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

February: No SMART Talk - SMART IRB Boot Camp

March 2024: Understanding VA Requirements for Single IRB

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

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
Medical University of South Carolina

Lubabah Helwani
University of California, Los Angeles

Key Resources

IF YOU ARE NEW TO SINGLE IRB:
2024 SMART IRB Boot Camp

This beginner-level online session will be held on February 7 & 8 (11am-2pm ET, each day) will train IRB and HRPP personnel on successful implementation of the single IRB (sIRB) review model and demonstrate how they can leverage SMART IRB resources to achieve that success.

- Watch session recordings and download slides from the 2023 Boot Camp.
- 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

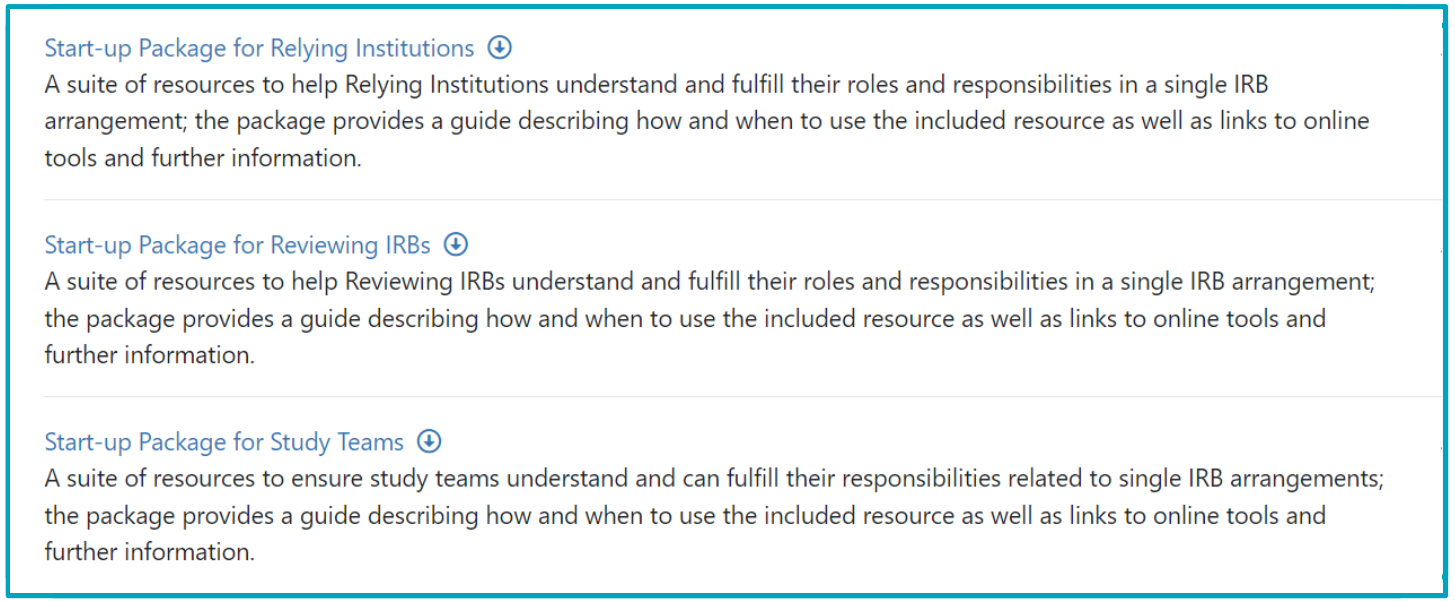
Start-Up Packages	Implementing the Agreement	Reviewing IRBs	Relying Institutions	Getting Started
Online Reliance System	Resources for IRB/HRPPs	**SMART Talk Forum**	sIRB Boot Camp	Training Study Teams

- All have been recorded since September 2019
- Available at https://smartirb.org/irb-admin/
- Some highlights from 2023:
  - The Impact of Single IRB on HRPPs
  - Exploring the Financial Aspects of Single IRB
  - Single IRB Workflow From Beginning to End

Start Up Packages at smartirb.org/resources/

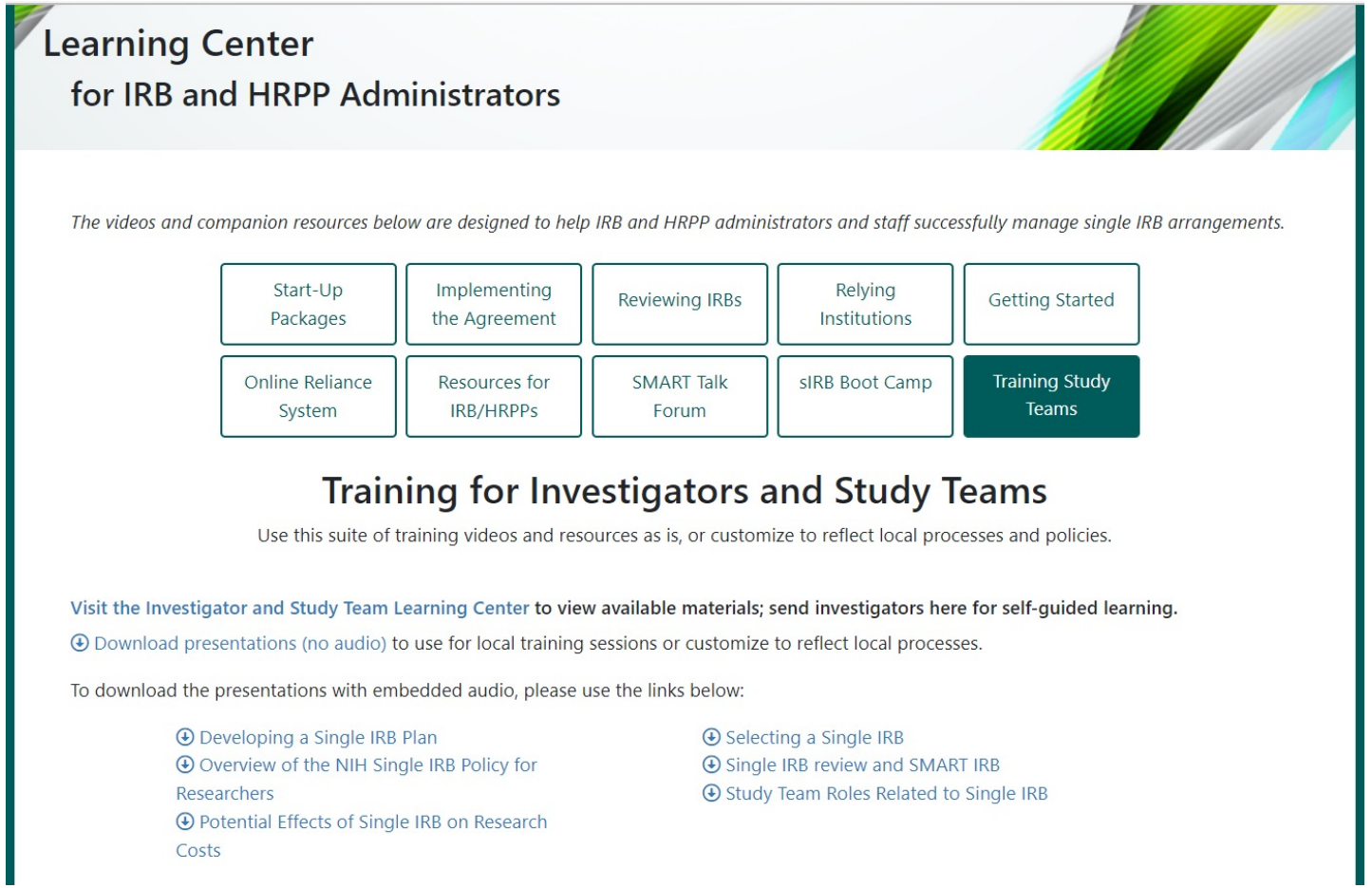
These packages contain a suite of resources based on role: Study Teams, Reviewing IRBs, and Relying Institutions. Also found in the SMART IRB Learning Center.

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

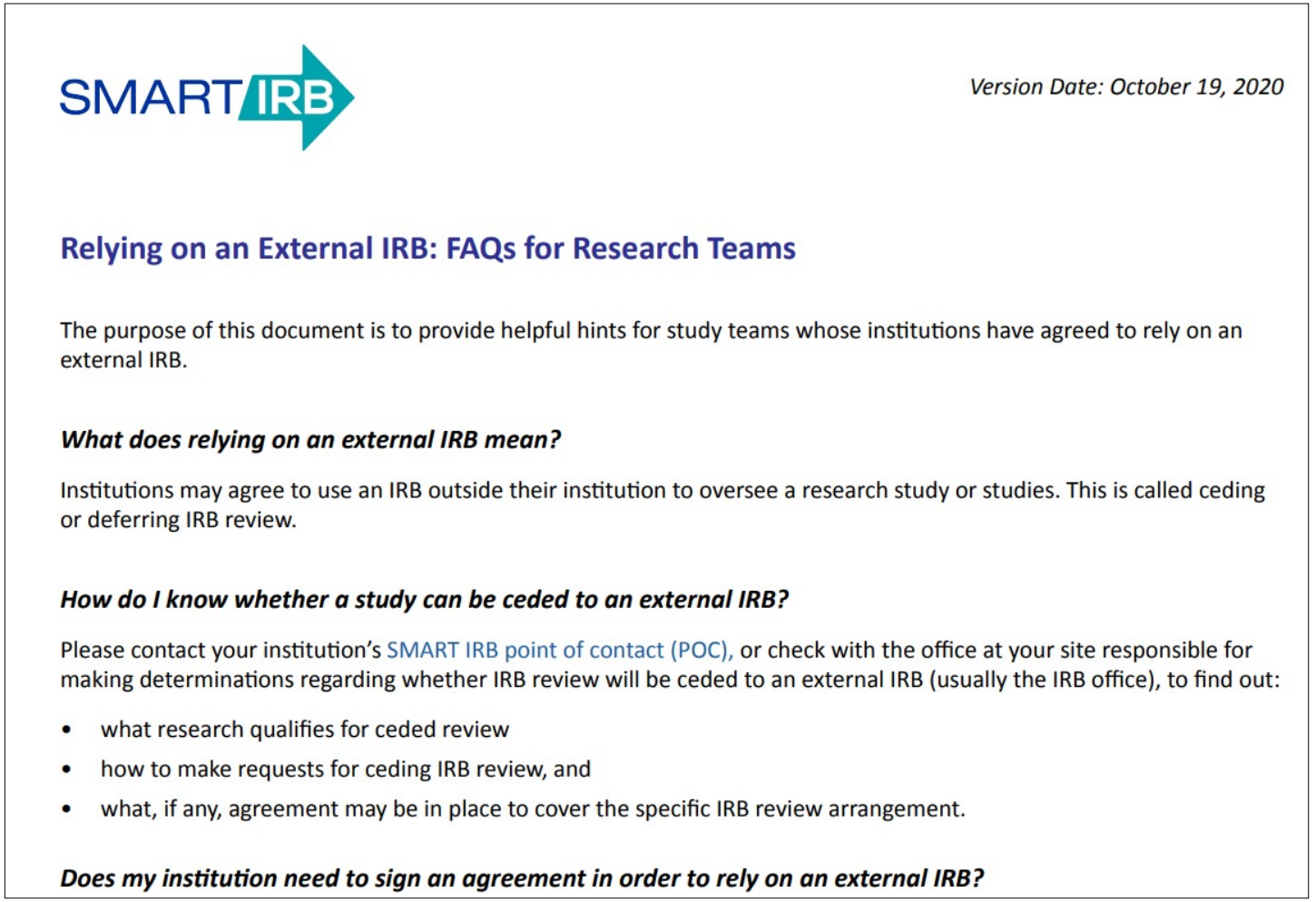
These can be helpful for IRB/HRPP administrators new to single IRB as well!



FAQs for Research Teams - Relying on an External IRB

Provides helpful hints for study teams whose institutions have agreed to rely on an external IRB.

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



SMART IRB

Version Date: October 19, 2020

Relying on an External IRB: FAQs for Research Teams

The purpose of this document is to provide helpful hints for study teams whose institutions have agreed to rely on an external IRB.

What does relying on an external IRB mean?

Institutions may agree to use an IRB outside their institution to oversee a research study or studies. This is called ceding or deferring IRB review.

How do I know whether a study can be ceded to an external IRB?

Please contact your institution's SMART IRB point of contact (POC), or check with the office at your site responsible for making determinations regarding whether IRB review will be ceded to an external IRB (usually the IRB office), to find out:

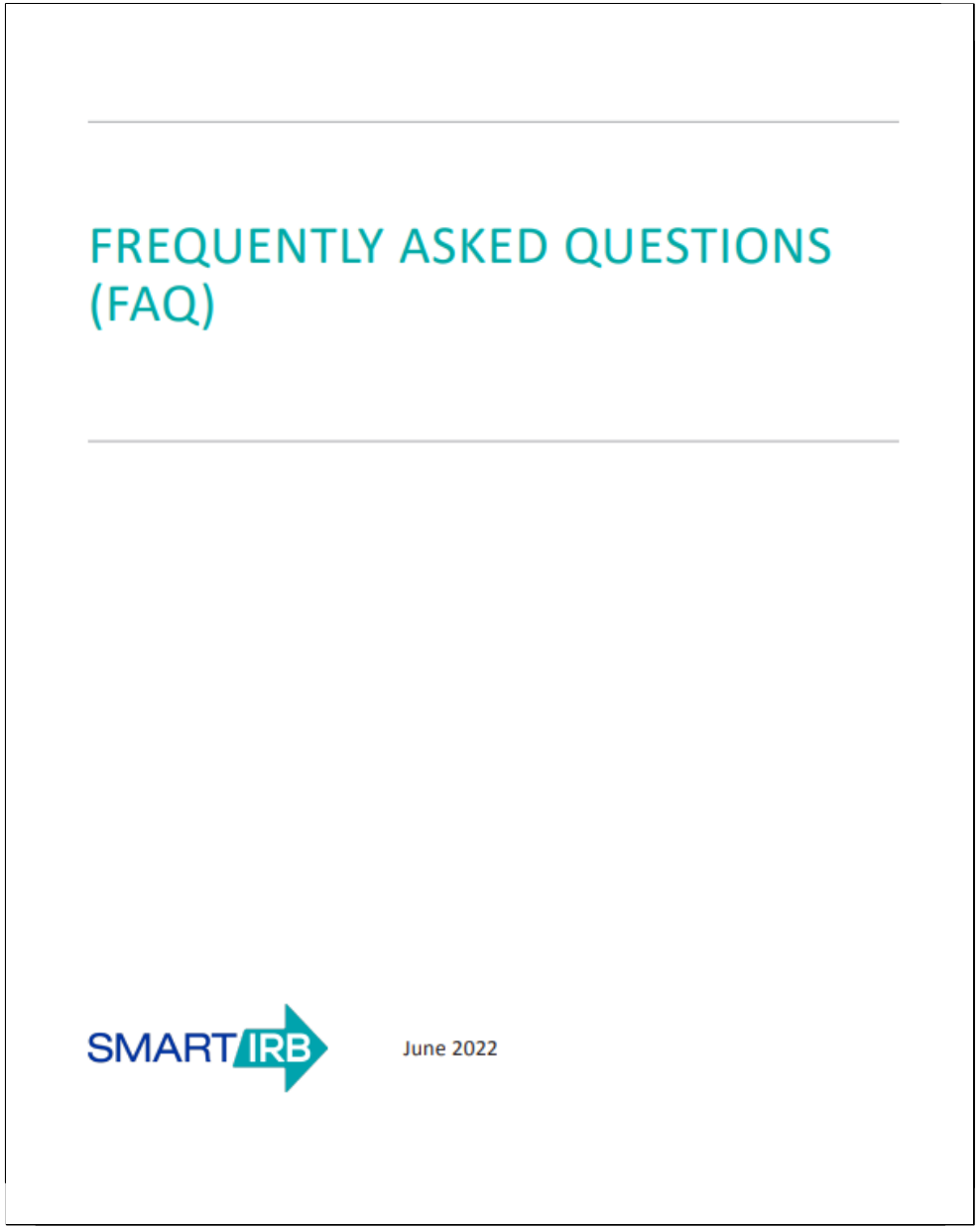
- what research qualifies for ceded review
- how to make requests for ceding IRB review, and
- what, if any, agreement may be in place to cover the specific IRB review arrangement.

Does my institution need to sign an agreement in order to rely on an external IRB?

FAQs

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

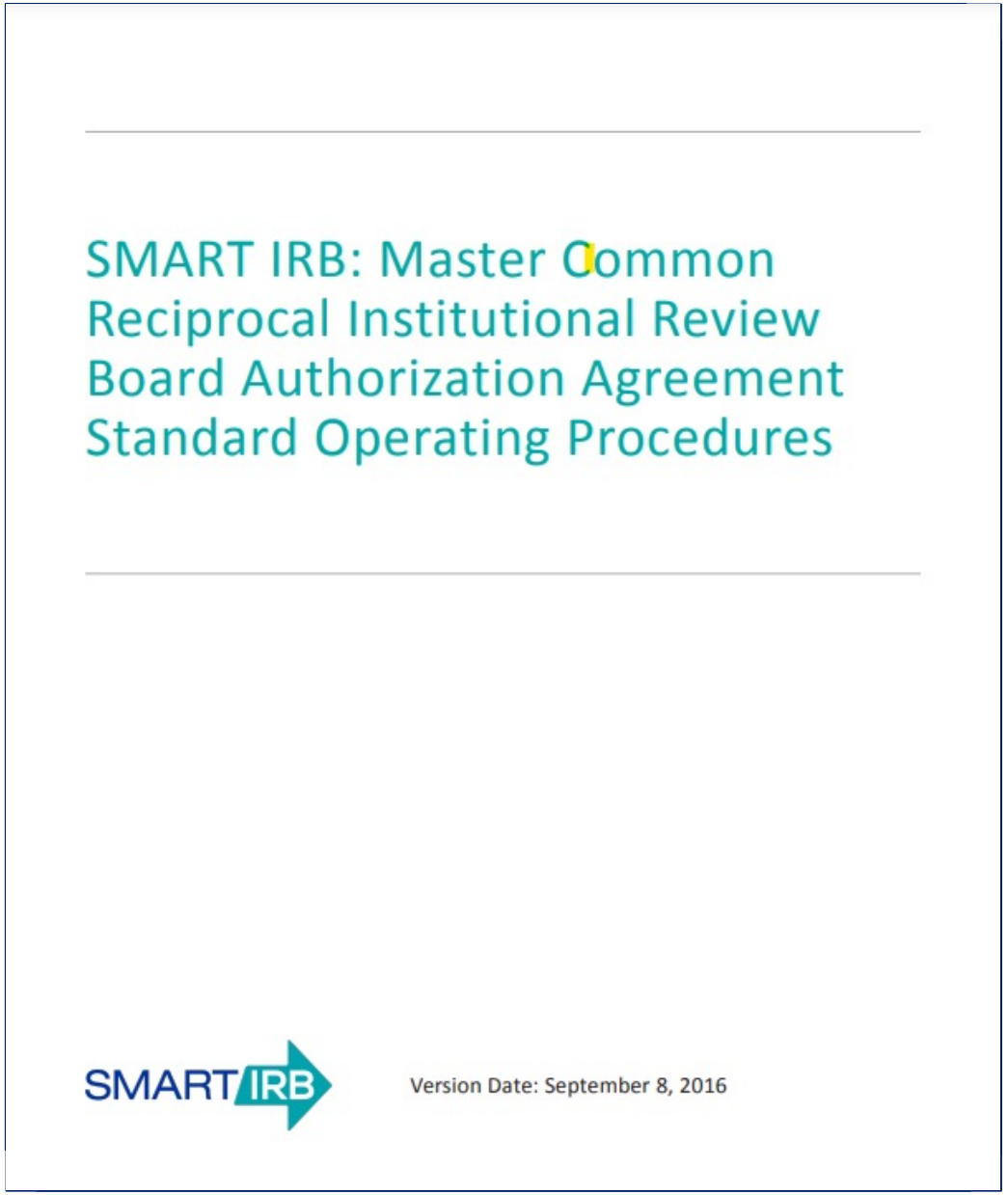
https://smartirb.org/assets/files/faq.pdf



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.

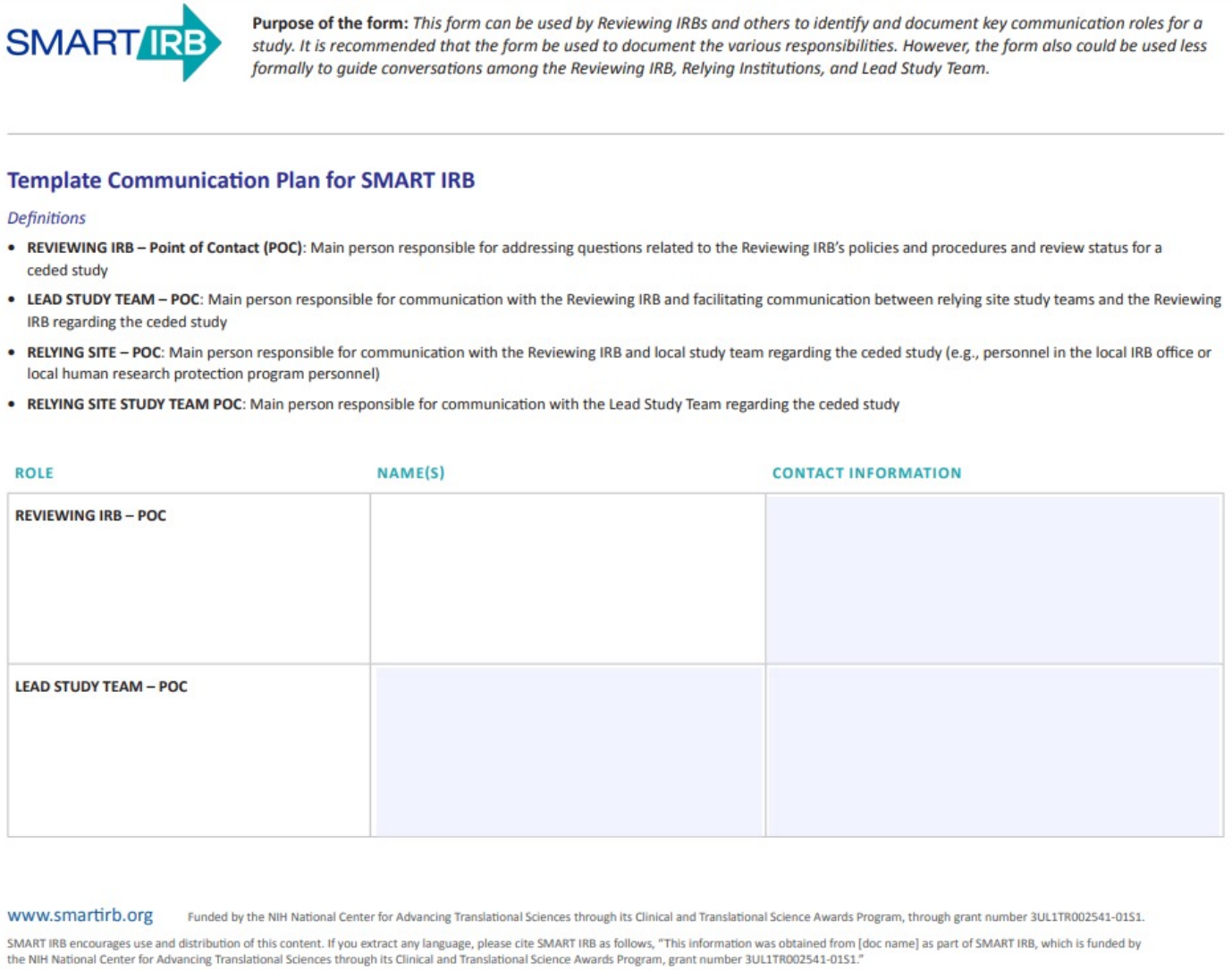
https://smartirb.org/assets/files/SMART_IRB_SOP-090816.pdf



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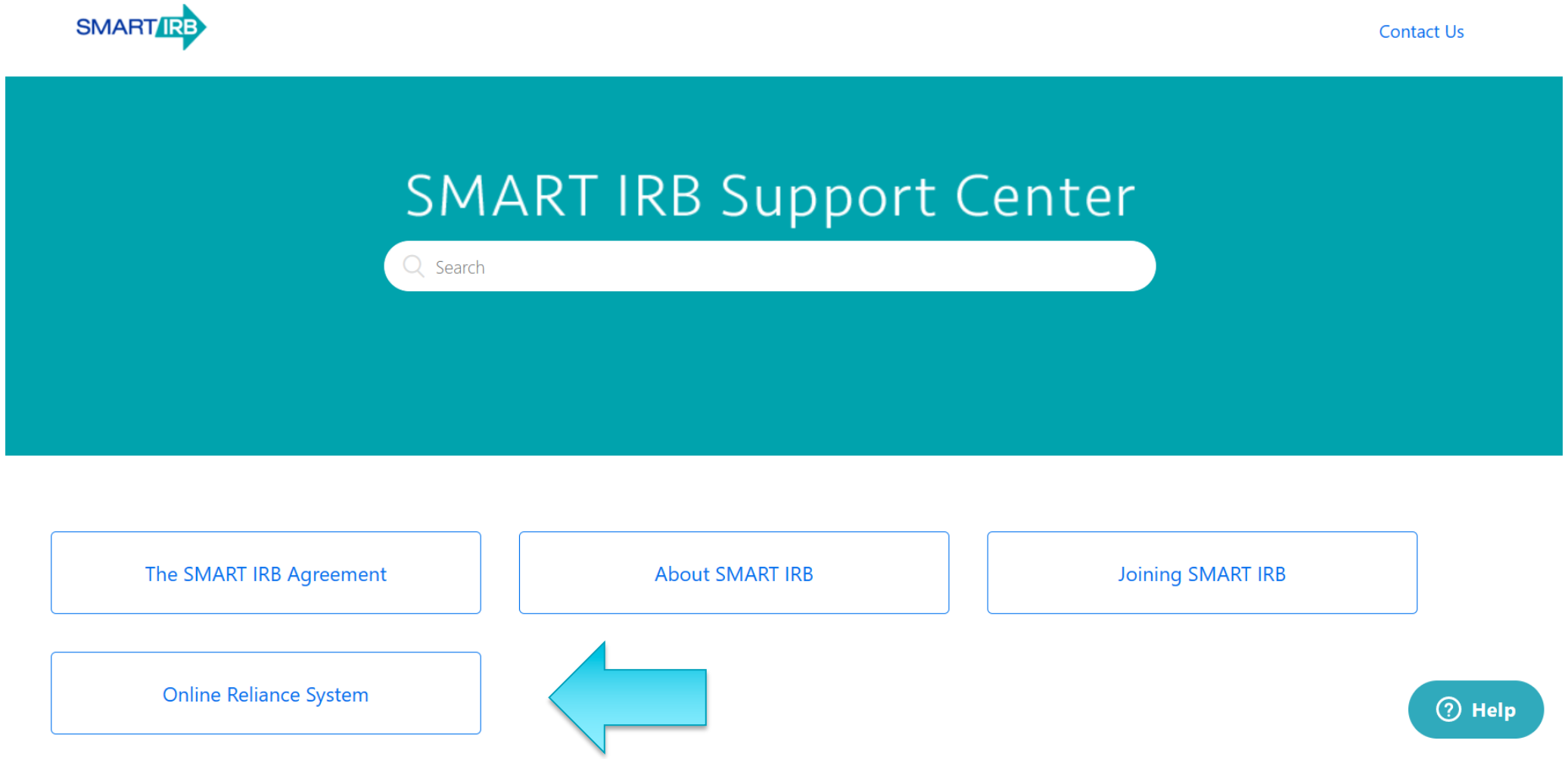
https://support.smartirb.org/hc/en-us



The Impact of Single IRB on Study Teams

Today's panelists:

- **Emma Barkman,** Manager, Regulatory Quality Improvement & Compliance, Clinical Research Management Office, Marlene & Stewart Greenebaum Comprehensive Cancer Center University of Maryland
- **Meg Bradley**, Clinical Research Lead, Department of Pediatrics, UCLA
- **Susan Branscum**, Clinical Trials Administrator for Regulatory, Pediatrics Research Office, University of Alabama-Birmingham
- **Casey Jackson,** Director, Research Quality Improvement and Compliance, Office of Research and Scholarship, University of Maryland School of Nursing
- **Ariela Muzikansky**, cIRB Liaison, PETAL Network CCC, Massachusetts General Hospital
- **Monika Thielen**, Clinical Trial Manager, Aerogen Pharma

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

Understanding VA Requirements for Single IRB

March 20, 2024
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