SMART TALK

A Community Forum to Explore Issues Surrounding Single IRB Review

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, Federal Contract 75N95023C0008

FYI

Questions for the presenter or SMART IRB Team are welcome! Please post these under ‘Q/A’ (you can also use Mentimeter)

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…

A global 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

SMART IRB: Then and Now

October 2019

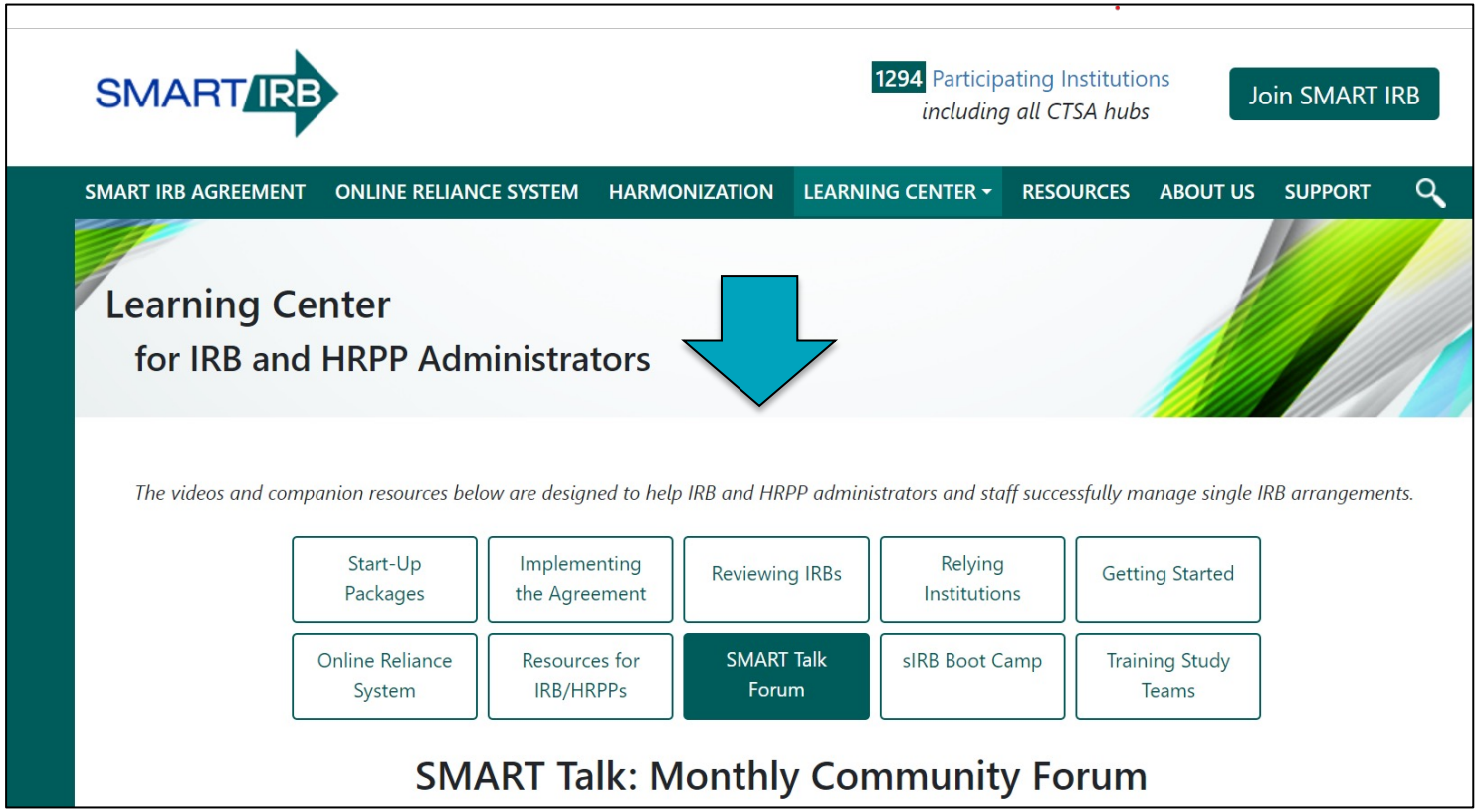
- 629 Participating Institutions
- 2,455 ORS Reliance ID Requests
- 3,495 Registered ORS Users
- 5 Harmonization Documents
- 1 SMART Talk

October 2024

- 1,294 Participating Institutions
- 9,462 ORS Reliance ID Requests
- 11,226+ Registered ORS Users
- 10 Harmonization Documents
- 44 SMART Talks (45 including today)

Happy 5th Anniversary to SMART Talks!

- Since September 2019, we've produced 44 (and about to be 45) webinars on a range of topics with an amazing group of experts
- Access them at https://smartirb.org/irb-admin/



Single IRB Lessons Learned (or the Secrets of Single IRB Success)

Today's presenters:

- Aaron Kirby, SMART IRB Ambassador for the Northeast/New England + Middle Atlantic
- Jeremy Lavigne, SMART IRB Ambassador for the Southwest + Mountain Regions
- Jonathan Green, SMART IRB Program Director for Strategic Initiatives
- Kathy Lawry, SMART IRB Ambassador at Large
- Lubabah Helwani, SMART IRB Ambassador for the West and Pacific Regions
- Mike Linke, SMART IRB Program Director for Education
- Polly Goodman, SMART IRB Ambassador for the Northeast/New England + Middle Atlantic
- Stacey Goretzka, SMART IRB Ambassador for the South/South Atlantic

Moderator:

- **Nichelle Cobb**, Senior Advisor and Ambassador at Large, SMART IRB

SMARTIRB.org

Poll question: Think about the last 5 years of single IRB implementation…

- Is single IRB:
  - A piece of cake – no problems implementing it most of the time
  - A work in progress – there are some successes and some challenges
  - A headache every time – we have significant challenges with almost every reliance arrangement

Poll question: Think about the last 5 years of single IRB implementation…Do you think that your organization needed:

- A net resource increase in response to single IRB
- No net resource increase or decrease in response to single IRB
- A net resource decrease in response to single IRB

Poll question: Think about the last 5 years of single IRB implementation…What do you think that IRBs and HRPPs have experienced:

- A net resource increase in response to single IRB
- No net resource increase or decrease in response to single IRB
- A net resource decrease in response to single IRB

Questions for the SMART IRB Team

- What do you think has changed over the past 5 years related to the implementation of single IRB?
- What is working well?
- What are some areas for improvement?

How frequently does your organization use these agreements for single IRB arrangements? (Most frequent=1; 5=least frequent)

- SMART IRB Agreement
- OHRP IRB Authorization Agreement
- Agreement developed by your institution
- Contract with an independent (commercial) IRB (e.g., WCG, Advarra, BRANY, Univo)
- Other agreement

How often does your organization use the SMART IRB Online Reliance System (ORS) to track reliance arrangements?

- As often as we can
- Sometimes - we don't insist on using it
- We don't use the ORS
- What's the ORS?

Poll: What tools do you use to track single IRB agreements and their terms? (open-ended responses

Questions for the SMART IRB Team

- Why use the SMART IRB Agreement vs other agreements?
- What are some methods/tools for tracking reliance agreements (and why do you need to track them)?

Do Reviewing IRBs routinely request local context from Relying Institutions (either on a per study basis or once and keep that information on file)?

- Most Reviewing IRBs request local context information
- Some Reviewing IRBs request local context
- A minority of Reviewing IRBs request local context

Does your organization require a formal Communication Plan that outlines the responsibilities of the Reviewing IRB, Relying Institution, and Study Teams related to a reliance arrangement?

- Always
- Most of the time
- Sometimes
- Rarely
- Never
- What's a communication plan?

Questions for the SMART IRB Team

- Why is local context information important?
- Recommendations for facilitating efficient communication between Reviewing IRB/Relying Institutions,/study teams?

Local Considerations - Roles & Timing

Study Development

Researchers develop protocols that take into account the differences at each participating institution

Initial IRB Review of a Site

Relying Site PIs/Relying Site Study Teams & Relying Institutions work together to provide the Reviewing IRB with accurate local considerations information

After Initial IRB Approval

Reviewing IRBs identify categories of changes that should trigger a review & Relying Institutions develop guidance for their study teams regarding what changes in research, events, and other information may impact local considerations and may require input from their institution's HRPP

Poll question: Think about the last 5 years of single IRB implementation…How often have you (or your organization) used these SMART IRB resources?

- SMART IRB Ambassadors
- Communication Plan
- Harmonization Recommendations
- Implementation Checklist for use of the SMART IRB Agreement
- Institutional Profile or Protocol-Specific Document for Local Context
- Checklists for Study Teams
- SMART IRB SOP Manual
- Start Up Packages (for IRBs/HRPPs or Study Teams)

Questions for the SMART IRB Team

- What are the SMART IRB resources you see the community using most frequently?
- What are examples of effective use of SMART IRB resources?
- Why use the SMART IRB resources?

Random Questions

Poll question: Does your institution serve as a Reviewing IRB (single IRB):

- More often than we are a relying institution
- About the same as we are a relying institution
- Rarely
- Never

Poll question: What do you think the impact of the FDA single IRB requirement will be?

- Very little
- Some impact
- A big deal

Poll question: Has anyone received an exception to the single IRB requirement from a Federal agency? (If you have, please describe the exception in Chat.)

- Yes
- No
- Don’t know

Questions for the SMART IRB Team

- What factors should you assess when considering serving as a Reviewing IRB?
- What are changes you have seen in transitioning from local IRB review to relying on an external Reviewing IRB?
- How can organizations collaborate best to ensure the rights and welfare of research participants are protected?

Wrap Up

Questions for the SMART IRB Team

- If you were giving advice to someone starting out with single IRB, what wisdom would you impart?

SMART Talk: The *New* SMART IRB Reliance System

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

Presenter:

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

Moderator:

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

Panel:

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

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

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

Register at smartirb.org

Sign up for our mailing list to be notified of future offerings

SMARTIRB.org