



## 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 1450+ signatories across North America



## Reliance System

Your home to request, document, and track reliance requests with fellow SMART IRB [Participating Institutions](#)



## 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

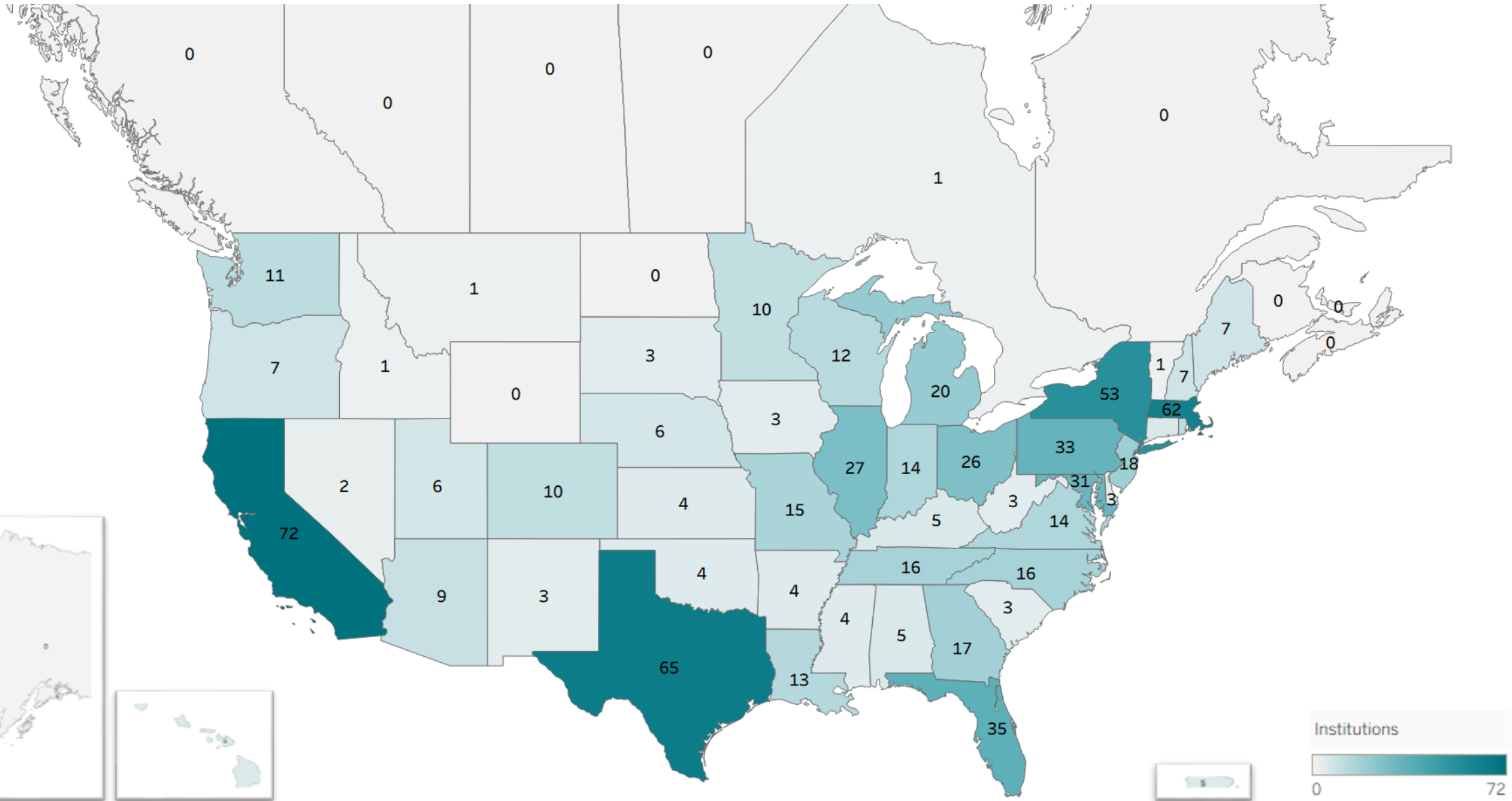


## Support

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



# 718 V3.0 Participating Institutions across North America



# SMART IRB Reliance System Patch, 6.02.26

- **‘Display Name’** now used rather than **‘Legal Name’** for all areas of Reliance System except for institutional Joinder Agreements
- **‘Reopened’** State is now editable for submitter/PI home institution
- **Participating Institutions** page
  - IRB/HRPP Website now listed (when applicable)
  - Group e-mail(s) now listed (when applicable)
  - CTSA Hubs now listed
  - Duplicate entry fixed

Next patch anticipated within next few weeks, stay tuned!

# Reliance System: Upcoming Patch Runway Highlights

Improvements we are currently working on include (but are not limited to) the following areas:

- Updates to **Institutional Profile (PDF)**
- **Editing + Updates for Life of Study**
- Improvements to **Reliance Request History Log**





## To Be Great Is to Be Misunderstood: Common SMART IRB Myths Debunked

Moderator:

**Nichelle Cobb**, SMART IRB Ambassador At Large + Senior Advisor

Panelists:

**Polly Goodman**, SMART IRB Senior Associate Director, Regulatory Affairs  
Operations + Ambassador Northeast/New England + Middle Atlantic

**Stacey Goretzka**, SMART IRB South Atlantic

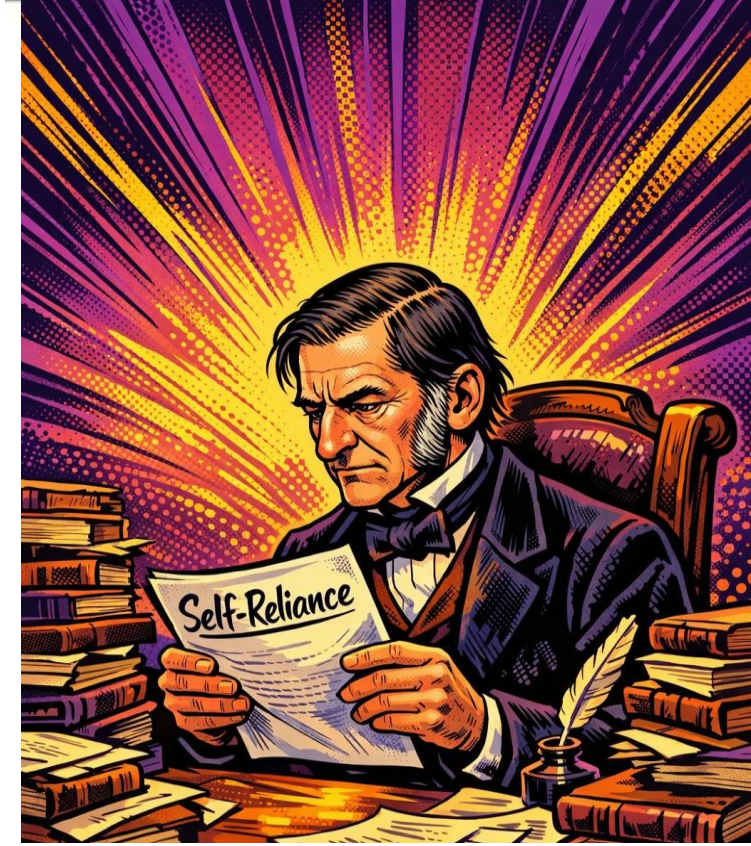
**Jeremy Lavigne**, SMART IRB Senior Officer + Ambassador West, Mountain, and  
Pacific

**Kathy Lawry**, SMART IRB Ambassador At Large

**Mike Linke**, SMART IRB Program Director, Education

**Ada Sue Selwitz**, SMART IRB Ambassador At Large + South + Puerto Rico

[SMARTIRB.org](https://SMARTIRB.org)



AI-generated image of  
Ralph Waldo Emerson

# Today's Myth Busters



Polly Goodman  
*Harvard Catalyst*



Ada Sue Selwitz  
*University of Kentucky*



Jeremy Lavigne  
*Harvard Catalyst*



Mike Linke  
*University of Cincinnati*



Kathy Lawry  
*AAHRPP*



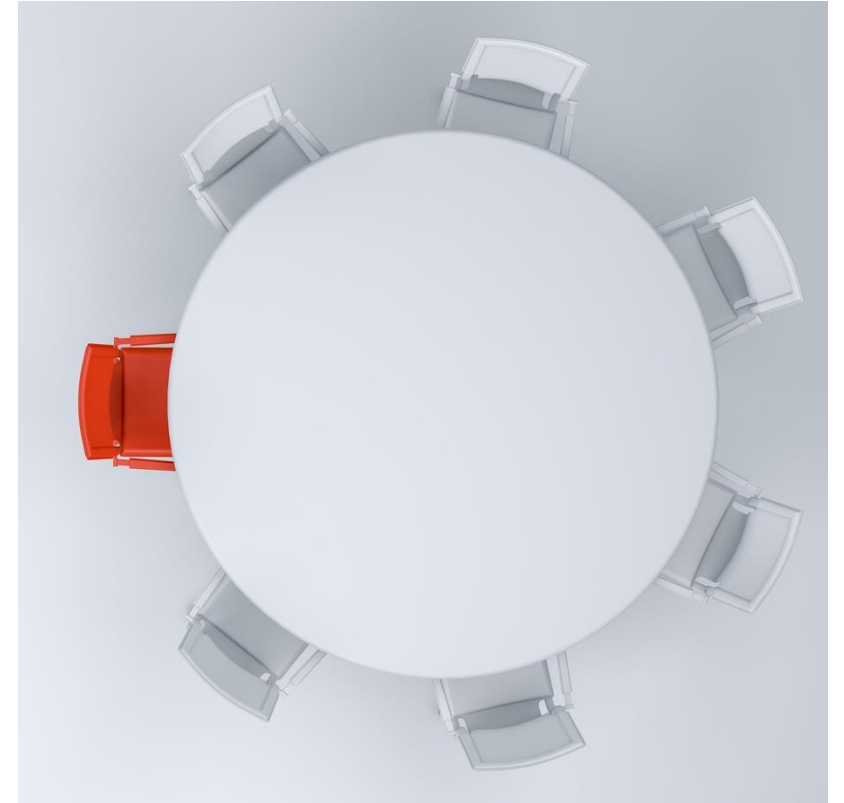
Stacey Goretzka  
*Independent Consultant*



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Myth: SMART IRB is an IRB

Myth: There is a fee to join  
SMART IRB



Myth: SMART IRB means the  
reliance platform

Myth: The SMART IRB  
reliance system is required



Welcome to SMART IRB

Log In With

Search Organization to log in



NIH



Login.gov

Don't have a SMART IRB Account? [Sign Up](#)

To preview the SMART IRB Agreement, please download a sample agreement by  
visiting the [SMART IRB Website Agreements Page](#).

Myth: NIH requires the use of  
SMART IRB

Myth: The SMART IRB agreement  
can only be used for NIH-funded  
research



[This Photo](#) by Unknown Author is licensed under [CC BY-SA-NC](#)

Myth: The language in the  
SMART IRB agreement can be  
modified



Myth: Flexible terms were introduced with V3.0 of the SMART IRB Agreement and has made the agreement more difficult to use



**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.

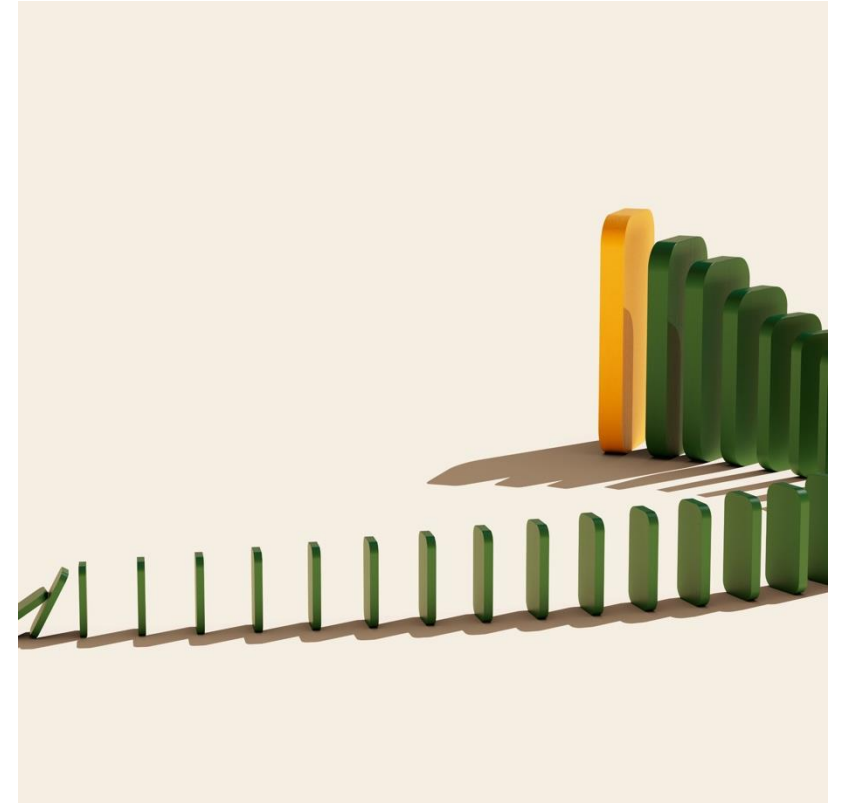
### Implementation Checklist and Documentation Tool

|                                                                                                                   |                                                                                                                                         |
|-------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| 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<br><input type="checkbox"/> Flexible Implementation Applies (as outlined below) |
| This Implementation Checklist was completed by<br>the following institutional representatives (Name, Role, Date): |                                                                                                                                         |

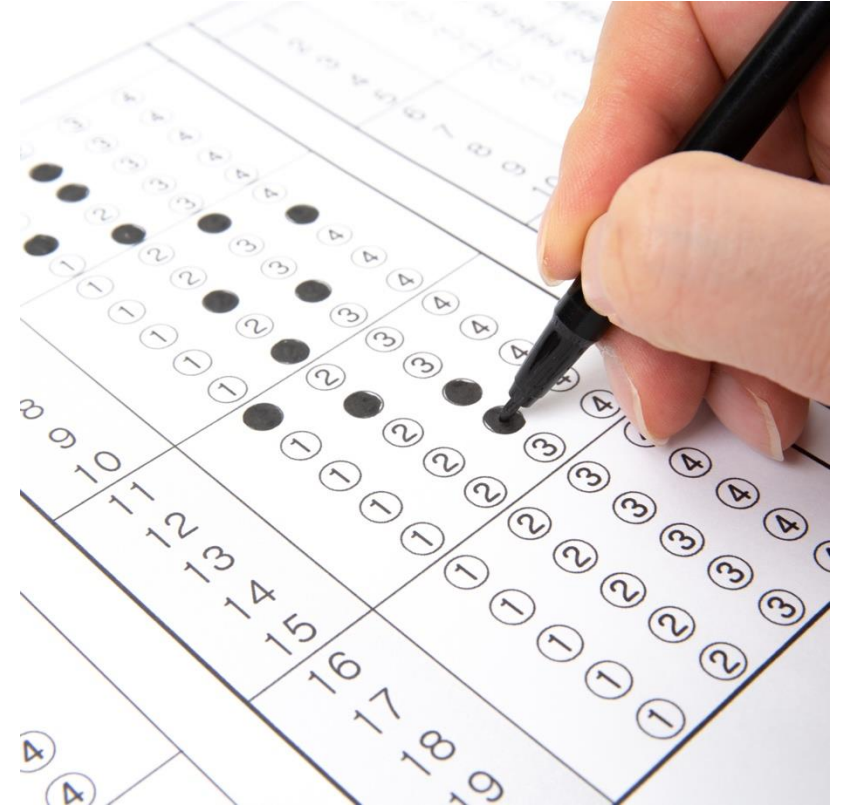
Myth: If my institution signs onto the SMART IRB agreement, we will be required to provide IRB review for other organizations



Myth: Only one institution that is part of a group of affiliated institutions with separate FWAs needs to join SMART IRB (in other words, SMART IRB allows daisy chaining reliance)



Myth: The SMART IRB  
agreement does not support  
social/behavioral/education  
research



# Myth: To join the SMART IRB Agreement, organizations are also required to execute an indemnification agreement



## SMART IRB Indemnification Addendum

This SMART IRB Indemnification Addendum ("Indemnification Addendum") sets forth certain terms providing for allocation of financial liability or responsibility between a Reviewing IRB/Reviewing IRB Institution and a Relying Institution resulting from their activities under the SMART IRB Reliance Agreement ("Agreement"). Any Participating Institution in the Agreement may join this Indemnification Addendum (each an "Indemnification Participating Institution") by executing a SMART IRB Indemnification Addendum Joinder Agreement available at [www.smartirb.org](http://www.smartirb.org), which will be in substantially the same form as in this Indemnification Addendum ("Indemnification Addendum Joinder Agreement"), as further set forth below. **Certain obligations of this Indemnification Addendum apply only to Private Institutions or only to Public Institutions (as those terms are defined in the Agreement) as identified by the relevant section headings below.**

A glossary of all acronyms and capitalized terms used in this Indemnification Addendum, even if they are defined within the Indemnification Addendum, is provided at Exhibit A to the Agreement. Acronyms and capitalized terms used but not otherwise defined in this Indemnification Addendum have the same meanings as given to them in the Agreement.

### 1. Eligibility and Process To Participate in the Indemnification Addendum

Any Participating Institution may participate in this Indemnification Addendum by executing the Indemnification Addendum Joinder Agreement. Executing the Indemnification Addendum Joinder Agreement documents the Indemnification Participating Institution's agreement to be bound by and subject to the applicable terms of the Indemnification Addendum with respect to the activities described more specifically in Section 2 hereof.

The Effective Date of the Indemnification Addendum with respect to any Indemnification Participating Institution is the date on which the Indemnification Participating Institution's Institutional Official/Signatory executes the Indemnification Addendum Joinder Agreement.

### 2. Scope of the Indemnification Addendum and Effect on Existing Indemnification Arrangements

This Indemnification Addendum applies with respect to all Covered Activities initiated by two (or more) Indemnification Participating Institutions as a Reviewing IRB/Reviewing IRB Institution or a Relying Institution under the Agreement after the Effective Date of the Indemnification Addendum, unless a more limited scope (i.e., application only to certain such Covered Activities) is otherwise agreed by the relevant Indemnification Participating Institutions involved in the activity. In cases where a more limited scope is agreed by the relevant Indemnification Participating Institutions, such institutions remain free to enter any other separate agreement providing for indemnification or similar arrangements for allocation of financial liability or responsibility resulting from

Myth: The SMART IRB Agreement must be re-executed if the institutional official has changed



Myth: Organizations are required to use SMART IRB Standard Operating Procedures to govern the reliance arrangement

Reliance Agreement  
Version 3.0

**Standard Operating  
Procedures**

# Myth: The SMART IRB Letter of Acknowledgement (LOA) must be signed



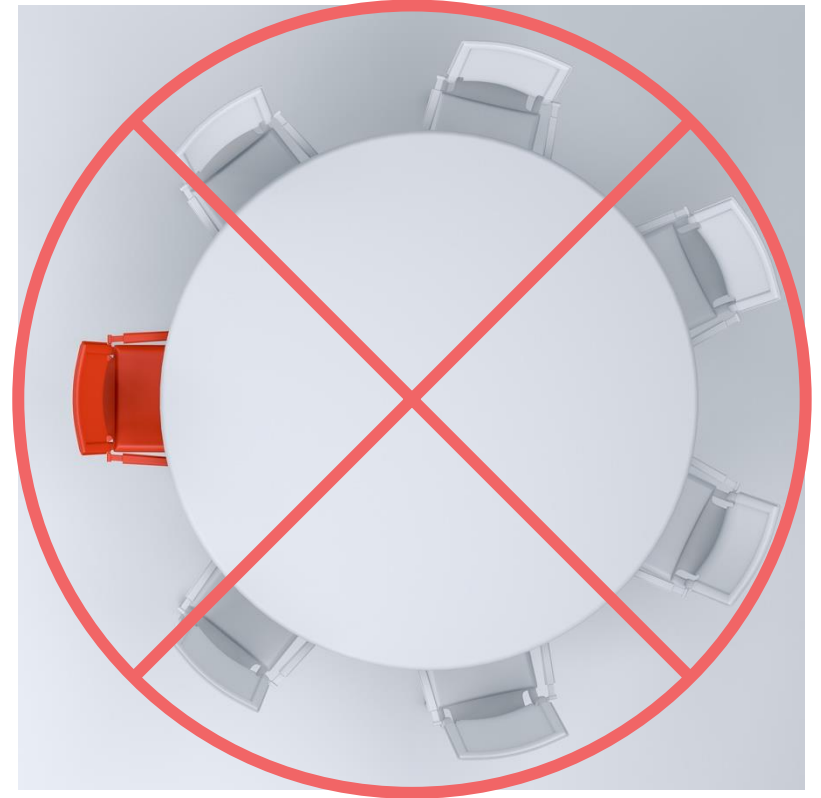
**Purpose of Form:** This form documents that the following Reviewing IRB Institution will serve as Reviewing IRB for the research noted below; and the following Relying Institution has agreed to cede IRB review to the Reviewing IRB listed below.

## Letter of Acknowledgment

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 <a href="#">Implementation Checklist</a> )<br><input type="checkbox"/> Flexible Implementation Applies (per <a href="#">Implementation Checklist</a> ) |
| <b>This Letter of Acknowledgment was completed by the following institutional representatives (Name, Role, Date):</b> |                                                                                                                                                                                                                     |
| Reviewing Institution POC/Designee                                                                                    |                                                                                                                                                                                                                     |
| Relying Institution POC/Designee                                                                                      |                                                                                                                                                                                                                     |

Myth: My institution does not maintain an IRB so we can't join SMART IRB



Myth: My institution cannot  
join SMART IRB because it is  
not yet AAHRPP accredited



Association for the Accreditation  
of Human Research Protection Programs, Inc.®

Myth: SMART IRB resources,  
like the communication  
plan, cannot be modified



# Myth: The SMART IRB Agreement cannot be used to cover reliance arrangements for exempt human subjects research



## Code of Federal Regulations

A point in time eCFR system



Title 45

Displaying title 45, up to date as of 6/01/2026. Title 45 was last amended 5/26/2026. [view historical versions](#)

Enter a search term or CFR reference (eg. fishing or 1 CFR 1.1)



Title 45 / Subtitle A / Subchapter A / Part 46 / Subpart A / § 46.104

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### ECFR CONTENT

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#### EDITORIAL NOTE ON PART 46

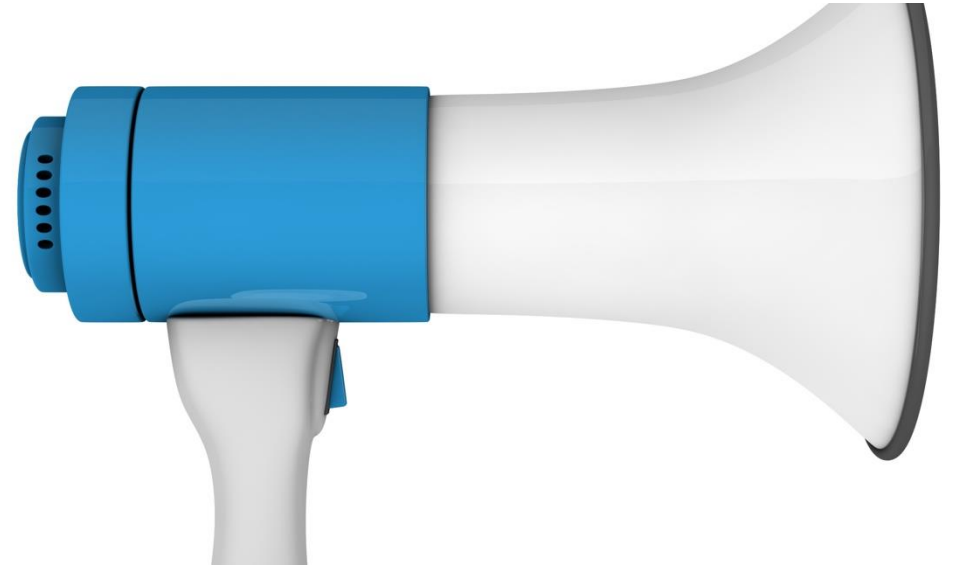
**Editorial Note:** The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost-sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9208, Mar. 4, 1982.

§ 46.104 Exempt research.

Myth: The SMART IRB Agreement does not require Reviewing IRBs to consider any Local Considerations, Other Considerations, and other local information communicated to it by Relying Institutions



Myth: The SMART IRB Agreement requires the Reviewing IRB to be responsible for reporting events (e.g., serious or continuing noncompliance or unanticipated problems) to Federal agencies



Myth: The SMART IRB Agreement requires Reviewing IRBs to review the congruence of any federal grant application/proposal with the research protocol submitted to the IRB



Questions and further discussion



Myth Debunked: SMART IRB is not of this Earth

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THANK YOU!