



SMART TALK

A Community Forum to Explore
Issues Surrounding Single IRB
Review

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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

November: break for PRIM&R
AER 2021 meeting

December: When You're Not the
Reviewing IRB - Impact of Using
External IRBs on Organizations

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 Updates



Harmonization Steering Committee Recommendations

- **NEW: 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
- Close to being posted: Ancillary Review

What Is Single IRB Review?



Single IRB review refers to the use of one IRB to review and approve all or most sites participating in a multisite research study, rather than each site obtaining approval for their activities from a different IRB.



Other terms for a single IRB include:

Central IRB
Reviewing IRB

Brief History of Single IRB Review

Prior to 2018

Using one IRB to oversee multisite (aka cooperative) research occurred on a limited basis



January 25, 2018

Most multisite research supported by the National Institutes of Health (NIH) requires single IRB review



January 20, 2020

Most multisite research subject to the Common Rule requires single IRB review

The FDA has yet to issue a requirement to use a single IRB, but does not oppose the use of a single IRB for multisite research.

NIH Single IRB Policy

Required funding applications to include a single IRB plan for most multisite research - now single IRB identified at JIT

Applies to both biomedical and social behavioral research that meets the definition of a clinical trial

Now permits the use of federal funding to pay for certain IRB costs, which can affect research budgets

The policy is generally similar to the single IRB requirement within the Common Rule

Common Rule Cooperative Research Requirement

- Requires single IRB for most non-exempt human subjects research that involves more than one institution
- Applies to research
 - Conducted in the US
 - Approved by an IRB on or after January 20, 2020
- Does not apply when
 - More than a single IRB required by lawor
 - A Federal department or agency conducting or supporting the research determines and documents that the use of a single IRB is not appropriate for the specific context
- Extends the NIH policy that went into effect in 2018

Documenting Single IRB Agreements

To use a single IRB for a multisite research study, institutions must document reliance agreements, including which institution will serve as the Reviewing IRB, which will cede IRB review, and the responsibilities of each institution.



Single IRB for Social, Behavioral, and Education Research

- **Cecilia Brooke Cholka**, IRB Specialist, University of Nevada, Reno
- **Melissa McGee**, Assistant Director, Research Integrity Services, University of New Hampshire
- **Cindy Shindledecker**, Director of the Health Sciences and Social Behavioral Sciences IRB, University of Michigan
- **Julie Simpson**, Director, Research Integrity Services, University of New Hampshire

Moderator: Nichelle Cobb

SMARTIRB.org

Discussion & questions

Save the date for the next
SMART Talk
December 15, 2021
2:00-3:30 pm ET

When You're Not the
Reviewing IRB - Impact of
Using External IRBs on
Organizations

Questions?
Contact
help@smartirb.org

Register at smartirb.org

Sign up for our mailing list to be
notified of future offerings¹⁴