# 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

**September: Recommendations for the Harmonization of Local Considerations**

# 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

## 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 posted for comment until September 22, 2023**

**NEW Working Group: SMART IRB Reliance for Exemptions**

# Prior SMART Talks

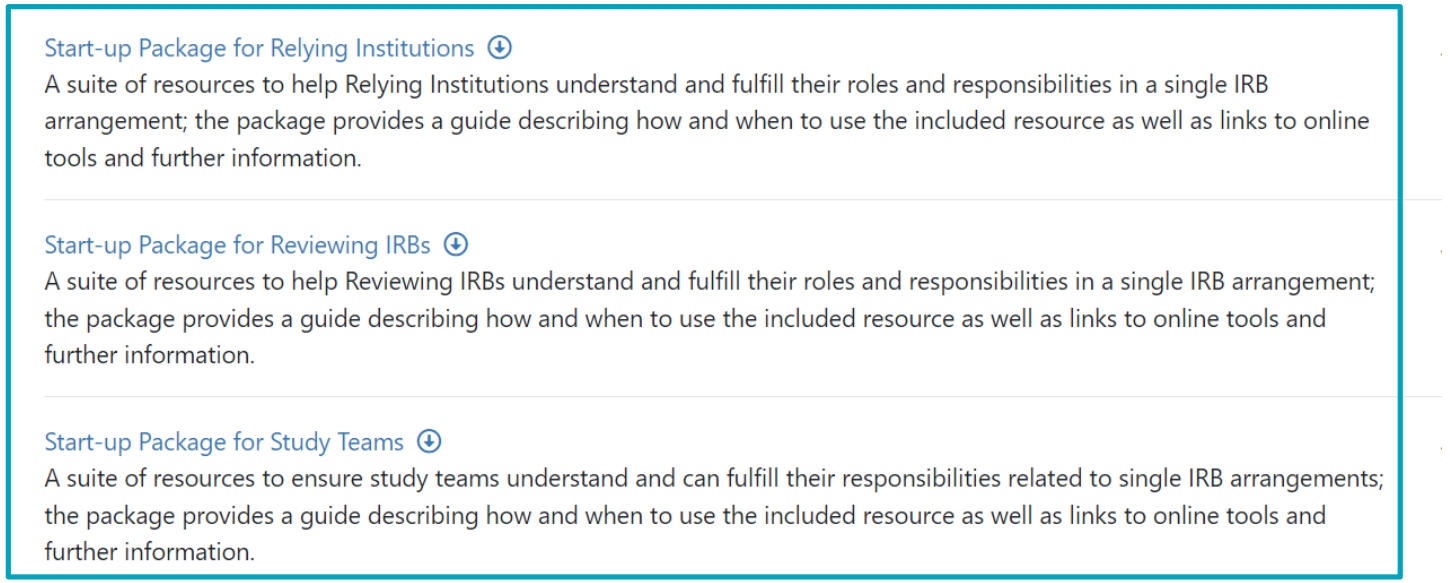
| | | | | |
|---|---|---|---|---|
| Start-Up Packages | Implementing the Agreement | Reviewing IRBs | Relying Institutions | Getting Started |
| Online Reliance System | Resources for IRB/HRPPs | **SMART Talk Forum** | sIRB Boot Camp | Training Study Teams |

- All have been recorded since September 2019
- Available at https://smartirb.org/irb-admin/
- July 2023: Exploring the Financial Aspects of Single IRB, https://vimeo.com/848496007
- November 2022: A Conversation with the FDA and OHRP about Single IRB, https://player.vimeo.com/video/773359200
- February 2021: sIRB Issues Related to Planned Emergency Research, https://player.vimeo.com/video/513922852

# Start Up Packages at smartirb.org/resources/

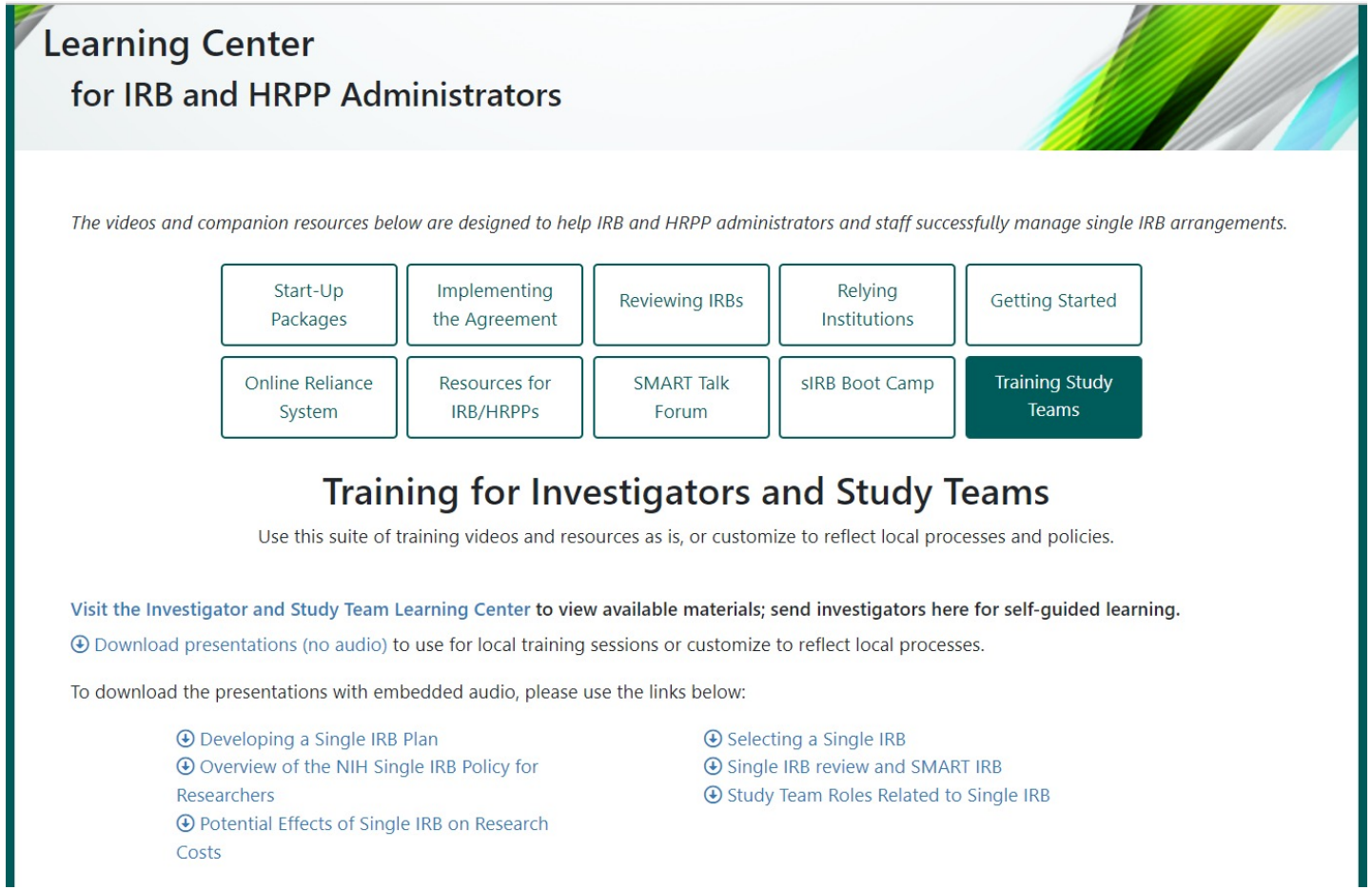
These packages contain a suite of resources based on role: Study Teams, Reviewing IRBs, and Relying Institutions. Also found in the SMART IRB Learning Center.

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

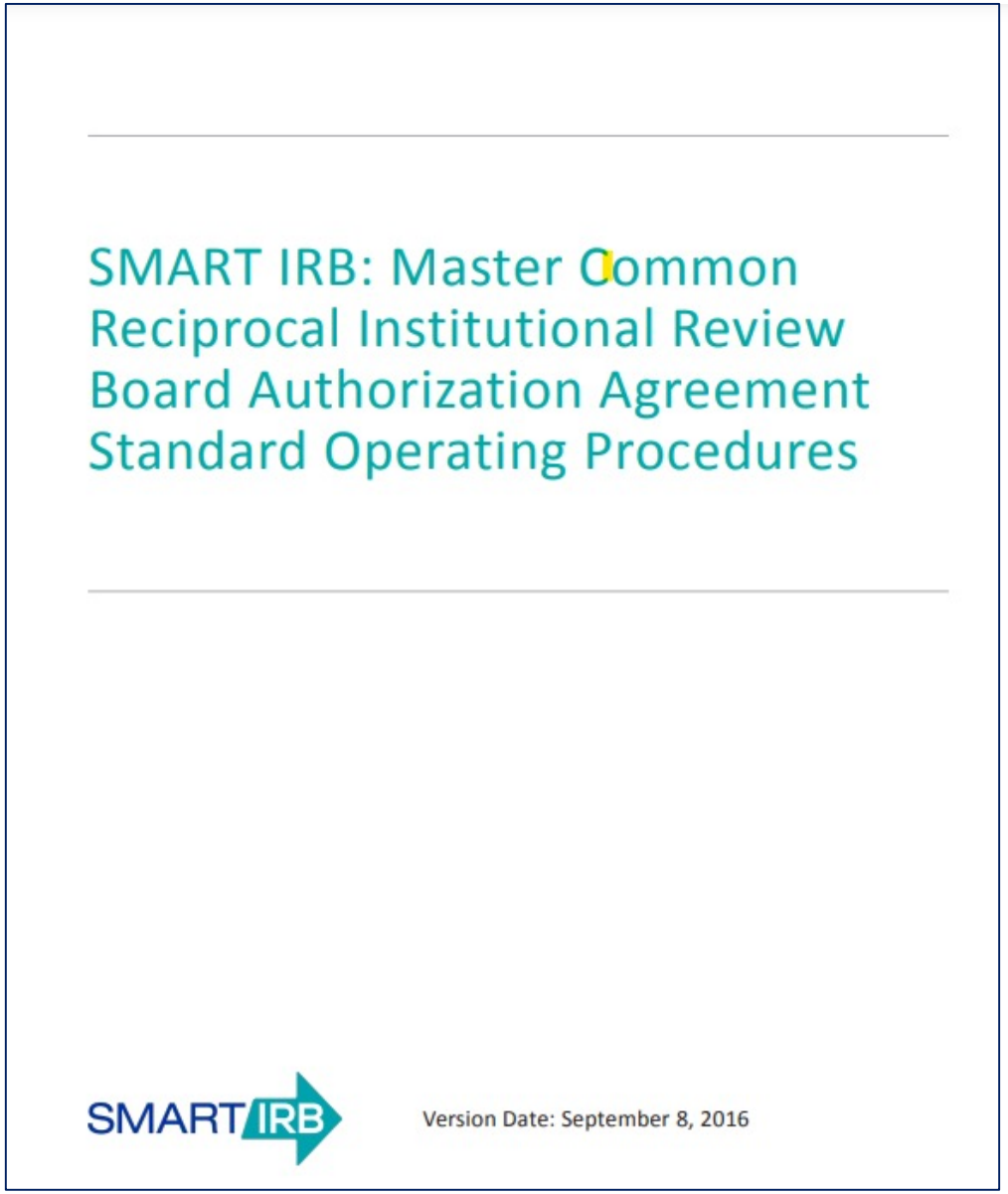
Frequently asked questions covering eligibility, how to join, agreement provisions, and other important topics.

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.

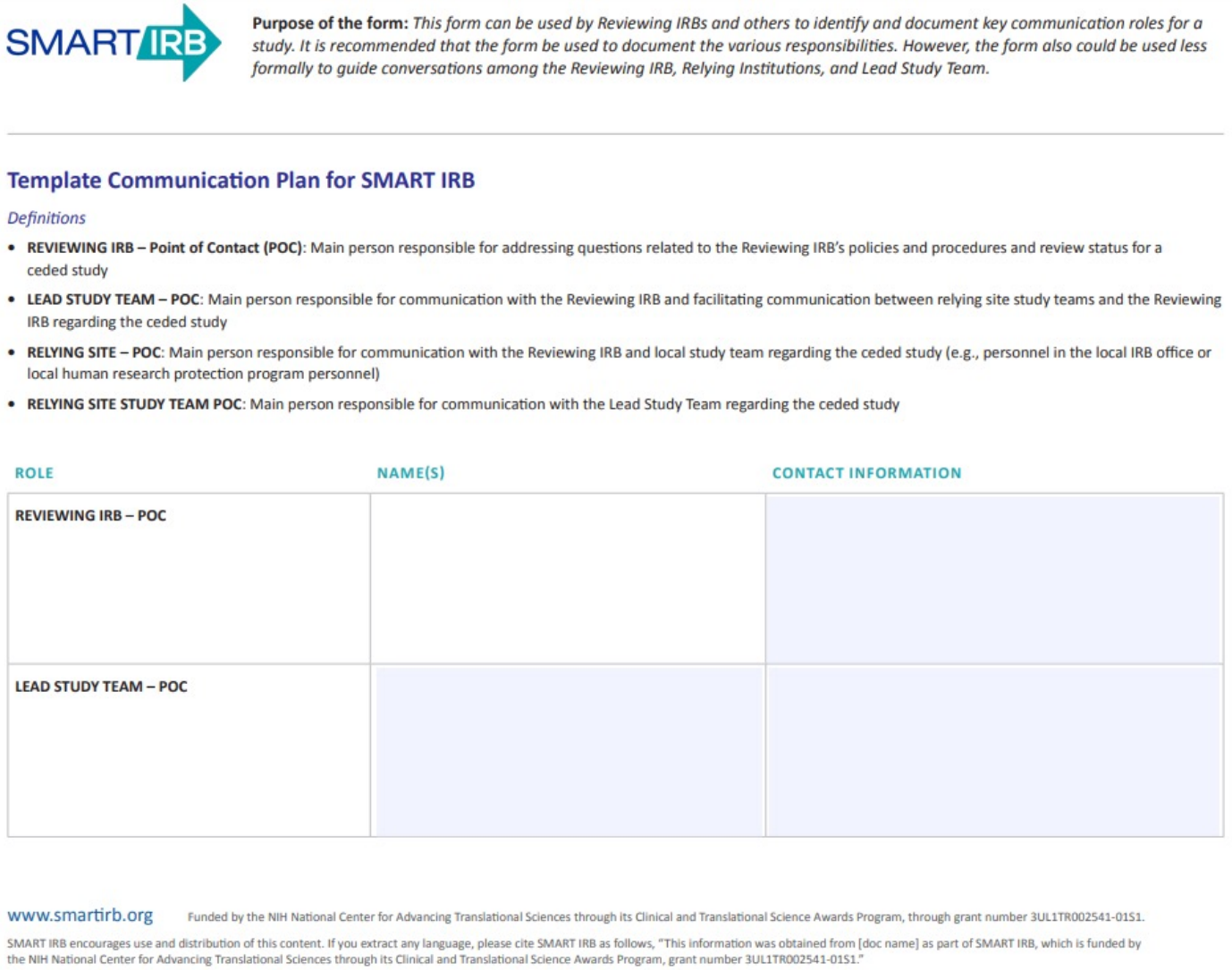
https://smartirb.org/assets/files/SMART_IRB_SOP-090816.pdf



# 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

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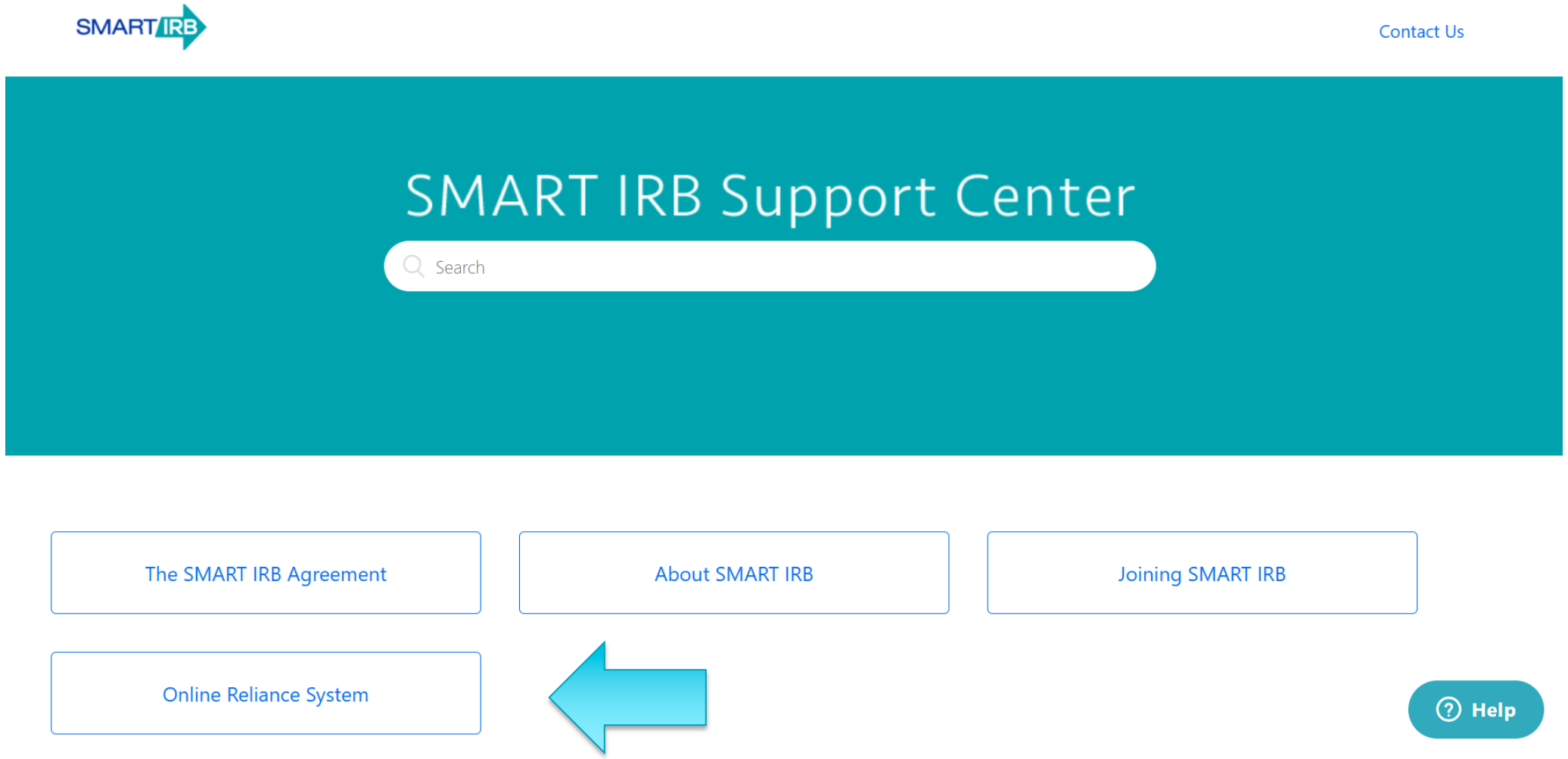
# https://support.smartirb.org/hc/en-us



# Single IRB Review Implementation: Persistent challenges and possible solutions

## Today's panelists:

- **Jonathan Green,** Director, Office of Human Subjects Research Protections, National Institutes of Health (NIH)
- **Martha Jones,** Vice President, Human Research Affairs, Mass General Brigham
- **Megan Kasimatis Singleton**, Associate Dean, Human Research Protections and Director of the Human Research Protections Program, Office of Human Subjects Research, Johns Hopkins University School of Medicine

## Moderator:

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

SMARTIRB.org

SMART IRB

# Single IRB review: Persistent Challenges and possible solutions

## Why is this still so hard?

Nichelle Cobb
Jonathan Green
Martha Jones
Megan Kasimatis Singleton

# Acknowledgement


- SMART IRB team
  - Barbara Bierer
  - Polly Goodman
  - Aaron Kirby
  - Nichelle Cobb
  - Mike Linke
- Workshop Participants

# Disclaimer

- The opinions expressed are mine and do not represent the views of the National Institutes of Health, Department of Health and Human Services, or US Government.

# Policy history


- 2018 – NIH sIRB policy
- 2020 –Cooperative Research Provision of revised Common Rule
- 2023 – FDA NPRM on sIRB review

# Objectives of sIRB review


Eliminate duplicative and often conflicting review determinations for the same protocol and therefore:

- Streamline IRB review
- Increase efficiency
- Reduce Burden

# 2020 SMART IRB workshop

- Identify persistent challenges and possible solutions
- Half-day video-conference
- 63 attendees from 47 institutions
- Divided into focus groups for discussion
- Reporting and consolidation of ideas

# Workshop focus groups

| Focus group | Discussion prompts |
|---|---|
| Policy/Regulation | • Identify any specific issues and their possible solutions, related to provisions of the NIH sIRB policy or the revised Common Rule that hinder effective implementation of the sIRB requirement.<br>• Discuss how the lack of harmonization between NIH, HHS, and FDA impacts implementation of the sIRB requirement.<br>• Discuss whether the current exceptions to the policy requirements are sufficient, and if not, what other exceptions should be considered. |
| Institutional Concerns | • Identify any institutional concerns that impact the acceptance and implementation of the sIRB requirements. For example, the impact on budget, planning and allocation of resources. |
| IRB Office Operational Challenges | • Identify any operational challenges within the IRB office of the reviewing IRB and/or the relying institution that continue to impact the ability to efficiently implement sIRB review. |
| IRB Committee Reviewer Challenges | • Identify any challenges unique to sIRB review that are faced by IRB committee members when reviewing research conducted at sites for which they may have little or no familiarity. |
| Harmonization of IRB Policies & Procedures | • Identify any barriers to the adoption of harmonized policies and operating procedures, such as those developed by SMART IRB, by participating institutions. |

# Goals for discussion

- What are the problems HRPPs are facing?
- What are some solutions
  - What worked? What didn't work?
  - What would you like to try?
  - What would you need to try it?

# Persistent Challenges

- New responsibilities for study teams
- Relying institutions reviews
- Local context
- How to handle non-compliance
- Need for greater flexibility and exceptions
- Need for cross-regulatory guidance
- Harmonization


GRACIAS!
THANK YOU!
GRAZIE
Thanks!
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Grazie!
Gracias!
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THANK YOU!
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Save the date for the next SMART Talk

**Recommendations for the Harmonization of Local Considerations**

September 20, 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**