



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, grant
number 3UL1TR002541-04S2.

What Is SMART Talk?

An approximately monthly forum with:

- Presentations on topics relevant for single IRB review
- Q&A on topic presented as well as questions submitted when participants register

Open and free to anyone with interest

Upcoming sessions

May 2023: No SMART Talk

TBD (working with the speakers on the date) → June or July: Exploring the Financial Aspects of Single IRB

If you missed this year's SMART IRB Boot Camp

This online session, held February 7 & 9, 2023, provided training for IRB and HRPP personnel on successful implementation of the sIRB review model and demonstrated how to leverage SMART IRB resources to achieve that success. Watch session recordings and download slides.

- Slides and videos available
- Day 1:
https://smartirb.org/assets/files/Day1_FINAL_2023SMARTIRBBootcamp.pdf
- Day 2:
https://smartirb.org/assets/files/Day2_FINAL_2023SMARTIRBBootcamp.pdf

FYIs

Please provide feedback by completing the survey - a link will be posted in chat and emailed.

A recording of this talk will be posted on the SMART IRB website

A link to the talk will be sent to those who registered for the talk when it is posted

If you have any questions for the panelists, please use the chat function or Q&A function to submit them

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 master IRB reliance agreement
An Online Reliance System to initiate and track reliance
Other resources free to institutions and researchers



SMART IRB is NOT...

An IRB
An electronic system for Reviewing IRBs to receive studies for review

If We Don't Answer Your
Questions Today...



Reach out to a SMART IRB Ambassador

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



Aaron Kirby
*Harvard
Catalyst*



Ada Sue Selwitz
*University of
Kentucky*



Carissa Minder
*Washington
University in St.
Louis*



Stacey Goretzka
*Medical University
of South Carolina*



Kathy Lawry
AAHRPP



Lubabah Helwani
*University of California,
Los Angeles*



Nichelle Cobb
AAHRPP



Polly Goodman
Harvard Catalyst

Key Resources



Harmonization Steering Committee Recommendations

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

- Ancillary Review
- Conflict of Interest
- Post-Approval Auditing for Studies Subject to Single IRB Review
- Single IRB Continuing Review Process
- Single IRB Review: Responsibilities Associated with the Review of Study Personnel
- Reportable Events
- Institutional Profile
- Protocol-specific Document
- Fees and Costing Models under NIH sIRB Policy
- Institution v. IRB Responsibilities Guidance

In progress:
Local
considerations
recommendations

SMART Talks in 2022

(available at <https://smartirb.org/resources/>)

- **January 2022:** A Conversation with NIH and OHRP about Single IRB
- **March 2022:** Single IRB from the Perspective of Research Teams
- **April 2022:** SMART IRB 2022: Where We've Been and Where We're Heading
- **June 2022:** Serving as a Reviewing IRB for Large Multi-Site Studies
- **July 2022:** A Conversation with the Department of Defense (DOD), Department of Energy (DOE), and Department of Veterans Affairs (VA) about Single IRB
- **August 2022:** Everything You Wanted to Know about Single IRB but Were Afraid to Ask
- **September 2022:** Single IRB and Noncompliance - A Case Study
- **November 2022:** A Conversation with the FDA and OHRP about Single IRB

[Start Up Packages at smartirb.org/resources/](https://smartirb.org/resources/)

These packages contain a suite of resources based on role: Study Teams, Reviewing IRBs, and Relying Institutions. Also found in the SMART IRB Learning Center.

Each package provides a guide describing how and when to use the included resource as well as links to online tools and further information.

[Start-up Package for Relying Institutions](#) ⬇

A suite of resources to help Relying Institutions understand and fulfill their roles and responsibilities in a single IRB arrangement; the package provides a guide describing how and when to use the included resource as well as links to online tools and further information.

[Start-up Package for Reviewing IRBs](#) ⬇

A suite of resources to help Reviewing IRBs understand and fulfill their roles and responsibilities in a single IRB arrangement; the package provides a guide describing how and when to use the included resource as well as links to online tools and further information.

[Start-up Package for Study Teams](#) ⬇

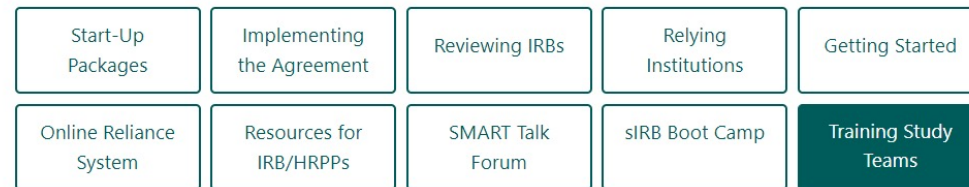
A suite of resources to ensure study teams understand and can fulfill their responsibilities related to single IRB arrangements; the package provides a guide describing how and when to use the included resource as well as links to online tools and further information.

Training and Education for Investigators and Study Teams

These can be helpful for IRB/HRPP administrators new to single IRB as well!

Learning Center for IRB and HRPP Administrators

The videos and companion resources below are designed to help IRB and HRPP administrators and staff successfully manage single IRB arrangements.



Training for Investigators and Study Teams

Use this suite of training videos and resources as is, or customize to reflect local processes and policies.

Visit the [Investigator and Study Team Learning Center](#) to view available materials; send investigators here for self-guided learning.

⬇ Download presentations (no audio) to use for local training sessions or customize to reflect local processes.

To download the presentations with embedded audio, please use the links below:

- ⬇ Developing a Single IRB Plan
- ⬇ Overview of the NIH Single IRB Policy for Researchers
- ⬇ Potential Effects of Single IRB on Research Costs
- ⬇ Selecting a Single IRB
- ⬇ Single IRB review and SMART IRB
- ⬇ Study Team Roles Related to Single IRB

FAQs

Frequently asked questions covering eligibility, how to join, agreement provisions, and other important topics.

<https://smartirb.org/assets/files/faq.pdf>

FREQUENTLY ASKED QUESTIONS
(FAQ)



June 2022

SMART IRB SOP Manual

Standard operating procedures (SOPs) for establishing and implementing reliance provide clarity during the review and conduct of research using the SMART IRB Agreement.

https://smartirb.org/assets/files/SMART_IRB_SOP-090816.pdf

SMART IRB: Master Common
Reciprocal Institutional Review
Board Authorization Agreement
Standard Operating Procedures



Version Date: September 8, 2016

Communication Plan for Single IRB Review

Institutions can use this template to document key communication roles, such as submitting initial and continuing reviews, amendments, and reportable events to the Reviewing IRB; providing conflict of interest management plans to the Reviewing IRB; and providing IRB-approved documents and communicating Reviewing IRB determinations to relying site study teams.

https://smartirb.org/assets/files/Communications_Plan_Form.pdf



Purpose of the form: This form can be used by Reviewing IRBs and others to identify and document key communication roles for a study. It is recommended that the form be used to document the various responsibilities. However, the form also could be used less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team.

Template Communication Plan for SMART IRB

Definitions

- **REVIEWING IRB – Point of Contact (POC):** Main person responsible for addressing questions related to the Reviewing IRB’s policies and procedures and review status for a ceded study
- **LEAD STUDY TEAM – POC:** Main person responsible for communication with the Reviewing IRB and facilitating communication between relying site study teams and the Reviewing IRB regarding the ceded study
- **RELYING SITE – POC:** Main person responsible for communication with the Reviewing IRB and local study team regarding the ceded study (e.g., personnel in the local IRB office or local human research protection program personnel)
- **RELYING SITE STUDY TEAM POC:** Main person responsible for communication with the Lead Study Team regarding the ceded study

ROLE	NAME(S)	CONTACT INFORMATION
REVIEWING IRB – POC		
LEAD STUDY TEAM – POC		

www.smartirb.org

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<https://support.smartirb.org/hc/en-us>



[Contact Us](#)

SMART IRB Support Center

[The SMART IRB Agreement](#)

[About SMART IRB](#)

[Joining SMART IRB](#)

[Online Reliance System](#)

[? Help](#)



Single IRB Workflow From Beginning to End

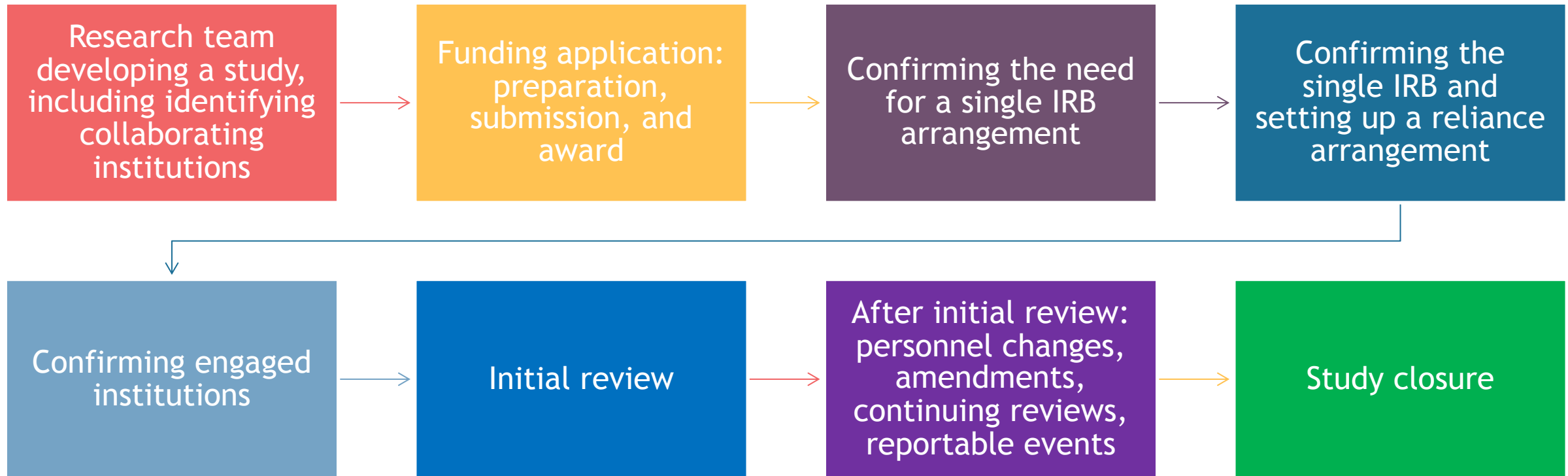
Today's panelists:

- **Marcella Cooks**, IRB Reliance Manager, Northwestern University
- **Julie Martin**, Assistant Director, Emory Institutional Review Board
- **John Roberts**, Executive Director of Human Research Protections, Drexel University

Moderator-

Nichelle Cobb, Senior Advisor, SMART IRB; Senior Advisor for Strategic Initiatives, Association for the Accreditation of Human Research Protection Programs (AAHRPP)

Single IRB Workflow



Save the date for the next
SMART Talk
June 21, 2023
2:00-3:30 pm ET

Questions?
Contact
help@smartirb.org

Register at
smartirb.org

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