

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.



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



ambassadors/

https://smartirb.org/

Carissa Minder Washington University in St. Louis



Kathy Lawry

AAHRPP



Nichelle Cobb

AAHRPP

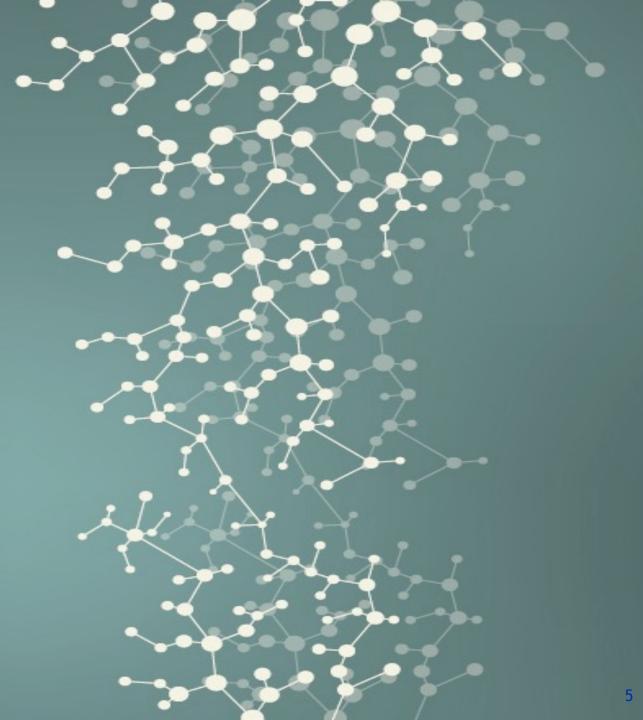


Stacey Goretzka



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



Questions? Contact us at Help@smartirb.org

See You In Seattle! PRIM&R 2024 National Conference

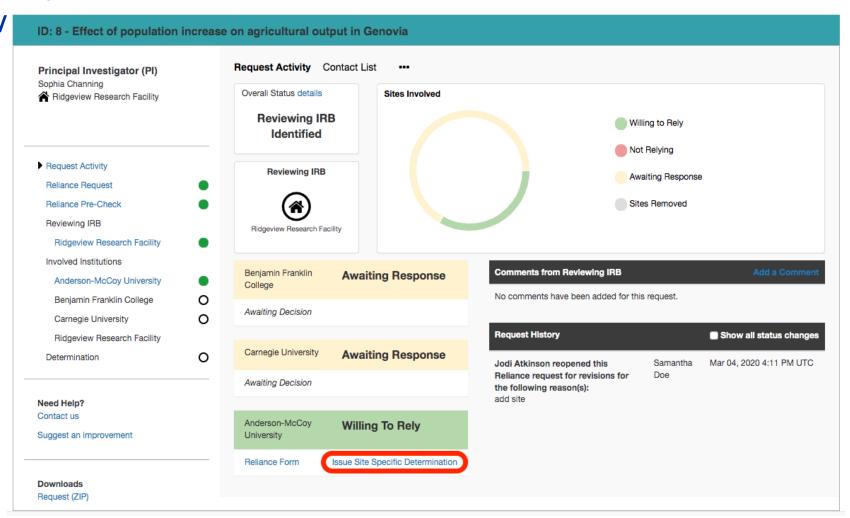
- Join us at the Exhibition hall:
 SMART IRB will be at Booth 422
- Say Hello to Polly and Jeremy!
- Free Swag and SMART-IRB related goodies!
- Learn more about our upcoming Reliance System, V3.0, website, and more!



Online Reliance System: Present State

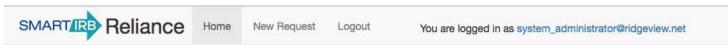
- System designed to allow study teams to drive the process
- 'Batching' Reliance requests
- As of 2020, Site-specific determinations can be provided

Request Details

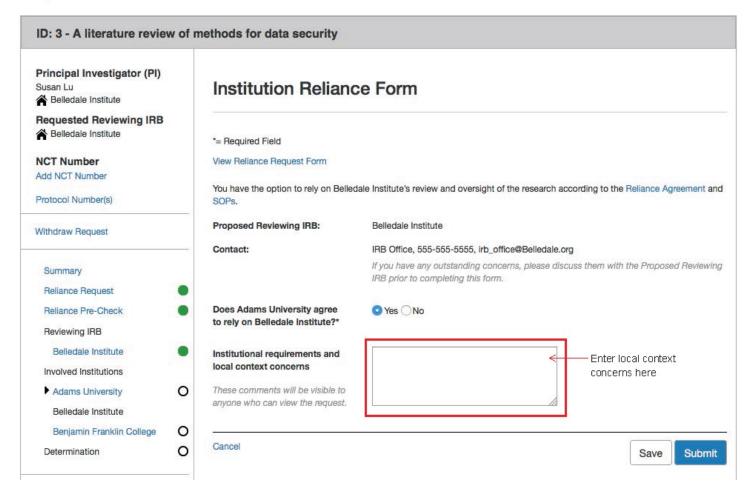


Online Reliance System: Present State (2 of 2)

- 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



Request Details



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