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

August: Single IRB Review Implementation: Persistent challenges and possible solutions

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

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

In progress:
Local considerations recommendations

Prior SMART Talks

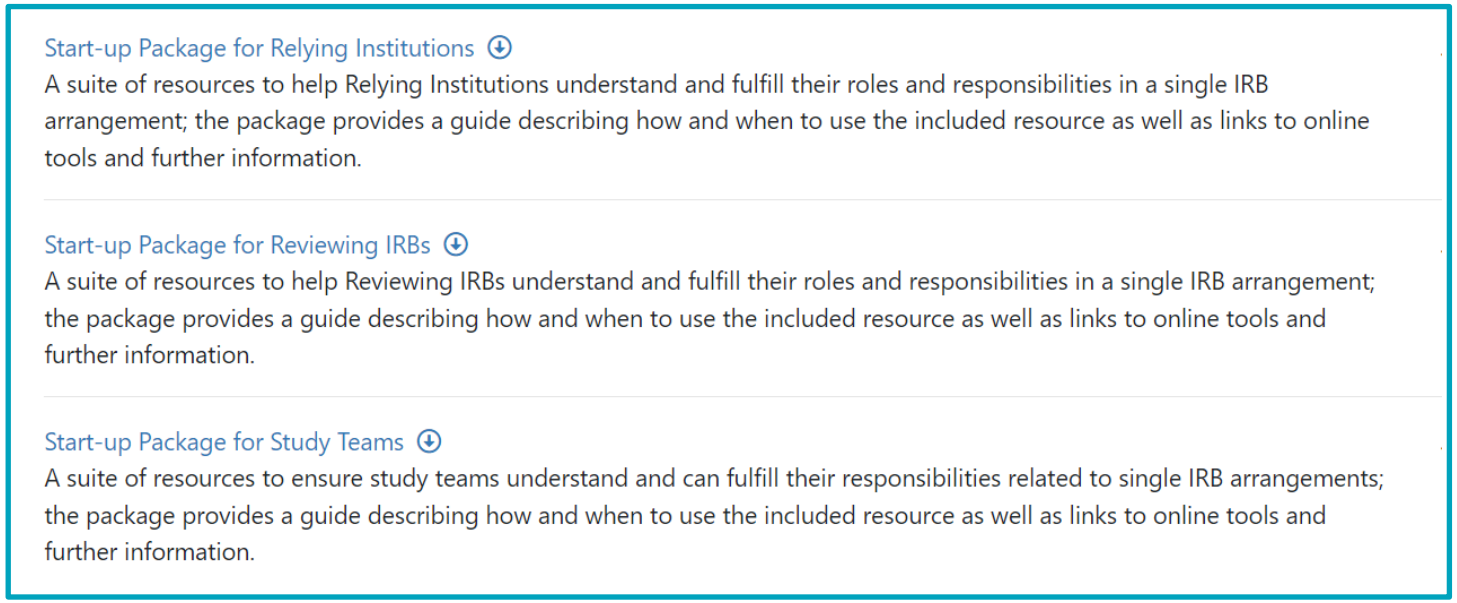
Start-Up Packages	Implementing the Agreement	Reviewing IRBs	Relying Institutions	Getting Started
Online Reliance System	Resources for IRB/HRPPs	**SMART Talk Forum**	sIRB Boot Camp	Training Study Teams

- All have been recorded since September 2019
- Available at https://smartirb.org/irb-admin/

Start Up Packages at smartirb.org/resources/

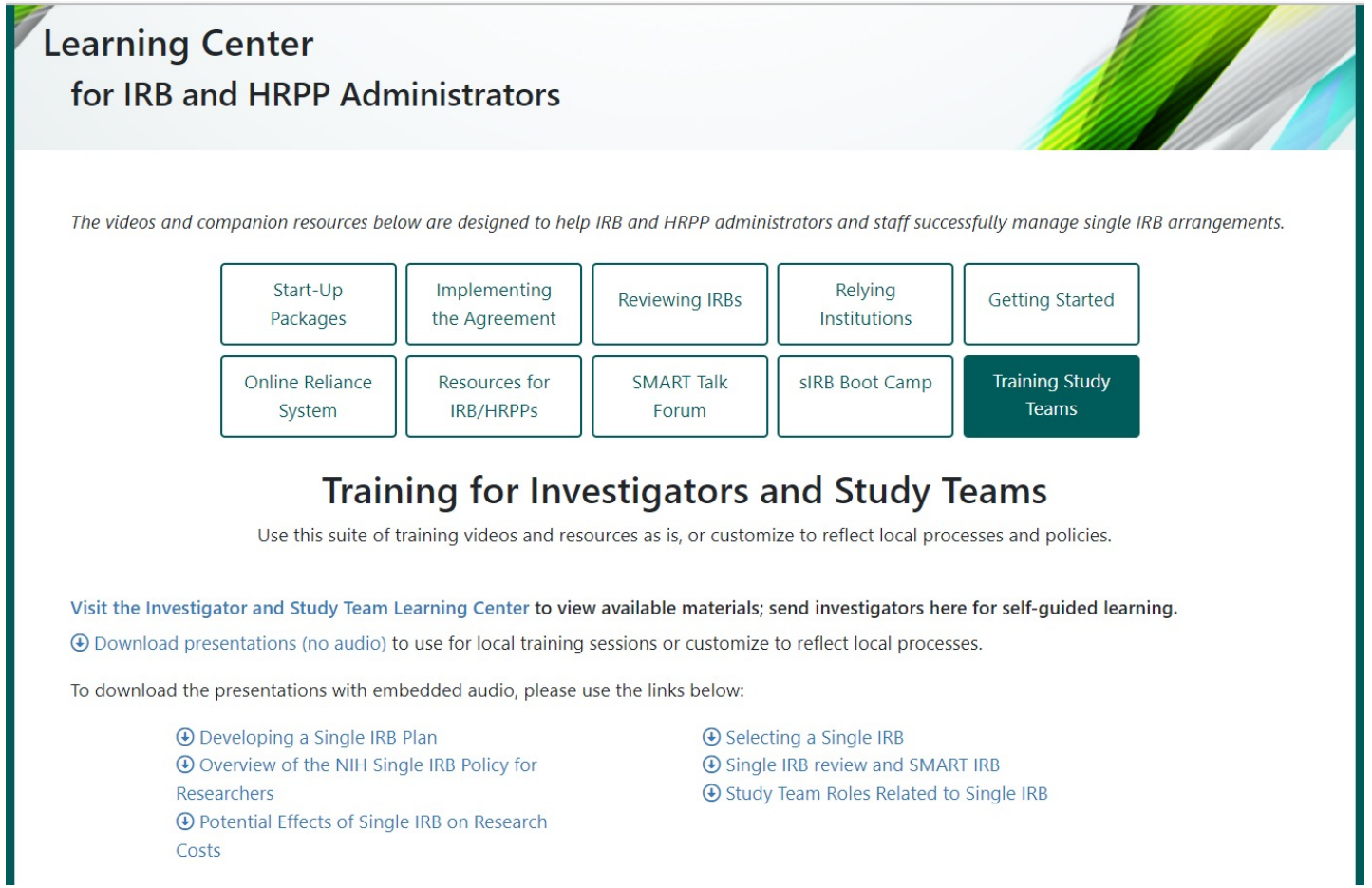
These packages contain a suite of resources based on role: Study Teams, Reviewing IRBs, and Relying Institutions. Also found in the SMART IRB Learning Center.

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

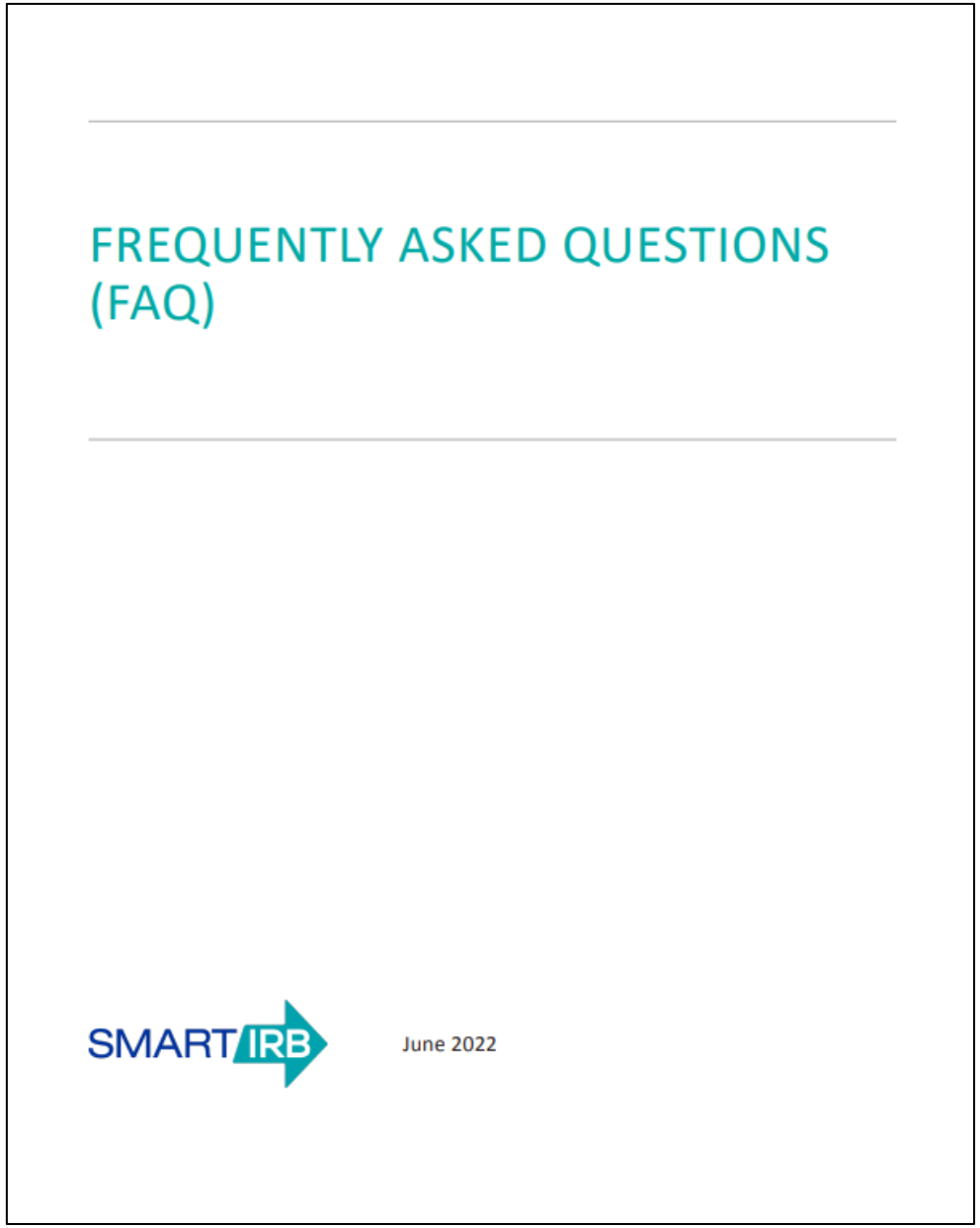
These can be helpful for IRB/HRPP administrators new to single IRB as well!



FAQs

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

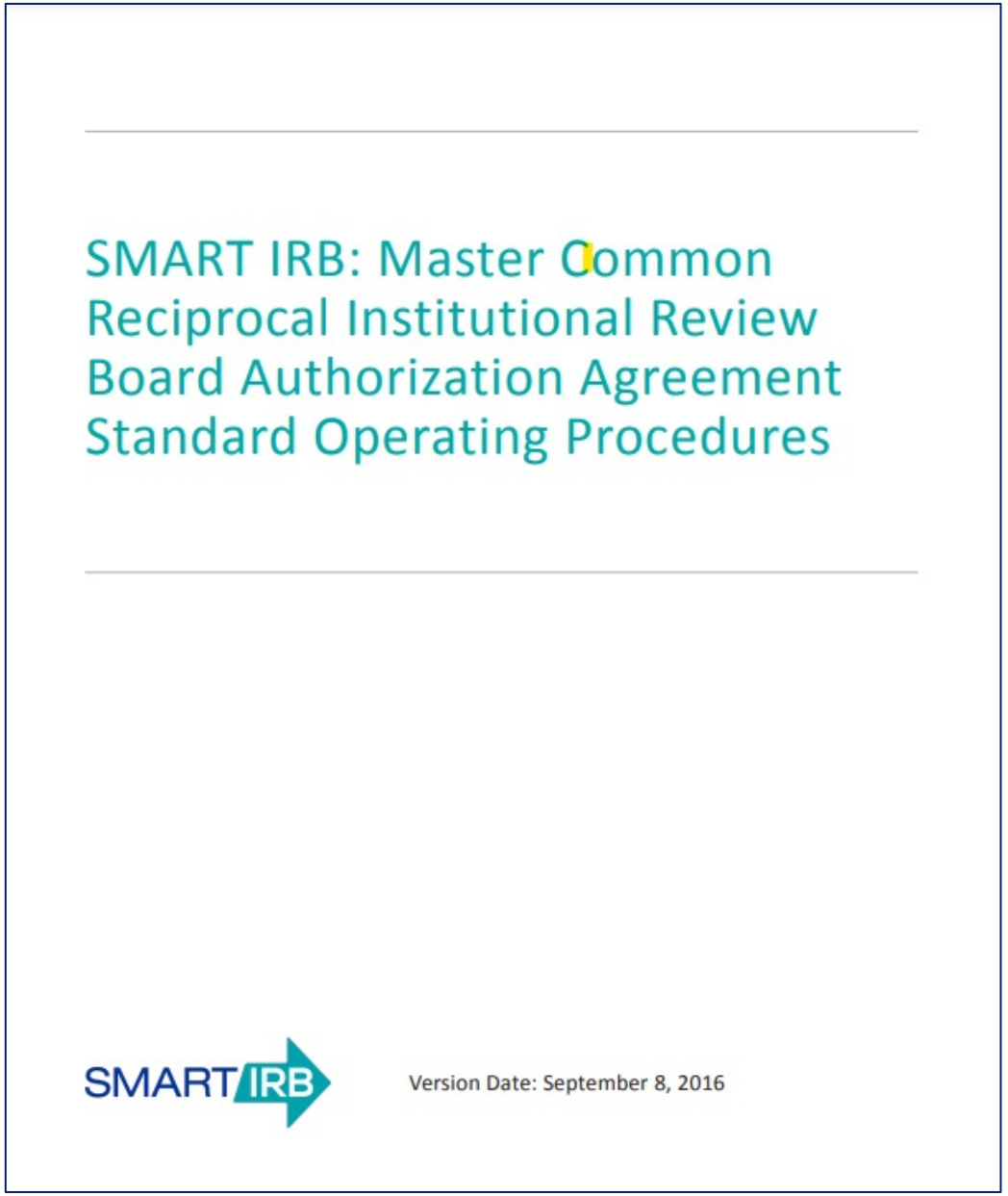
https://smartirb.org/assets/files/faq.pdf



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.

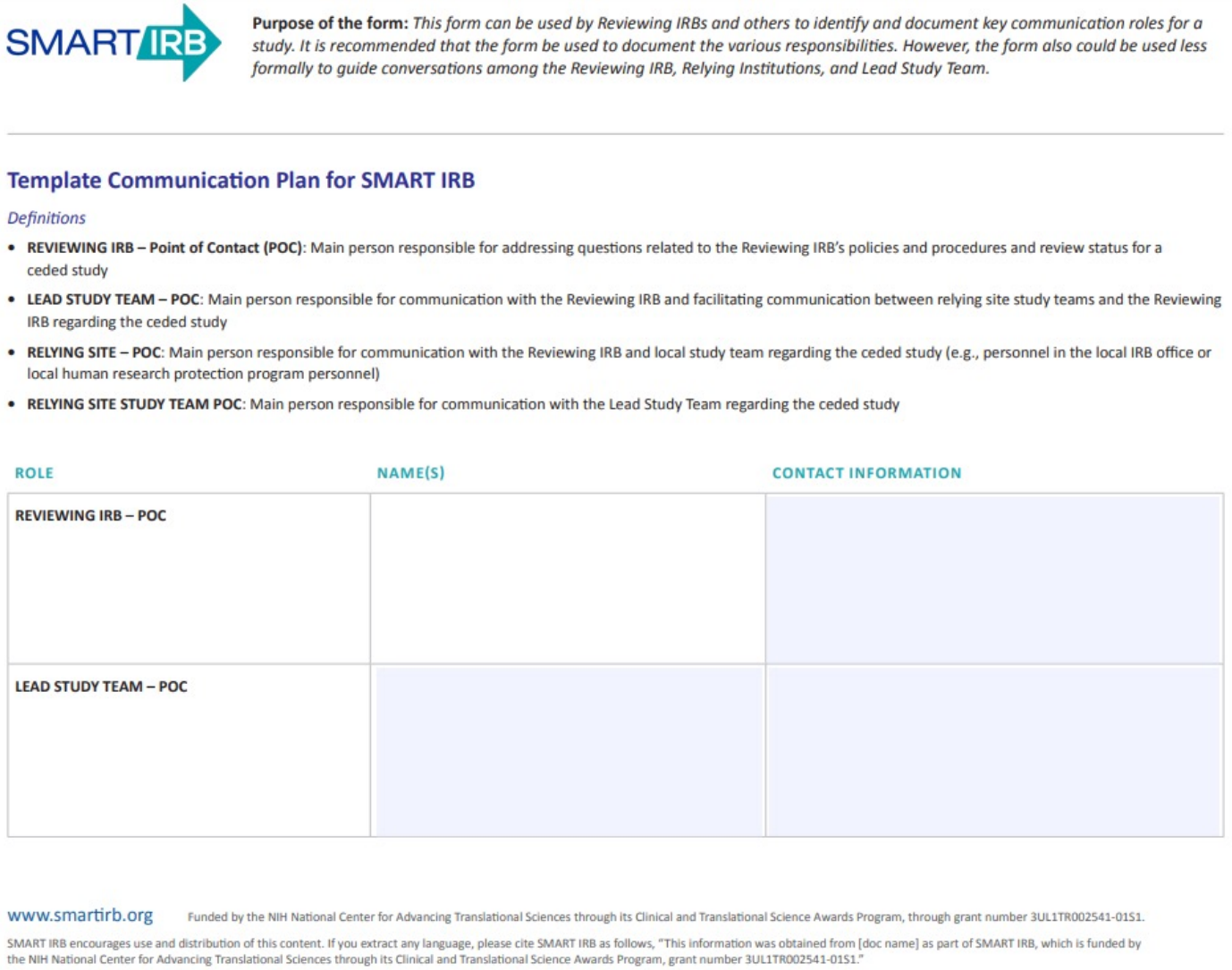
https://smartirb.org/assets/files/SMART_IRB_SOP-090816.pdf



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

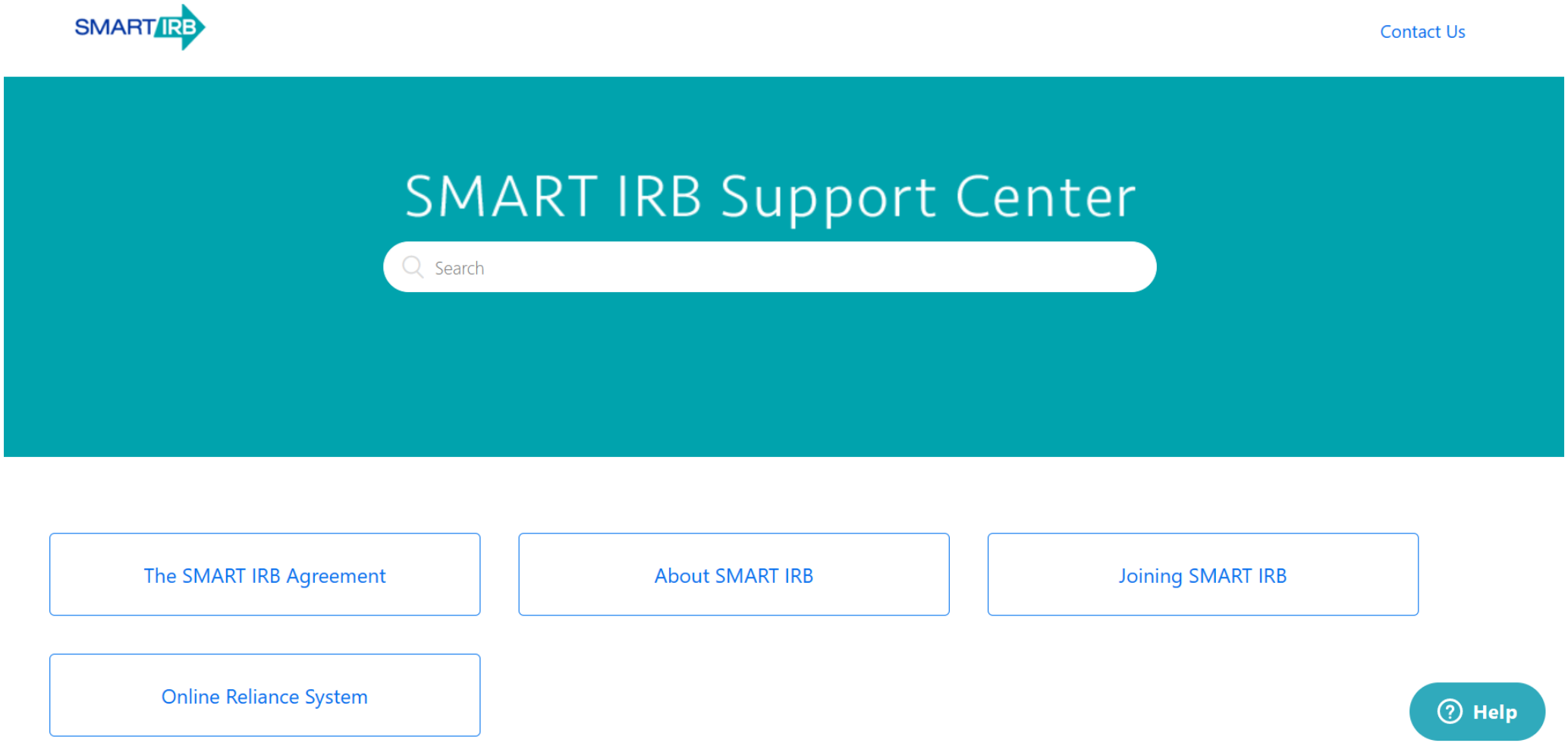
- **REVIEWING IRB – Point of Contact (POC)**: Main person responsible for addressing questions related to the Reviewing IRB's policies and procedures and review status for a ceded study
- **LEAD STUDY TEAM – POC**: Main person responsible for communication with the Reviewing IRB and facilitating communication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

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



Exploring the Financial Aspects of Single IRB

Today's panelists:

- **Lydia Kline, Team Lead,** Clinical Research Policy, Office of Science Policy, NIH
- **Lyndi Lahl**, Human Subjects Officer, Office of Extramural Research Division of Human Subjects Research, NIH
- **Heather J. Phillips,** Senior Financial Analyst, Vanderbilt University Medical Center HRPP/IRB
- **Rafael Santos,** HRPP Assistant Director, Reliance & Regulatory Support, Penn State University
- **Joel Snyderman,** Director, Division of Grants Compliance and Oversight, NIH
- **Matt Stafford,** Assistant Director, HRPP, Yale University

Moderator:

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

SMARTIRB.org

NIH Single IRB Policy Overview – Grants and Cooperative Agreements

SMART TALK – JULY 19, 2023

JOEL SNYDERMAN, DIRECTOR, DIVISION OF GRANTS COMPLIANCE AND OVERSIGHT

NIH OFFICE OF POLICY FOR EXTRAMURAL RESEARCH ADMINISTRATION

Overview

- Overview of the NIH Single Institutional Review Board (sIRB) Policy
- Grants Policy Guidance for sIRB
- Additional Resources

OVERVIEW OF THE NIH SIRB POLICY

National Institutes of Health
Office of Extramural Research

Development and Applicability of NIH's sIRB Policy

- Final NIH sIRB Policy Published June 2016, and applies to all competing grant applications for due dates on or after January 25, 2018
  - Required by the Revised Common Rule (rCR) at 45 CFR Part 46.114
  - NIH Grants Policy Statement, Section 4.1.5.10 NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

- NIH requires sites engaged in NIH-funded, multi-site research conducted at more than one domestic site to rely upon approval by a sIRB:
  - Where each domestic site conducts the same protocol involving non-exempt human subjects research
  - If NIH funds even one site in an applicable multi-site study, NIH expects all other sites using the same protocol will rely on a single IRB
  - Includes projects supported by career development (K) and fellowship (F) awards with initial IRB approval on/after January 20, 2020
  - Foreign sites participating in NIH-funded, multi-site studies will not be expected to use a single IRB

Exception Requests

- **Effective May 11, 2023, and in accordance with the expiration of the federal Public Health Emergency for COVID-19, NIH no longer has the authority to approve exception requests based on the COVID-19 public health emergency. See: NOT-OD-23-097**

- NIH Single IRB Policy exception requests not based on a federal/state/Tribal law, regulation, or policy require the review and approval of the NIH Office of the Director (OD).

- NIH will consider exception requests for studies subject to the NIH Single IRB Policy if they are NOT also subject to the revised Common Rule cooperative research sIRB provision.
  - Exceptions to use of sIRB are rare

- Exception requests must provide sufficient information to demonstrate a compelling justification for an exception to the NIH Single IRB Policy.
  - Cost associated with a single IRB **is not** as a compelling justification.
  - Consult your Program Official with questions or requests regarding exceptions

GRANTS POLICY GUIDANCE FOR SIRB

NIH sIRB Policy Guidance for Grants

NIH Grants Policy Statement, Section 4.1.5.10 NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

Applicants:

- NIH applicants who research is subject to the sIRB requirements must provide **the name of the sIRB** during the "Just-in-time" period – see NIH Grants Policy Statement, Section 2.5.1
  - For delayed-onset research, the name must be provided prior to initiating the multi-site research study/project
- Applicants may request direct costs for the additional costs associated with the establishment and review of the multi-site study/project by the sIRB
  - Such additional cost requests must include an appropriate budget justification
  - For more information on allowability of costs, see NIH Grants Policy Statement, Section 7.9 and the sIRB FAQ

Recipients:

- Recipients are responsible for ensuring that authorization agreements are in place,
  - Including ensuring a mechanism for communications between the sIRB and participating sites
- Participating sites are responsible for meeting all other regulatory requirements

ADDITIONAL NIH GUIDANCE

Choosing a sIRB

- NOFO or solicitation may describe any specific requirements to meet the policy (such as intent to set up a Central IRB for the project)
- Participating sites should work together ahead of time to determine the best IRB for the study
- Reliance agreements should be in place and up to date
- May include working with local IRBs to determine the best IRB, gather relevant local context and policies
- The Single IRB must be registered with OHRP and must have membership to adequately review the proposed study

Resources

- NIH Grants Policy Statement, Section 4.1.5.10 NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
- NIH sIRB Policy for Multi-Site or Cooperative Research (All NIH Research): https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm
- Revised Common Rule regulations for Single IRB: 45 CFR 46.114 -- Cooperative research
- FAQs: https://grants.nih.gov/faqs#/hs-single-IRB-policy-for-multi-site-research.htm

Learn More: See FSD FAQ

Questions?

- Division of Grants Policy:
  - E-Mail: GrantsPolicy@mail.nih.gov
- Division of Grants Compliance & Oversight:
  - E-Mail: GrantsCompliance@mail.nih.gov
- For general Single IRB questions
  - E-Mail: SingleIRB@mail.nih.gov

Save the date for the next SMART Talk

Single IRB Review Implementation: Persistent challenges and possible solutions

August 16, 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