Institutional Profile Form

(212) 555-1212

Version 3.0 Signature Process: Sending to IO

SMARTIRB

Back

Institution Details

Institution Information

Contact Lists

Agreements

New Submission

Past Submission

Indemnification

New Submission

Past Indemnifications

Institutional Profile

Purpose

Instructions

Notes

Complete Institutional Profile Form

Sample University

New Submission

Download Agreement

The SMART IRB 3.0 Agreement is ready to view and download.

Agreement PDF

SMART IRB Agreement Version 3.0

Share Agreement

Once you have reviewed and confirmed the information from Agreement PDF, Please have your institution's Signatory Official (as documented on the verified Institution Details form) sign the agreement.

Signatory Official (Institutional Official)

First Name

Mary

Last Name

Smith

Honorific

Dr

Phone Number

(212) 555-1212

Email Address

smartirbuser2@outlook.com

Request Signature

SMART IRB Participating Institutions

1426 Participating Institutions including all CTSA hubs

Reliance System: Log In >



Reliance Agreement ▾ Reliance System ▾ Harmonization Resources & Education ▾ Support ▾



RELIANCE AGREEMENT

Participating Institutions

Use the SMART IRB Agreement to enable IRB reliance

Confirm participation status and contact an institution or log in to request reliance.

Log In >

NEW!

As of March 17, 2025, all new reliance arrangements must be under SMART IRB Agreement V3.0. Participating Institutions may not initiate new reliance arrangements under SMART IRB Agreements (V1.0/2.0).

V3.0 Institutions are shown below by default. To view Legacy institutions that have not yet joined V3.0, click the checkbox below.

Q Enter keywords to search table

Download List Contact for API >

☒ Show V3.0 institutions ☐ Show Legacy institutions (V1.0/2.0)

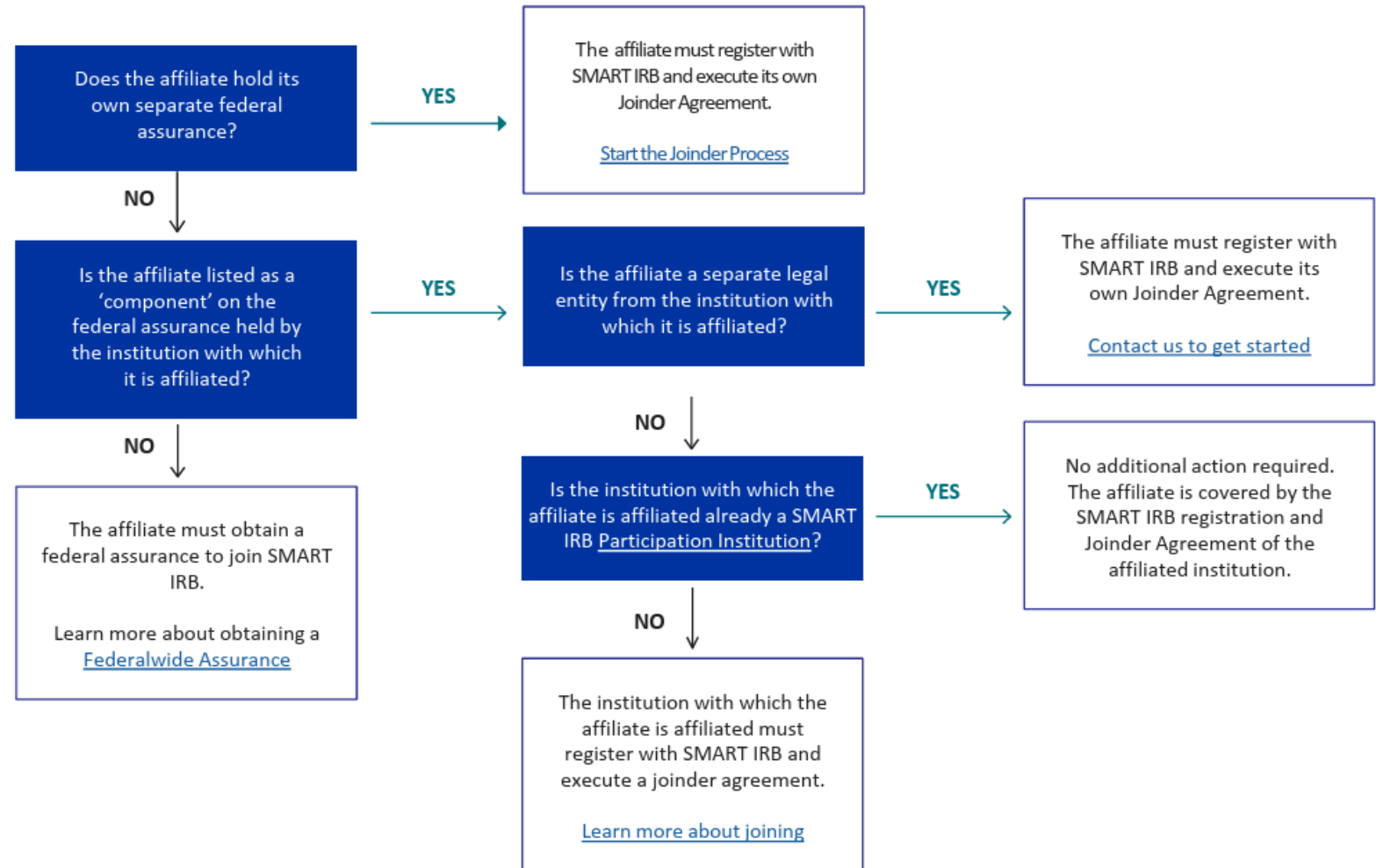
Name ¹	Version ¹	Indemnification ¹	City ¹	State ¹	Point of Contact (POC) ¹	Profile ¹
Abington Hospital- Jefferson Health	V3.0; V2.0;V1.0		Abington	Pennsylvania	Crystal Lijadu	PDF
Acacia Clinics	V3.0;V2.0	✓	Sunnyvale	California	Danielle DeSouza	PDF

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](#)”



Does my affiliate institution need to join as a separate SMART IRB institution?



www.smartirb.org

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 "Joining SMART IRB: Guidance for Affiliates" 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. 75N950C00008.

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>

www.smartirb.org

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

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 [doc name] as part of SMART IRB, which is funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, 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	<input type="checkbox"/> Default Implementation Applies (per Implementation Checklist) <input type="checkbox"/> 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	

www.smartirb.org

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 "Letter of Acknowledgment" 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. 75N950C00008.

‘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

www.smartirb.org

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 "Letter of Acknowledgment" 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. 75N950C00008.

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



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 Ceded Review
<i>Section 3.2.3</i> | <input type="checkbox"/> (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.

<input type="checkbox"/> 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.

<input type="checkbox"/> 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. |
|---|---|