



SMART TALK

A Community Forum to Explore
Issues Surrounding Single IRB
Review

Funded by the NIH National Center
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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

July: A Conversation with the VA, DOD, and DOE about Single IRB

August: Everything You Wanted to Know about Single IRB but Were Afraid to Ask

September: A Conversation with the FDA about Single IRB

FYIs

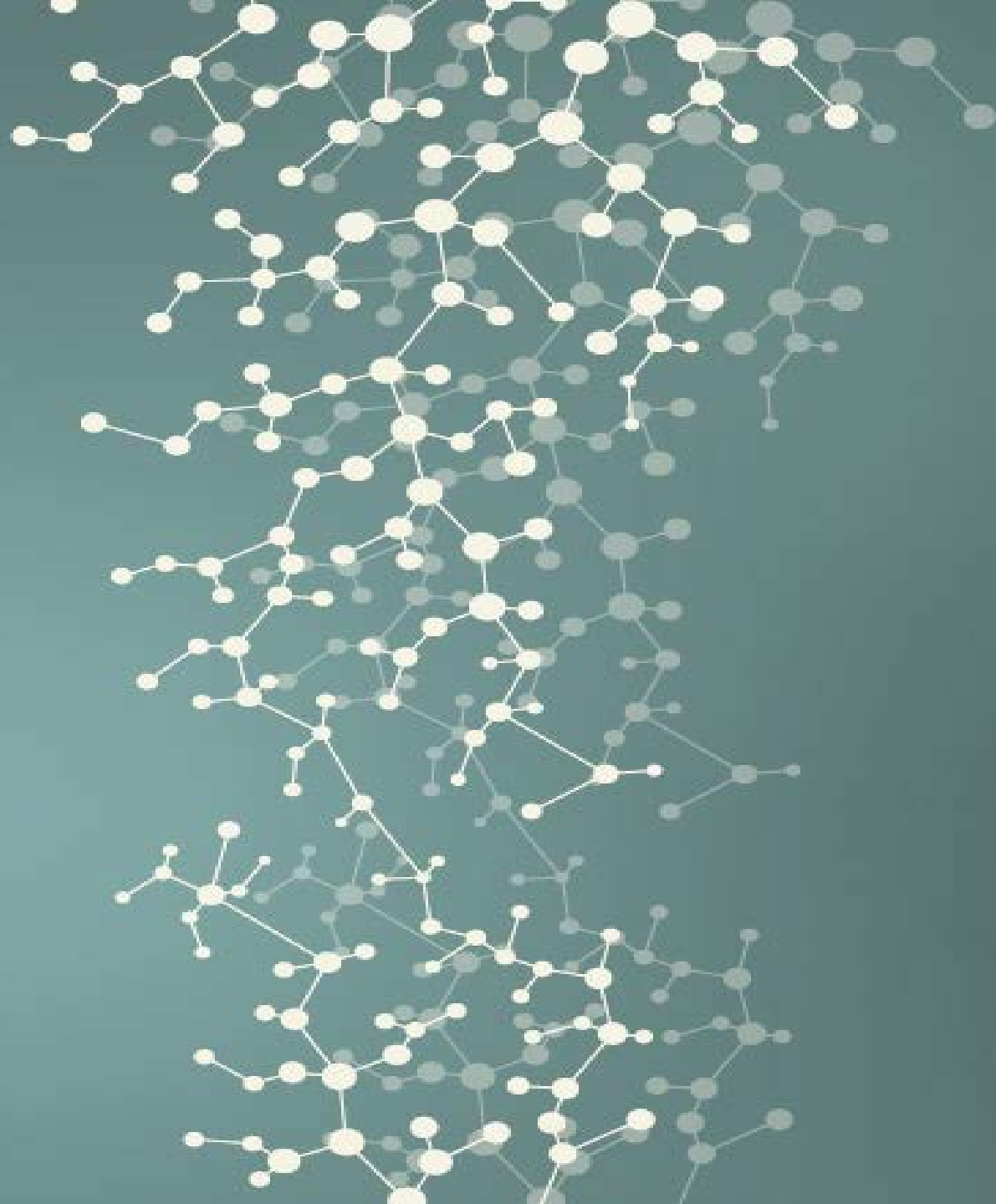
Please provide feedback by completing the survey - a link will be posted in chat and emailed.

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

SMART IRB Resource Reminders



A Selection of Previous SMART Talks and Webinars

- A Conversation with NIH and OHRP about Single IRB
- Process for Review of PI and Non-PI Personnel for Multi-Site Studies
- Recommendations for Harmonization of Post-Approval Auditing of Studies Subject to sIRB Review
- Relying Institution Roles, Responsibilities, and Opportunities
- Reviewing IRBs: Working with Relying Institutions and Study Teams
- Single IRB & Continuing Review
- Single IRB for Social, Behavioral, and Education Research
- Single IRB from the Perspective of Research Teams
- Single IRB Resources: What, When, Why, & How to Use Them
- Tackling Informed Consent under the Single IRB Model

Available at
<https://smartirb.org/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

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.

[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.

[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.

[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.

Looking for a Single IRB (1 of 3)



988 Participating Institutions
including all CTSA hubs

Join SMART IRB

- SMART IRB AGREEMENT
- ONLINE RELIANCE SYSTEM
- HARMONIZATION
- LEARNING CENTER ▾
- RESOURCES
- ABOUT US
- SUPPORT

Participating Institutions

The following institutions have joined SMART IRB and may use the SMART IRB Agreement to enable IRB reliance. To coordinate a reliance arrangement for a study, please contact the appropriate point(s) of contact (POCs) or submit a request through the [Online Reliance System](#).

NEW! POCs and Alternate POCs may complete or update an [Institutional Profile](#) in Joinder to document institutional, local, and state requirements, as well as information about the institution and its IRB(s), if applicable. If you have trouble accessing the system, please [contact us](#).

[Download CSV File](#)

API now available. Contact help@smartirb.org for more information.

Name ▲ ?	Version ▲ ?	City ▲	State ▲	Point of Contact (POC) ▲	POC Phone ▲	Profile ?
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Looking for a Single IRB (2 of 3)



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including all CTSA hubs

Join SMART IRB

Name	Version	City	State	Point of Contact (POC)	POC Phone	Profile
Cornea & Refractive Surgery Consultants of the Pacific, Inc., d/b/a EyeSight Hawaii Vision Institute NEW	v2.0	Honolulu	HI	Kristin Hirabayashi	8087351935	
AAFA	v1	Landover	MD	Deidre Washington	(202) 466-7643	
AHN Research Institute	v1	Pittsburgh	PA	Dawnmarie DeFazio	(412) 330-6192	



The following institutions are participating in a study, please contact them for more information.

NEW! POCs and phone numbers are provided as information about the institution and its IRB(s), if applicable. If you have trouble accessing the system, please [contact us](#).

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API now available. Contact help@smartirb.org for more information.

Name	Version	City	State	Point of Contact (POC)	POC Phone	Profile
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Looking for a Single IRB (3 of 3)



988 Participating Institutions
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Join SMART IRB

SECTION 2. This section should be completed by any institution that may serve as a Reviewing IRB. A potential Relying Institution will review and consider the information in this section during the ceding process.

Is your institution willing to serve as an IRB of record (Reviewing IRB) for other institutions?

Yes

as information about the institution and its IRB(s), if applicable. If you have trouble accessing the system, please [contact us](#).

Enter your search terms

[Download CSV File](#)

API now available. Contact help@smartirb.org for more information.

Name Version City State Point of Contact (POC) POC Phone Profile



Being a Single IRB for a Study with Many Sites

- Nadia Johnson, Assistant Director, Human Research Protections, External Relations, Office of Science & Research, NYU Langone Health
- Adam McClintock, Director, Office of the Institutional Review Board, University of Alabama at Birmingham
- Jesse Ripton, Manager, External Relations, Policy & Quality, Boston Children's Hospital

Moderator: Nichelle Cobb, SMART IRB and AAHRPP

Discussion & Questions

Save the date for the next
SMART Talk
July 20, 2022
2:00-3:30 pm ET

A Conversation with the VA, DOD, and DOE about Single IRB

Questions?
Contact
help@smartirb.org

Register at
smartirb.org

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