SMART TALK

A Community Forum to Explore Issues Surrounding Single IRB Review

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: **Relying Institution Roles, Responsibilities, and Opportunities**

Updates on SMART IRB Harmonization Efforts – QA/QI, Continuing Review

Single IRB and planned emergency research

Future: NIH's Approach to the Implementation of the NIH Single IRB policy

FYIs

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 to submit them

New SMART IRB Resource: Start Up Packages

Start-up Package for NIH Grant Preparation ⊕

A suite of resources to help investigators prepare NIH grant applications that require single IRB review; the package provides a guide describing how and when to use the included resource as well as links to online tools and further information.

SMART IRB

Start-up Package for Relying Institutions ⊕

A suite of resources to help Relying Institutions understand and fulfill their roles and responsibilities in a single IRB arrangement; the package provides a guide describing how and when to use the included resource as well as links to online tools and further information.

SMART IRB

Start-up Package for Reviewing IRBs ⊕

A suite of resources to help Reviewing IRBs understand and fulfill their roles and responsibilities in a single IRB arrangement; the package provides a guide describing how and when to use the included resource as well as links to online tools and further information.

SMART IRB

Start-up Package for Study Teams ⊕

A suite of resources to ensure study teams understand and can fulfill their responsibilities related to single IRB arrangements; the package provides a guide describing how and when to use the included resource as well as links to online tools and further information.

SMART IRB

Go to SMARTIRB.ORG, click on the Resources or Learning Center tabs

Downloads
Key Documents
and Explains
How and When
to Use Them

Start-up Package for Study Teams

These resources will help you understand your roles and responsibilities related to single IRB review, including when you are part of a Lead Study Team. See also the Start-up Package for NIH Grant Preparation.

When to use? When you are . . .	What?	Why?
Identifying a Reviewing IRB and requesting a reliance arrangement	FAQs for Research Teams - Relying on an External IRB	Helpful hints for when your institution relies on an external IRB.
Understanding study team responsibilities related to Single IRB	Overall PI (and Lead Study Team) Checklist	Helps an Overall PI (and Lead Study Team, where applicable) understand and fulfill their responsibilities under single IRB review.
	Relying Site Investigator Checklist	Helps site investigators and study teams understand and fulfill their responsibilities when a study has been ceded to an external institution.
	Communication Plan for Single IRB Review	Helps IRBs, relying institutions, and study teams identify and assign key communication responsibilities for studies using a Single IRB.
Requesting and tracking single IRB arrangements	SMART IRB Online Reliance System	Allows study teams to work with their home institutions to propose a Single IRB arrangement.
Collecting and providing information for IRB review	Relying Site Study Team Survey	The Overall PI/Lead Study Team may use this tool to obtain key information from relying site study teams and determine whether particular regulatory or institutional requirements should be communicated to the Reviewing IRB.
	Informed Consent Documents: Inserting Local Context Language	Provides guidance to IRBs, relying institutions, and study teams regarding the different roles that may be involved in inserting local context language in informed consent documents.

Learn more by watching the videos in the SMART IRB Learning Center

Today's Speakers:
Robert Frenck, Cincinnati Children's Hospital
Susan Kornetsky, Boston Children's Hospital
Lori Roesch & Cassandra Baumgart, Children's Hospital lof Wisconsin

Moderator: Barbara Bierer, Harvard Catalyst

Join us for the next
SMART Talk
August 19, 2020
2:00-3:30 pm EDT

Relying Institution Roles, Responsibilities, and Opportunities

Register at smartirb.org

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

Questions?
Contact help@smartirb.org