SMART IRB

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

April 2023: in the process of confirming topic and speakers

May 2023: No SMART Talk

If you missed this year's SMART IRB Boot Camp

- 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

John Baumann
Indiana University

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

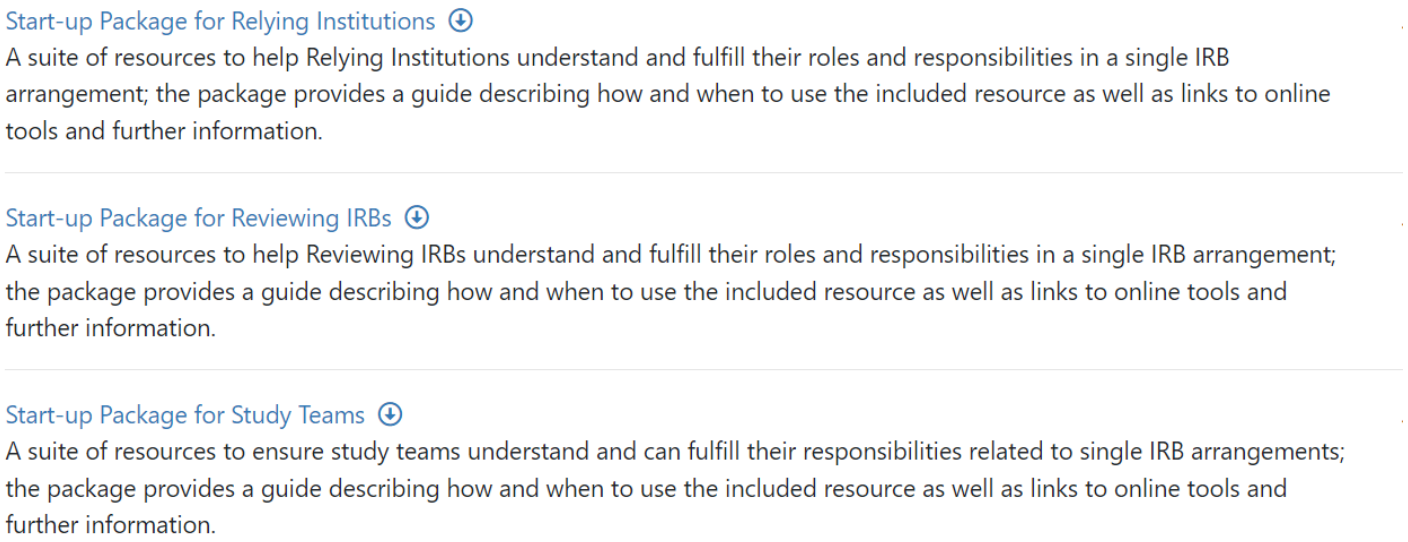
SMART Talks in 2022
(available at https://smartirb.org/resources/)

- 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/

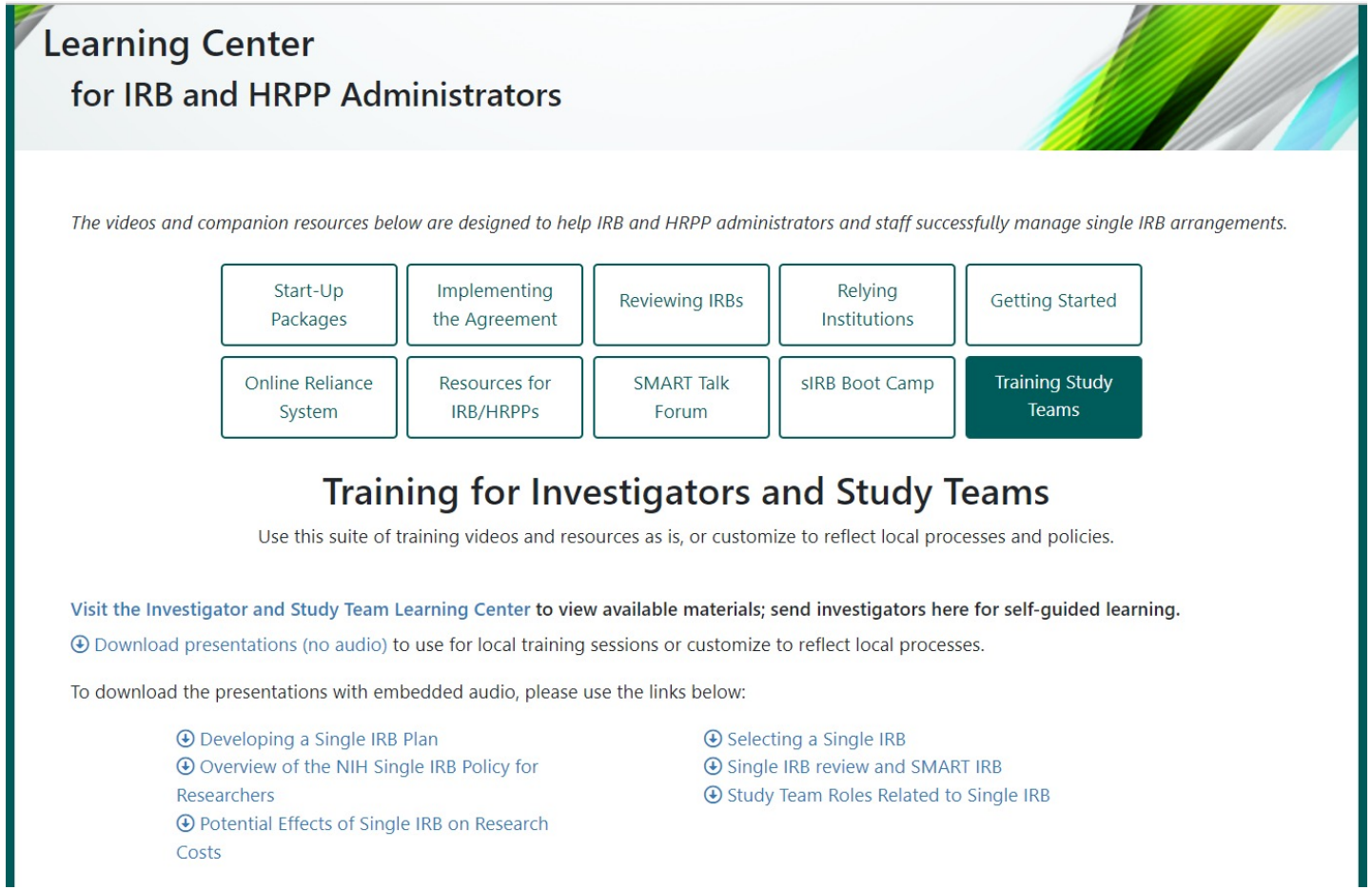
These packages contain a suite of resources based on role: Study Teams, Reviewing IRBs, and Relying Institutions. Also found in the SMART IRB Learning Center.

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

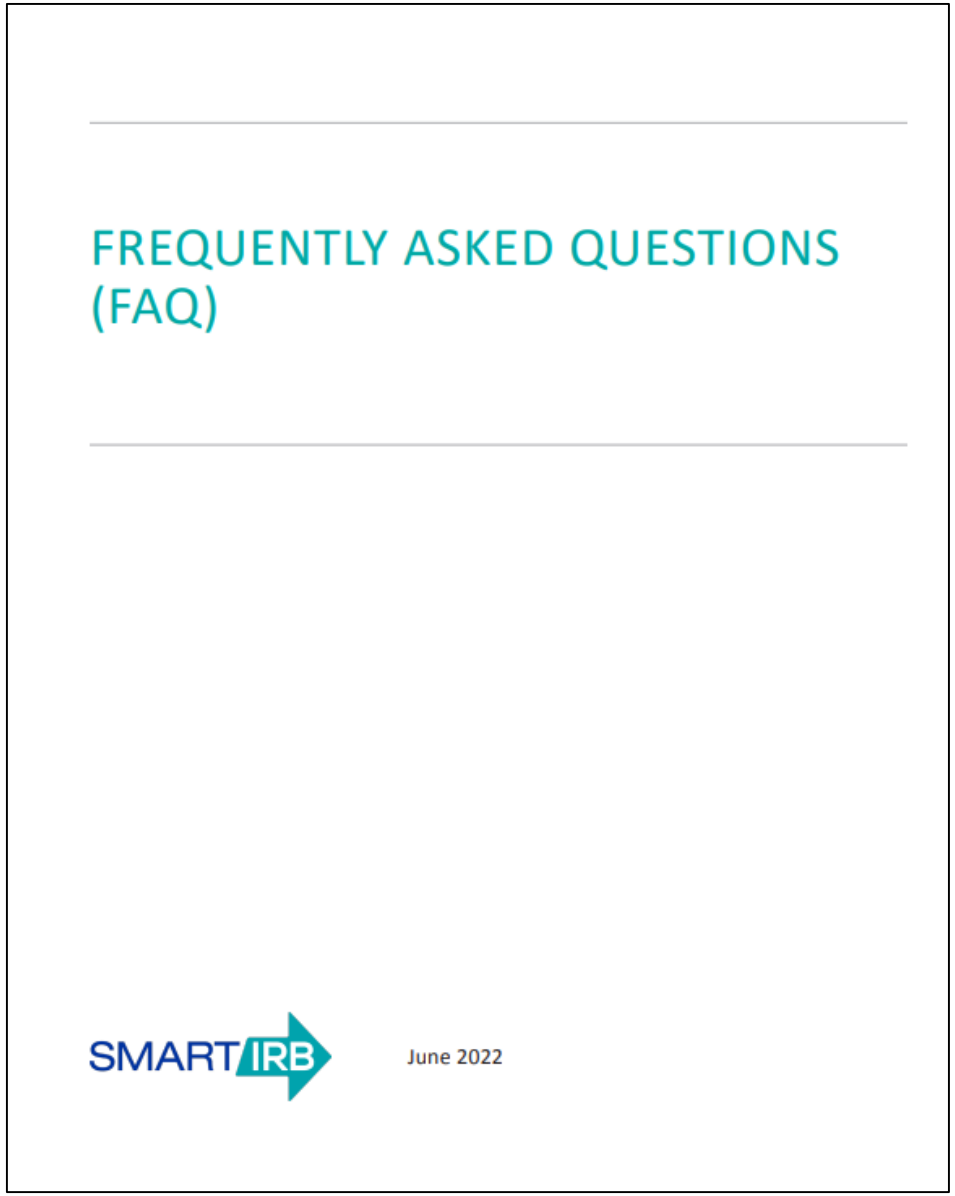
These can be helpful for IRB/HRPP administrators new to single IRB as well!



FAQs

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

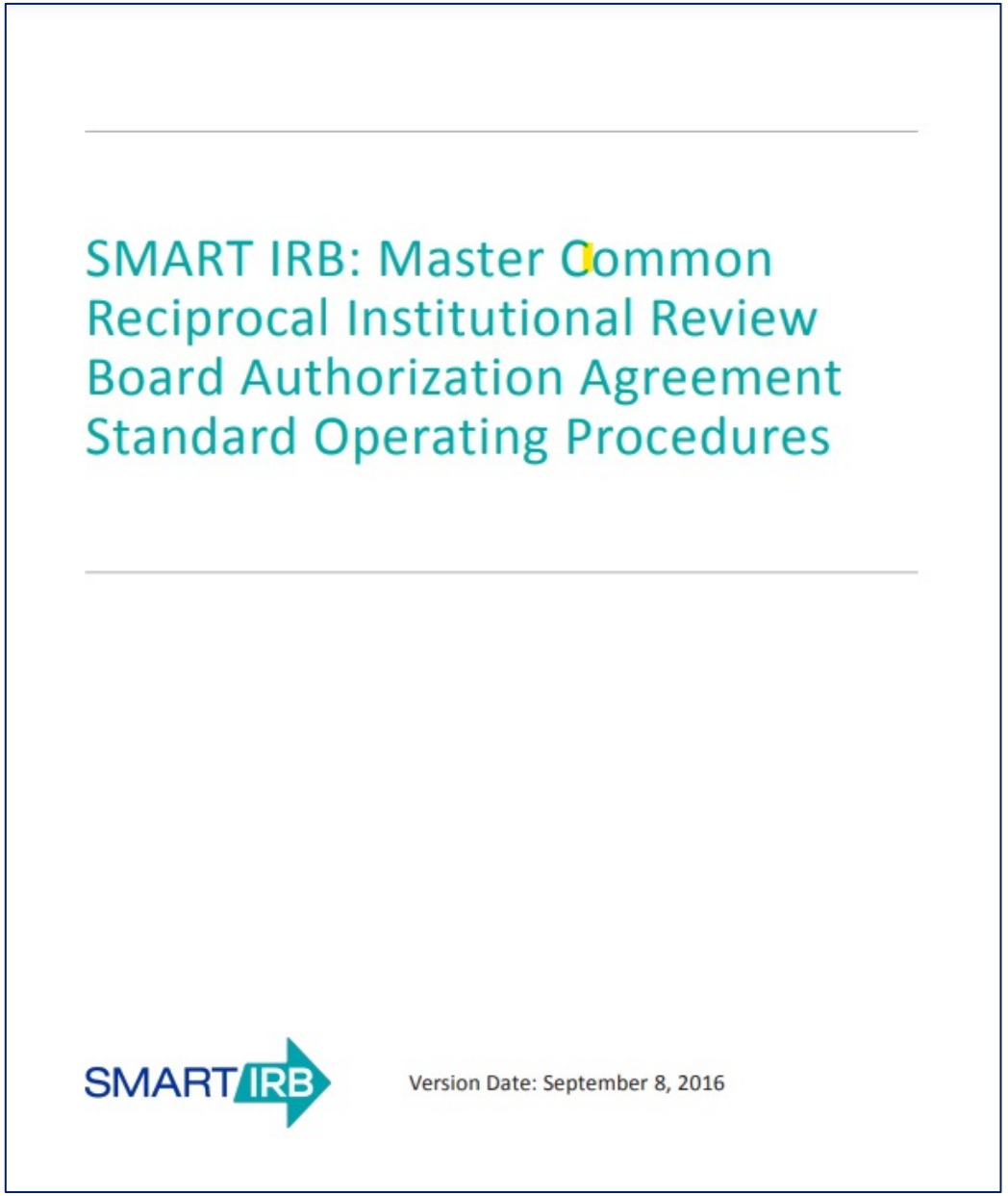
https://smartirb.org/assets/files/faq.pdf



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.

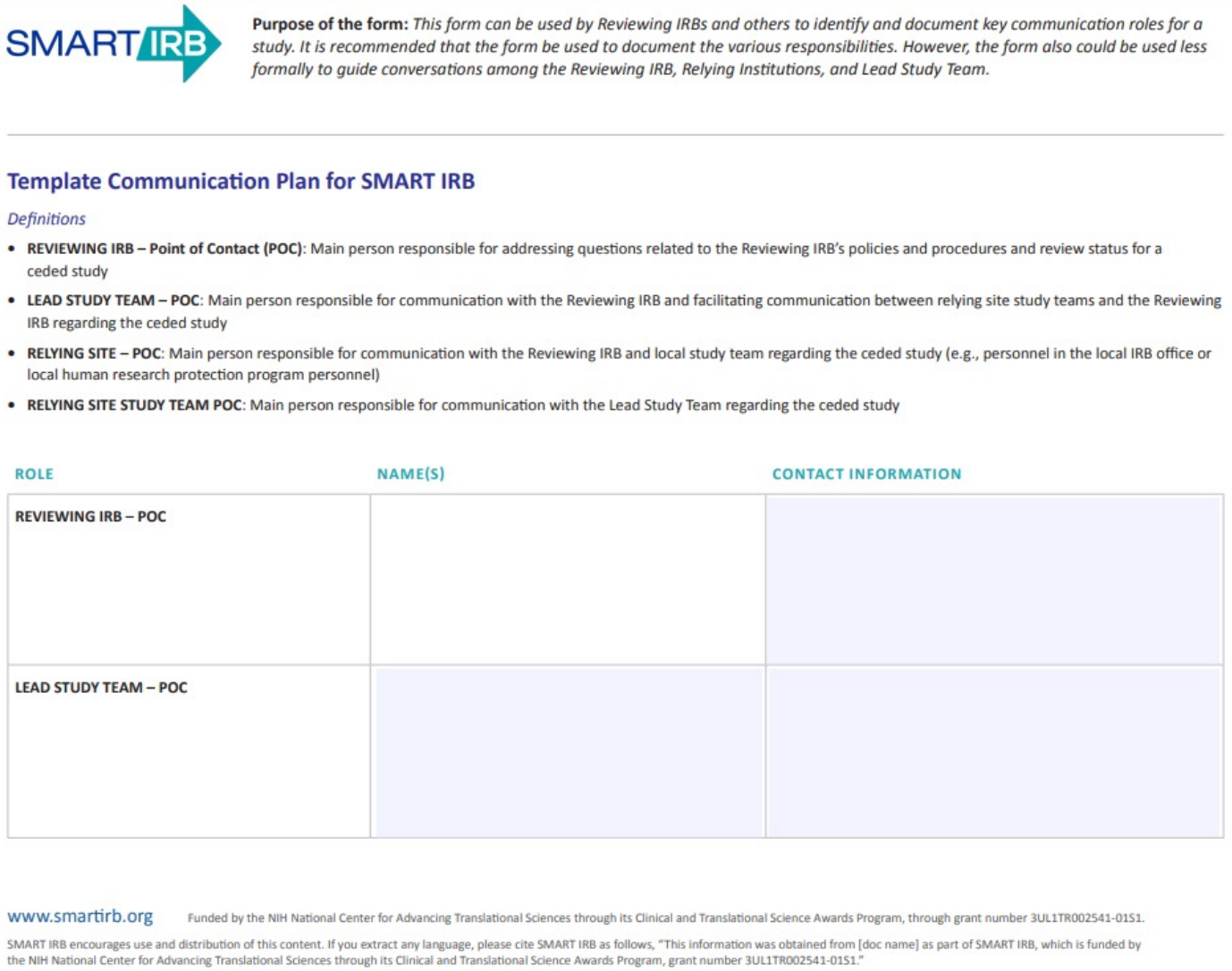
https://smartirb.org/assets/files/SMART_IRB_SOP-090816.pdf



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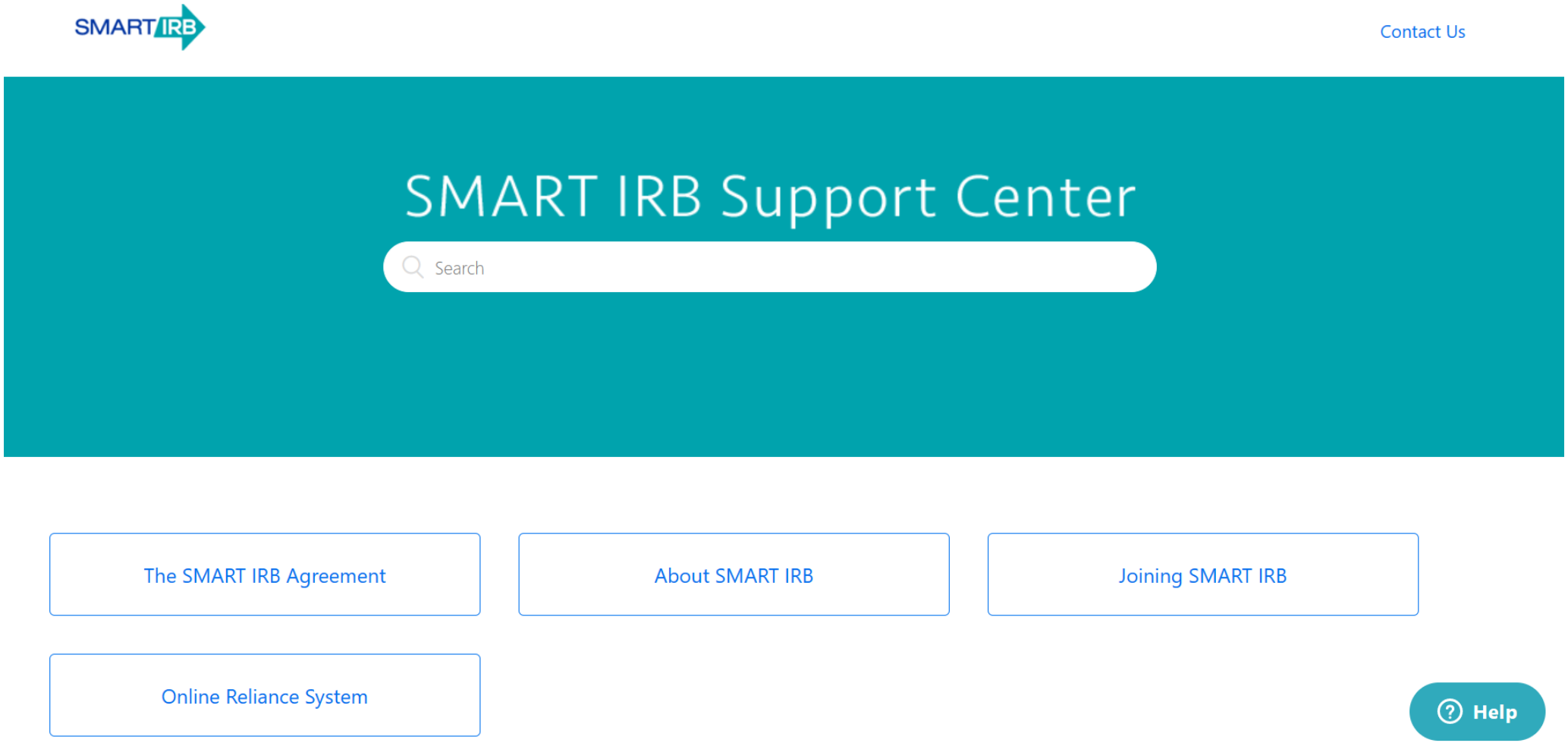
https://support.smartirb.org/hc/en-us



Is it Yours or Mine? Pinpointing Responsibilities in a Single IRB Situation

Today's panelists:

- Laverne Estañol, Director, Office of Research Compliance Administration, UC Santa Cruz
- Michelle LeMenager, Senior SIRB Manager, Stanford University
- Candice Mulder, Manager, Clinical Research Regulatory Affairs, Human Subjects Protection Program, Children's Hospital Los Angeles
- Sarah Mumford, Director, Office for the Protection of Research Subjects, University of Illinois at Urbana-Champaign

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

SMARTIRB.org

Glossary

- Reviewing IRB: The “IRB of record” (including an IRB Organization) to which authority for IRB review and oversight has been ceded by another institution.
- Relying Institution: An institution that cedes IRB review to a Reviewing IRB.
- Lead Study Team: The Lead Study Team is designated by the Overall PI and, working in collaboration with the Reviewing IRB, ensures coordination of communication to and from all Relying Site Study Teams, routing all IRB submissions to the Reviewing IRB and communicating IRB determinations to Site Investigators.

Save the date for the next
SMART Talk
April 19, 2023
2:00-3:30 pm ET

TOPIC BEING DEVELOPED - IT WILL BE A GOOD ONE!

Questions?
Contact
help@smartirb.org

Register at
smartirb.org

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