



## 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 for the presenter or SMART IRB Team are welcome!  
Please post these under 'Q/A'

Questions for 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  
An Online 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

# Reach out to a SMART IRB Ambassador



Aaron Kirby  
*Harvard Catalyst*



Polly Goodman  
*Harvard Catalyst*



Jeremy Lavigne  
*Harvard Catalyst*



Ada Sue Selwitz  
*University of Kentucky*

<https://smartirb.org/ambassadors/>



Carissa Minder  
*Washington University in St. Louis*



Kathy Lawry  
*AAHRPP*



Nichelle Cobb  
*AAHRPP*



Stacey Goretzka



Lubabah Helwani  
*University of Southern California*

**What We've Been Up To...**



# SMART IRB Reliance Agreement Version 3.0: Public Comment Period

- Public Comment Period (2<sup>nd</sup> Round)  
Coming VERY Soon!
- **30 Day Comment Period**
- [www.smartirb.org/agreement](http://www.smartirb.org/agreement)
- Agreement Materials and support documents including:
  - Executive Summary
  - FAQ
  - Redlined Copy
  - PowerPoint Slides



Questions? Contact us at [Help@smartirb.org](mailto:Help@smartirb.org)

# See You In Seattle! PRIM&R 2024 National Conference

- Join us at the Exhibition hall: SMART IRB will be at **Booth 422**
- Say Hello to Polly and Jeremy!
- **Free Swag** and SMART-IRB related goodies!
- Learn more about our upcoming Reliance System, V3.0, website, and more!



**I'm Exhibiting!**

PRIM&R Annual Conference  
November 17-20, 2024  
Seattle, Washington



#PRIMR24 #PRIMRConference #ResearchEthics

# Online Reliance System: Present State

- System designed to allow study teams to drive the process
- ‘Batching’ Reliance requests
- As of 2020, Site-specific determinations can be provided

## Request Details

**ID: 8 - Effect of population increase on agricultural output in Genovia**

**Principal Investigator (PI)**  
Sophia Channing  
Ridgeview Research Facility

**Request Activity** Contact List ...

**Overall Status details**  
**Reviewing IRB Identified**

**Reviewing IRB**  
Ridgeview Research Facility

**Sites Involved**

● Willing to Rely  
● Not Relying  
● Awaiting Response  
● Sites Removed

**Benjamin Franklin College** **Awaiting Response**  
Awaiting Decision

**Carnegie University** **Awaiting Response**  
Awaiting Decision

**Anderson-McCoy University** **Willing To Rely**

Reliance Form **Issue Site Specific Determination**

**Comments from Reviewing IRB** [Add a Comment](#)  
No comments have been added for this request.

**Request History** [Show all status changes](#)

Jodi Atkinson reopened this Reliance request for revisions for the following reason(s): add site  
Samantha Doe Mar 04, 2020 4:11 PM UTC

**Need Help?**  
[Contact us](#)  
[Suggest an improvement](#)

**Downloads**  
[Request \(ZIP\)](#)

# Online Reliance System: Present State (2 of 2)

- Opportunities to share local site context, other relevant information
- Notifications to study teams and IRB/HRPPs at each step along the way
- Clear, centralized documentation of reliance arrangements

The screenshot displays the SMART IRB Reliance system interface. At the top, the navigation bar includes the SMART IRB Reliance logo, Home, New Request, and Logout links, along with the user login information: 'You are logged in as system\_administrator@ridgeview.net'.

The main content area is titled 'Request Details' and shows 'ID: 3 - A literature review of methods for data security'. The left sidebar contains a navigation menu with the following items: Summary, Reliance Request (marked with a green dot), Reliance Pre-Check (marked with a green dot), Reviewing IRB (Belledale Institute, marked with a green dot), Involved Institutions (Adams University, Belledale Institute, Benjamin Franklin College, all marked with white circles), and Determination (marked with a white circle). A 'Withdraw Request' link is also present.

The main form area is titled 'Institution Reliance Form'. It includes a legend for required fields (\*= Required Field) and a link to 'View Reliance Request Form'. The form text states: 'You have the option to rely on Belledale Institute's review and oversight of the research according to the Reliance Agreement and SOPs.' The 'Proposed Reviewing IRB' is 'Belledale Institute' and the 'Contact' is 'IRB Office, 555-555-5555, irb\_office@Belledale.org'. A note says: 'If you have any outstanding concerns, please discuss them with the Proposed Reviewing IRB prior to completing this form.' The question 'Does Adams University agree to rely on Belledale Institute?\*' has 'Yes' selected. The 'Institutional requirements and local context concerns' section has a text area highlighted with a red box and an arrow pointing to it with the text 'Enter local context concerns here'. Below the text area is a 'Cancel' button and 'Save' and 'Submit' buttons.

# Online Reliance System IT Transition

- Last major system upgrade in 2020
- System oversight transitioned from Harvard to NCATS in May 2021
  - **AXLE Informatics** leading development and informatics for ORS
- Significant changes to come:
  - Accommodate Version 3.0 (e.g. indemnification provision, electronic signature)
  - Inclusion of US Dept of Veterans Affairs, Department of Defense, and Department of Energy
  - Incorporate frequently asked system enhancements



## SMART Talk: The \*New\* SMART IRB Reliance System

November 13, 2024, 1:00-2:30pm ET

Presenter:

-**Kalifa Alexander**, Business Analyst- IRB SME, AXLE Informatics

Moderator:

-**Jeremy Lavigne**, Senior Officer, SMART IRB

Panel:

-**Kevin Thirkell**, IT Engagement Director, AXLE Informatics

-**Polly Goodman**, Senior Associate Director of Regulatory Affairs + Operations, SMART IRB

-**Nadia Johnson**, Assistant Director of IRB Operations, NYU Langone

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