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.

Upcoming sessions

Special November 29th session:
Introducing Draft SMART IRB Agreement v3.0

December: No SMART Talk – enjoy PRIM&R!

January 2024: working on it!

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

Polly Goodman
Harvard Catalyst

Senior SMART IRB Officer

Welcome, Jeremy!

Ada Sue Selwitz
University of Kentucky

Carissa Minder
Washington University in St. Louis

Kathy Lawry
AAHRPP

Nichelle Cobb
AAHRPP

Stacey Goretzka
Medical University of South Carolina

Lubabah Helwani
University of California, Los Angeles

Key Resources

IF YOU ARE NEW TO SINGLE IRB:
2023 SMART IRB Boot Camp

This online session, held February 7 & 9, 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

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

Local considerations recommendations reviewing and revising based on comments received

NEW Working Group: SMART IRB Reliance for Exemptions

Prior SMART Talks

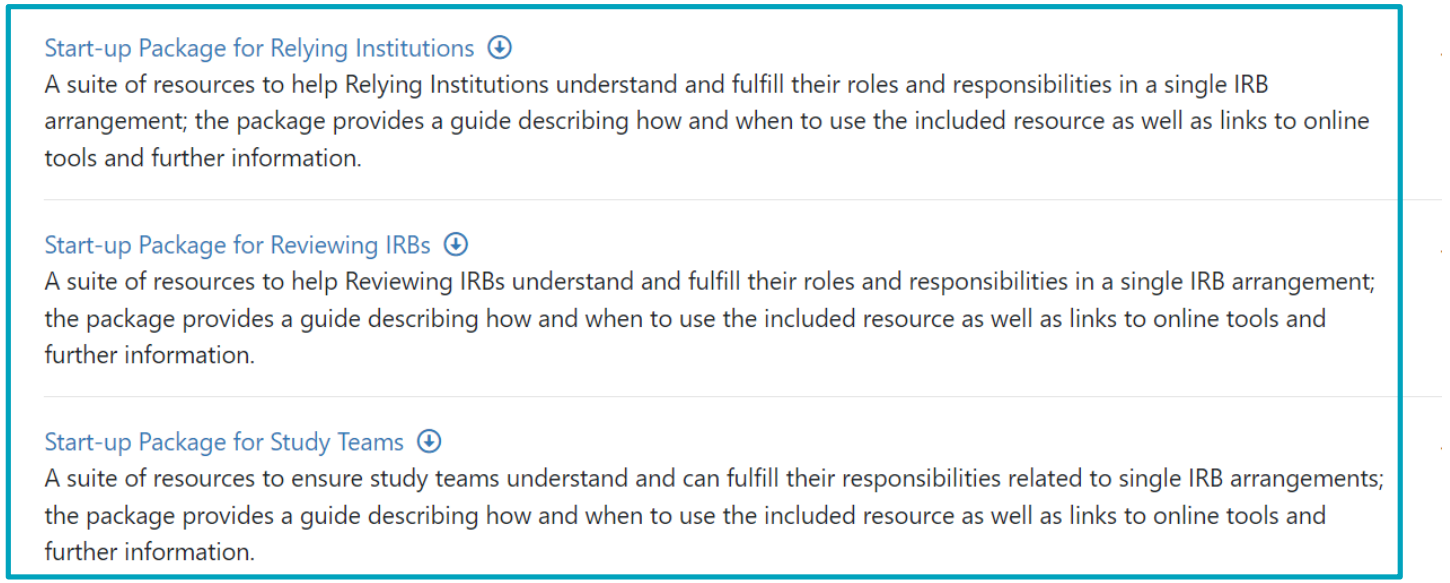
Start-Up Packages	Implementing the Agreement	Reviewing IRBs	Relying Institutions	Getting Started
Online Reliance System	Resources for IRB/HRPPs	**SMART Talk Forum**	sIRB Boot Camp	Training Study Teams

- All have been recorded since September 2019
- Available at https://smartirb.org/irb-admin/
- November 2022: A Conversation with the FDA and OHRP about Single IRB, https://player.vimeo.com/video/773359200

Start Up Packages at smartirb.org/resources/

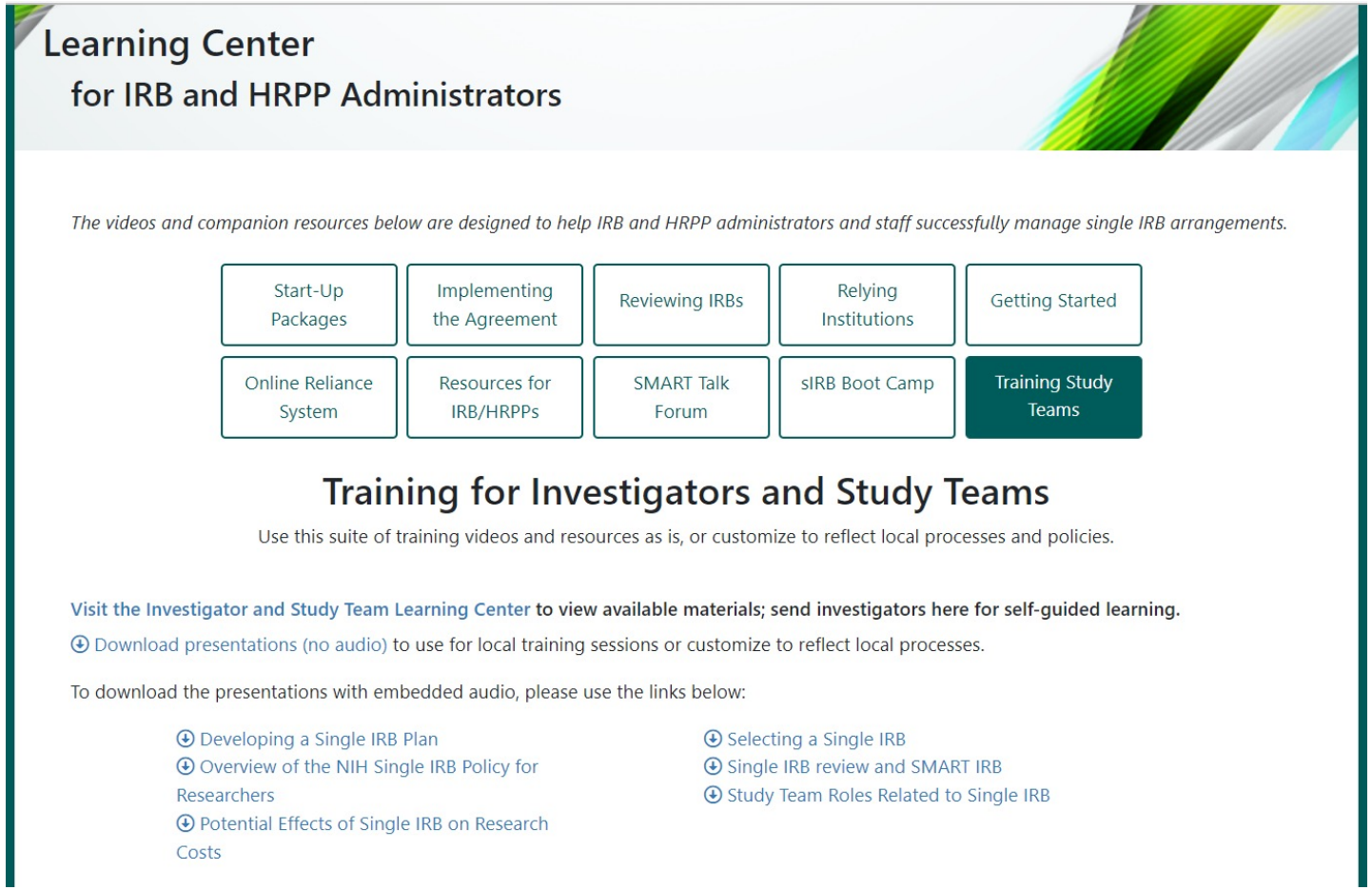
These packages contain a suite of resources based on role: Study Teams, Reviewing IRBs, and Relying Institutions. Also found in the SMART IRB Learning Center.

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



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.

Start-Up Packages | Implementing the Agreement | Reviewing IRBs | Relying Institutions | Getting Started

Online Reliance System | Resources for IRB/HRPPs | SMART Talk Forum | sIRB Boot Camp | Training Study Teams

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

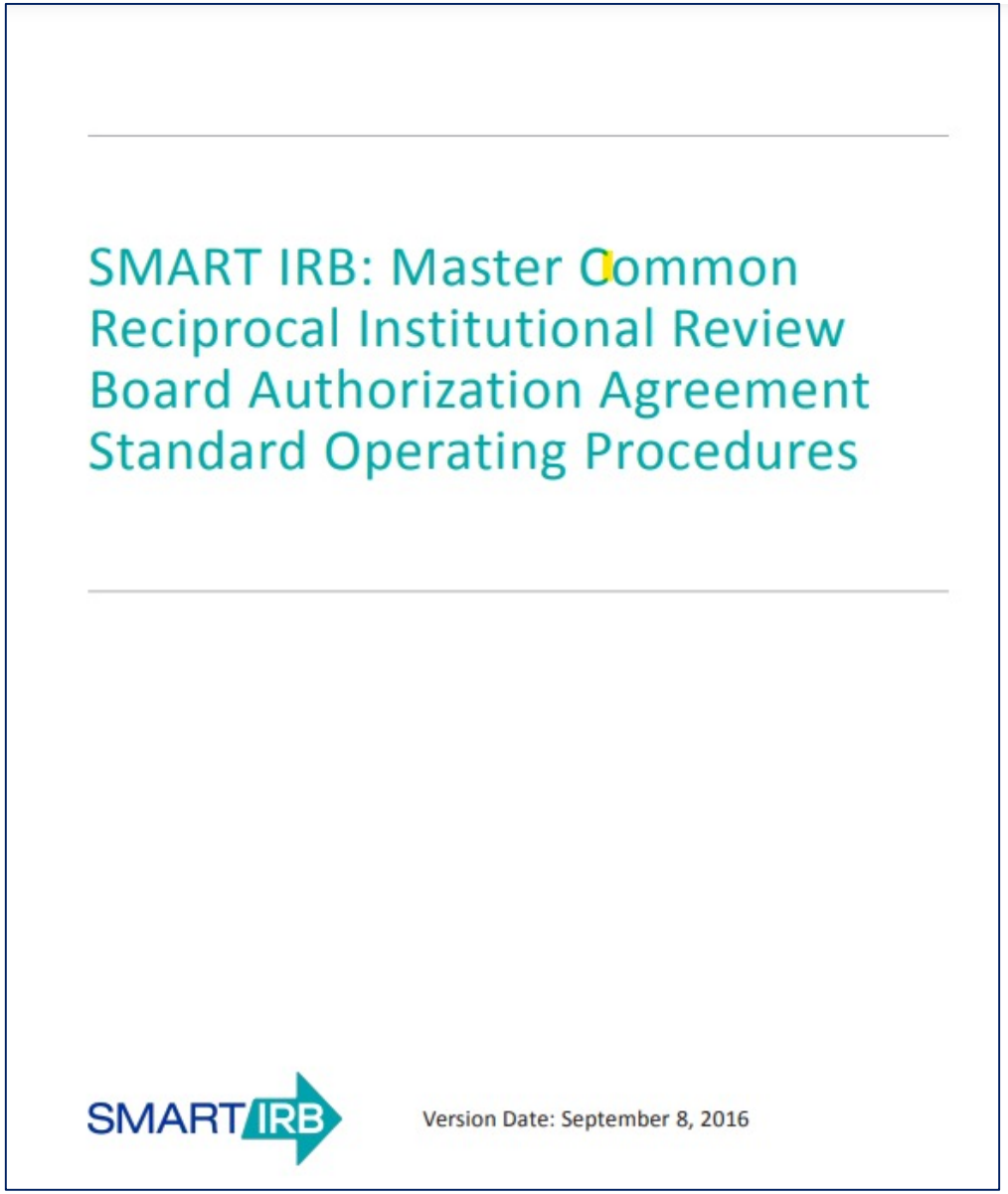
Frequently asked questions covering eligibility, how to join, agreement provisions, and other important topics.

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

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.

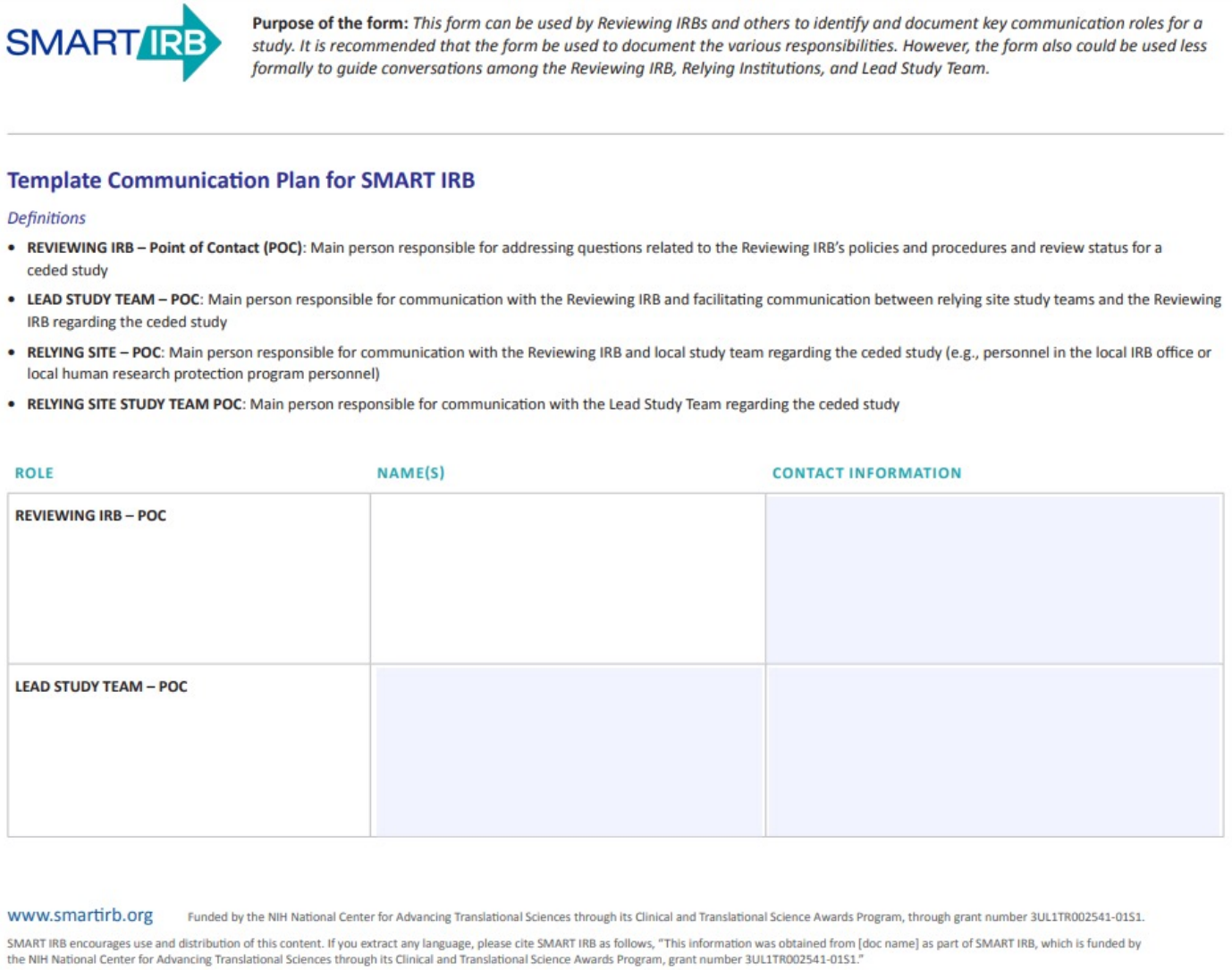
https://smartirb.org/assets/files/SMART_IRB_SOP-090816.pdf



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



SMART IRB

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

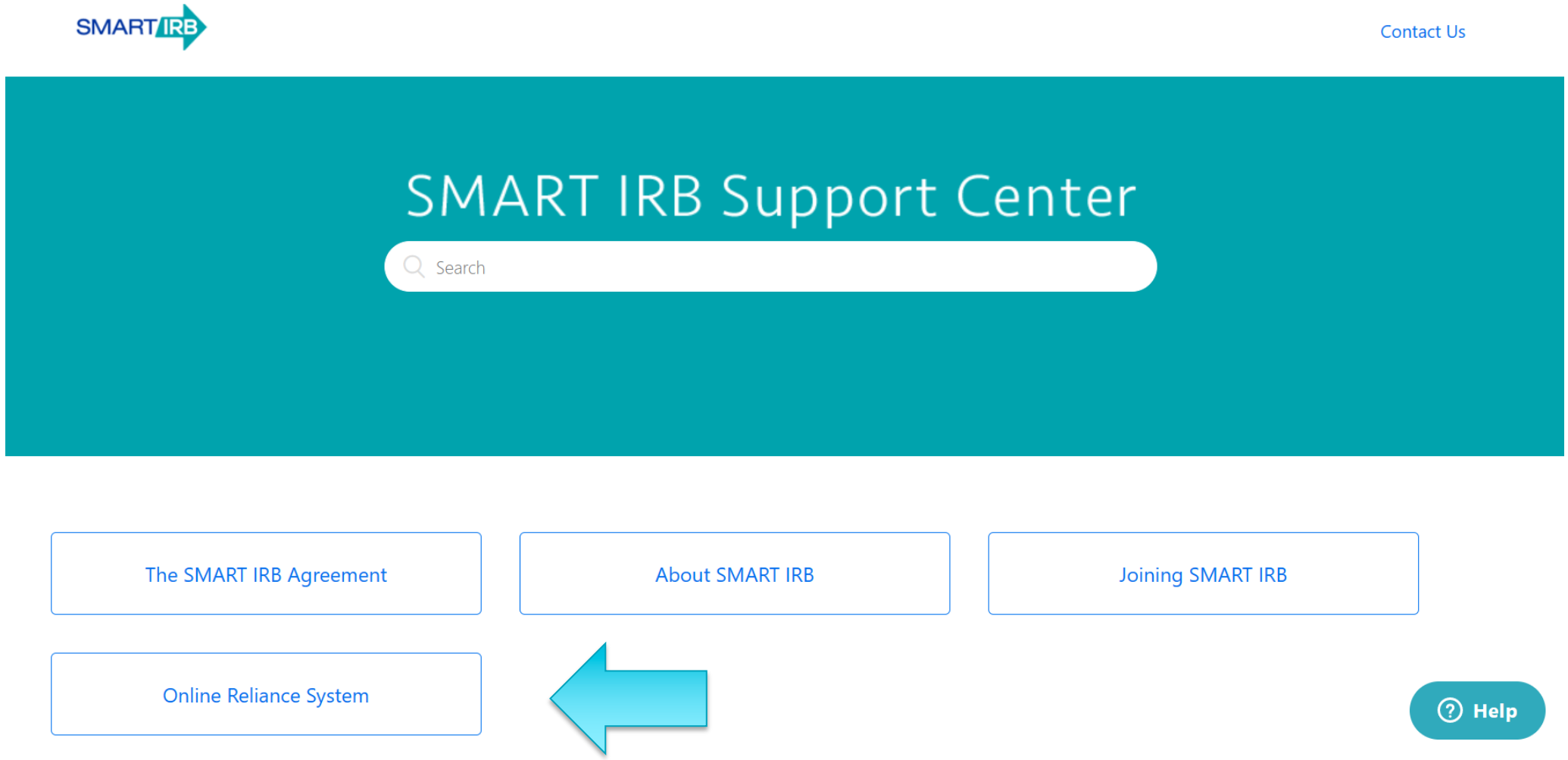
- **REVIEWING IRB – Point of Contact (POC)**: Main person responsible for addressing questions related to the Reviewing IRB's policies and procedures and review status for a ceded study
- **LEAD STUDY TEAM – POC**: Main person responsible for communication with the Reviewing IRB and facilitating communication 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

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, through grant number 3UL1TR002541-01S1.

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



Background

Brief History of Federal Single IRB Review Mandates

Prior to 2018

Using one IRB to oversee multisite (aka cooperative) research occurred on a limited basis

January 25, 2018

Most multisite research supported by the National Institutes of Health (NIH) requires single IRB review

January 20, 2020

Most multisite research subject to the Common Rule requires single IRB review

September 2022

The FDA issues a Notice of Proposed Rulemaking that outlines it proposed single IRB requirements.

Proposed FDA revisions

- FDA is proposing:
  - To replace the current requirements under § 56.114 “Cooperative research” of part 56 (21 CFR part 56) with new regulatory text that would require any institution located in the United States participating in cooperative research to rely on approval by a single IRB for that portion of the research that is conducted in the United States, with some exceptions.
  - An IRB recordkeeping requirement for research that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution.

This proposed regulatory text differs from the revised Common Rule at 45 CFR 46.114(b)(1) by using FDA's term “participating,” rather than “engaged.”

https://www.federalregister.gov/documents/2022/09/28/2022-21089/institutional-review-boards-cooperative-research

Potential Differences between the Common Rule & FDA Cooperative Research Requirements

Area	Common Rule	FDA Regulations
Who identifies the reviewing IRB	The Federal Department or Agency supporting or conducting the research, or to be proposed by the lead institution subject to the acceptance of the Federal Department or Agency supporting the research	FDA is not proposing to require that a particular party identify the single IRB
Exceptions	The following research is excepted: (1) cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an AI/AN tribe) or (2) research for which any Federal Department or Agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.	• cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an AI/AN tribe) • research involving a highly specialized FDA-regulated medical product for which unique, localized expertise is required • research on drugs that is exempt from the IND regulations • research on medical devices that meets the abbreviated requirements or the requirements for exempted investigations

What is your experience?

Poll #1

- Do you think the implementation of a single IRB mandate by the FDA will have:
  - A big impact on organizations
  - Some impact on organizations
  - No real impact on organizations
  - Unsure

Poll #2

- With the transition to single IRB review, has your institution:
  - Added positions to your IRB/HRPP offices
  - Decreased the number of positions in your IRB/HRPP offices
  - Had no change in number of positions in your IRB/HRPP offices, but responsibilities have changed because of single IRB
  - Had no change in number of positions in your IRB/HRPP offices and no change in responsibilities related to single IRB
  - Unsure

Poll #3

- Does your institution have any positions dedicated to handling reliance arrangements or working with external IRBs?
  - We have at least one position whose full-time job is working with reliance
  - We have at least one position that has includes working with reliance amongst other duties
  - We do not have any positions that include reliance responsibilities
  - Unsure

The Impact of Single IRB on HRPPs

Today's panelists:

- **Janice Piazza**, Director, Office of Human Research Protection, Prisma Health
- **Adrienne Meyer**, Assistant Director of Reliances, University of Washington
- **Jeanne Velders**, Executive Director, Human Research Protection Office, Washington University in St. Louis

Moderator:

- **Nichelle Cobb**, Senior Advisor, SMART IRB; Senior Advisor for Strategic Initiatives, Association for the Accreditation of Human Research Protection Programs

SMARTIRB.org

Save the date for the next SMART Talk

Introducing Draft SMART IRB Agreement v3.0

November 29, 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