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

February 2023: SMART IRB Boot Camp (no SMART Talk)

March 2023: Is it Yours or Mine? Pinpointing Responsibilities in a Single IRB Situation

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

The Panelists

SMART IRB Ambassadors

https://smartirb.org/ambassadors/

Carissa Minder
Washington University in St. Louis

Nichelle Cobb
AAHRPP

Ada Sue Selwitz
University of Kentucky

Kathy Lawry
AAHRPP

Aaron Kirby
Harvard Catalyst

Stacey Goretzka
Medical University of South Carolina

John Baumann
Indiana University

Other SMART IRB Leadership

Lubabah Helwani
University of California, Los Angeles

Polly Goodman, CIP
Harvard Catalyst

Program Director, Strategic Initiatives
Jonathan M. Green, National Institutes of Health

Program Director, Education
Michael Linke, University of Cincinnati

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

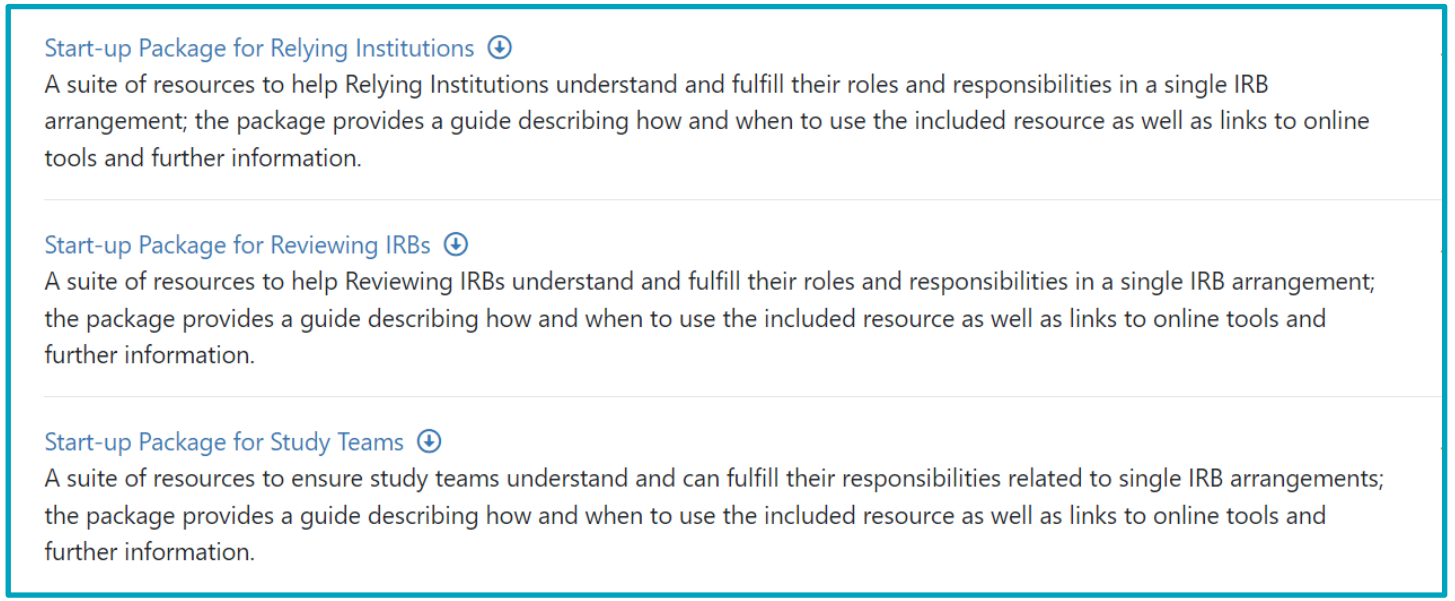
SMART Talks in 2022
(available at https://smartirb.org/resources/)

- 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/

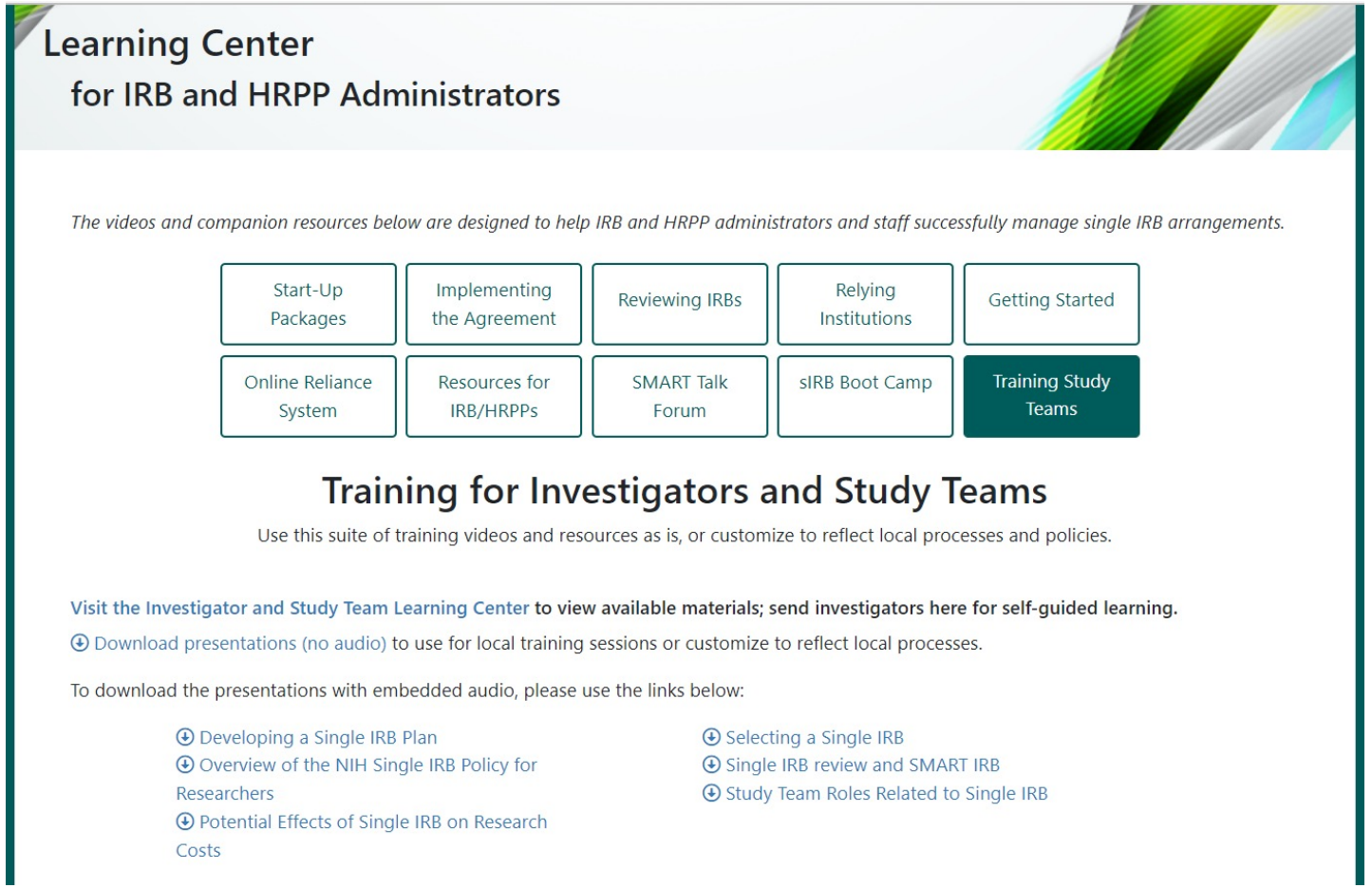
These packages contain a suite of resources based on role: Study Teams, Reviewing IRBs, and Relying Institutions. Also found in the SMART IRB Learning Center.

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

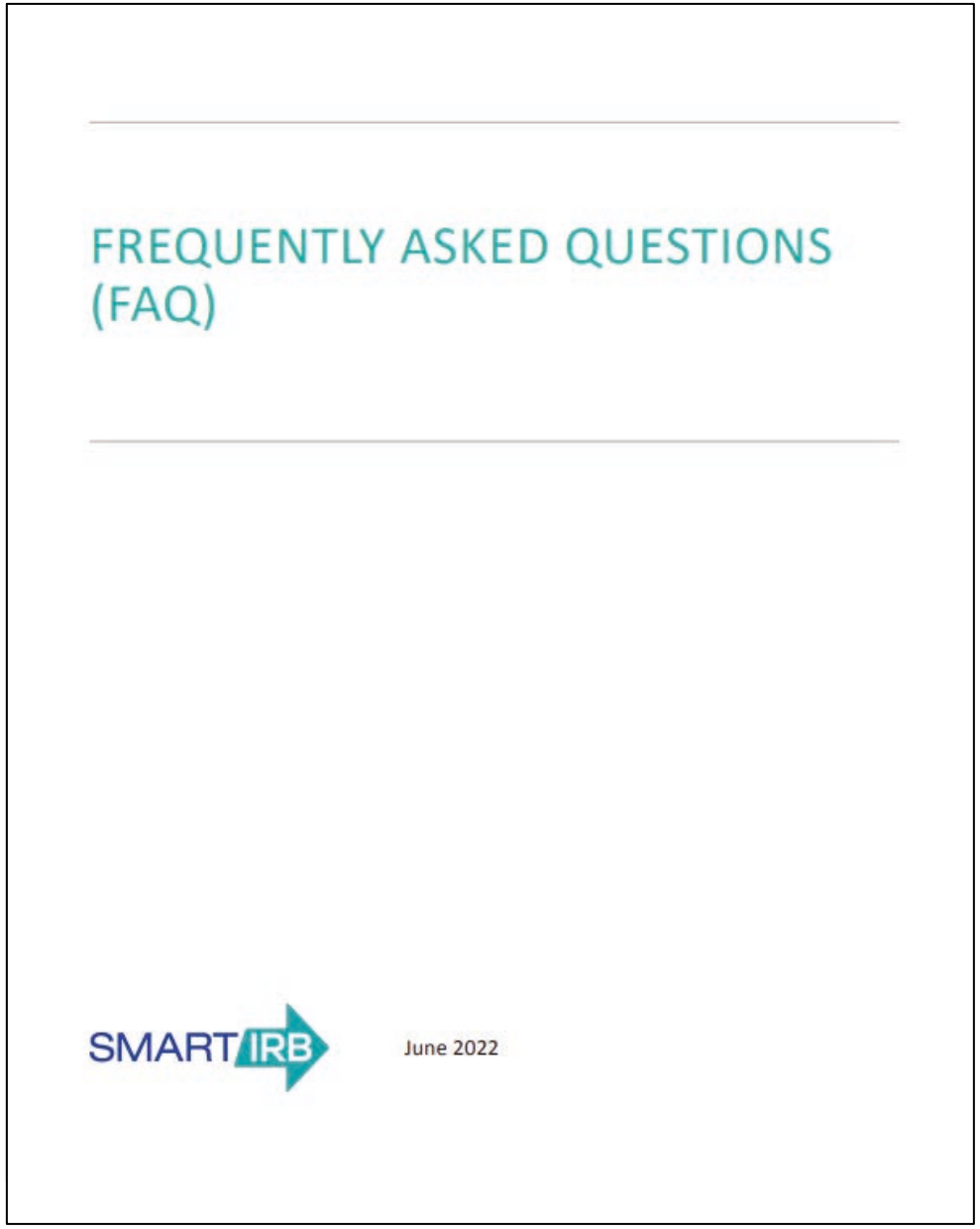
These can be helpful for IRB/HRPP administrators new to single IRB as well!



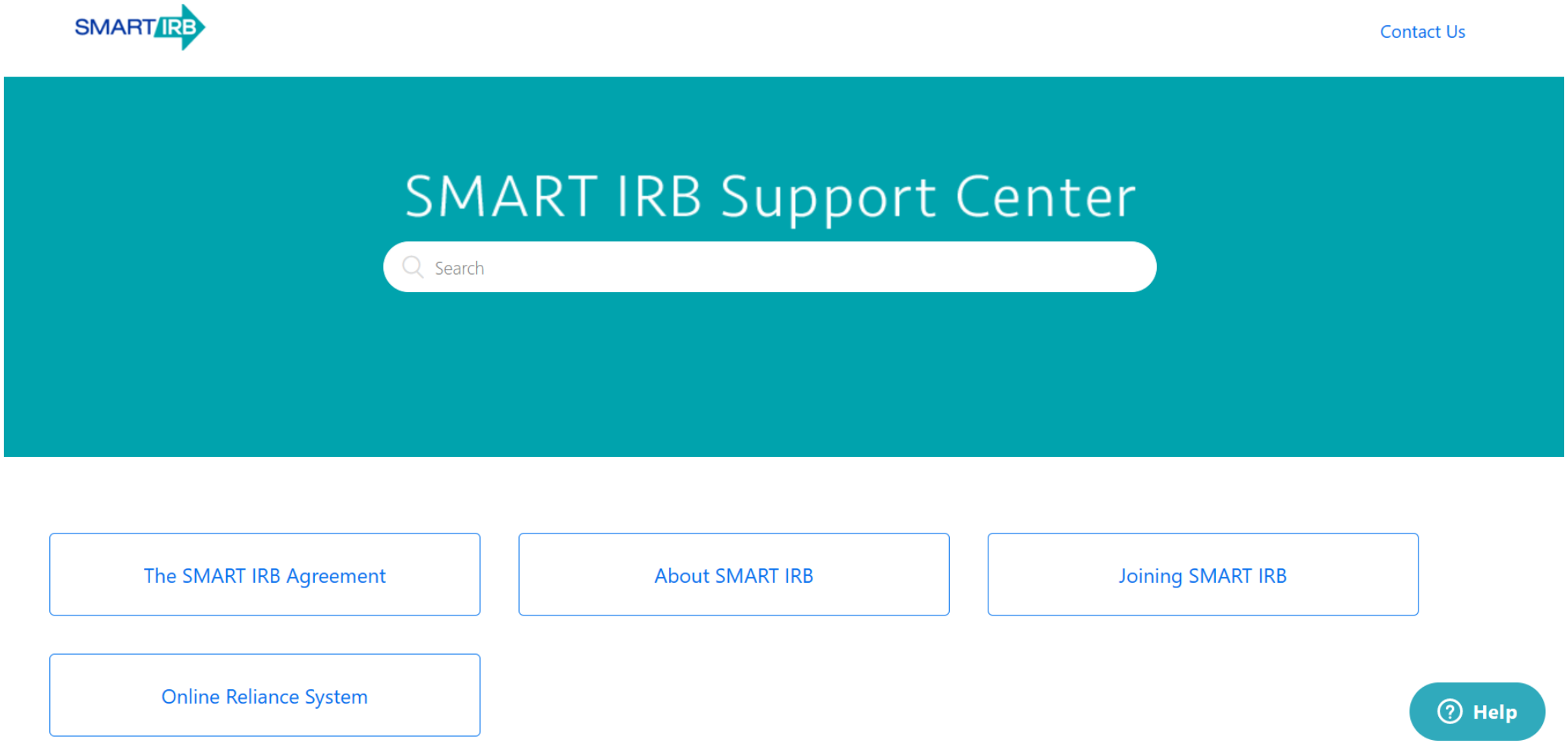
FAQs

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

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



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



https://support.smartirb.org/hc/en-us/articles/115002826094-Making-changes-to-a-Reliance-Request

Making changes to a Reliance Request

Paul Fricker

3 years ago · Updated

This article covers the following:

All reliance requests first go to the Overall PI's home institution Reliance POC for a "Pre-Check"; this step in the workflow is an opportunity for the POC to identify any areas that require correction, as well as to assess whether the study is eligible for a reliance arrangement.

How investigators/submitters can make changes to an in-progress request

If the request has been submitted but it has not yet passed the Pre-Check step, the submitter of the request can reopen it and make any necessary changes (e.g., correcting a typo in the study title or an email address, or making a change to the requested reviewing IRB) by following these steps:

A few questions and answers to start off with…

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

How much does SMART IRB cost?

- The SMART IRB Master Agreement, Online Reliance System, and other resources are available to the community at no cost
- SMART IRB is funded by the NIH National Center for Advancing Translational Sciences through its Clinical and 24 Translational Science Awards Program, through grant number 3UL1TR002541-04S2

How do you use SMART IRB when the investigator is not a member?

- Encourage the investigator's institution to join SMART IRB
- The Reviewing IRB can enter into a separate reliance agreement with the Relying Institution that has not joined SMART IRB and use the SMART IRB Agreement for institutions that have joined SMART IRB so that all sites can rely on the same IRB under two different agreements
  - Institutions that have not joined SMART IRB are not eligible to use the SMART IRB Online Reliance System

Can the SMART IRB agreement be used for international studies?

- A foreign site that has an FWA and meets other current eligibility criteria is eligible to participate in the Agreement; there is nothing in the Agreement itself that is meant to preclude participation of such foreign sites. However, we have been cautious in holding out the Agreement with respect to foreign sites/international reliance because SMART IRB cannot assure that the terms of the Agreement meet any requirements for reliance that might exist under the foreign site's own laws, regulations, or policies. The Agreement was created solely with U.S. law/regulations in mind, and we have not tried to assess it against any particular foreign country's laws or regulations.

Who should initiate the external reliance process for each study in the SMART IRB Online Reliance System?

- While we have designed the Online Reliance System to be investigator-driven in an effort to accommodate the wide range of institutions, with varying research portfolios and research infrastructure, we recognize that some institutions prefer to act on behalf of their investigators. Reliance POCs and POC Backups can submit requests on behalf of investigators. As a Reliance POC or POC Backup, you may determine whether it is appropriate to authorize such an exception at your institution.
- If you are a Reliance POC or POC Backup who would like to be able to submit requests on behalf of your investigators, you will need to set up a separate investigator-level account using an unique email address that differs from your POC email address.

Is it ok that some Reviewing IRBs ask to wait to sign the Agreement until after their review & approval to add a relying site?

- The execution of a reliance agreement between the Reviewing IRB and a relying institution should occur before that IRB reviews and approves the site.
- Because institutions that join SMART IRB are signing on to a standing agreement, the SMART IRB only needs to be signed once. The Reviewing IRB and Relying Institutions then document that they are using the SMART IRB for a study or studies.

Save the dates for the upcoming
SMART IRB Boot Camp
February 7 & 9, 2023
12:00-4:00 pm ET

Questions?
Contact
help@smartirb.org

Register at
smartirb.org

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

Save the date for the next
SMART Talk
March 15, 2023
2:00-3:30 pm ET

March 2023: Is it Yours or Mine? Pinpointing Responsibilities in a Single IRB Situation

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