Single IRB Presentation & Panel Discussion

Featuring: Nichelle Cobb, PhD; University of Wisconsin-Madison; Smart IRB Director

And Panelists:  
James Cnota, MD; Cincinnati Children’s
Jeremy Corsmo, MPH; Cincinnati Children’s
Pooja Khatri, MD, MSc; University of Cincinnati
Mike Linke, PhD; University of Cincinnati

Single IRB as a Team Sport:
Roles, Responsibilities & Resources

Nichelle Cobb, PhD
Director, SMART IRB Operations &
Human Subjects Protection Officer, Institute for
Clinical & Research, University of Wisconsin-Madison
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
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.

Before Single IRB Review
Multisite Study

Each study team submits an application to their Local IRB to review
Before Single IRB Review

Local IRBs often served as a gatekeeper to help ensure institutional requirements in addition to IRB review were met (e.g., ancillary reviews).

IRB A: Holds approval until all institutional requirements complete
Site A

IRB B: Holds approval until certain institutional requirements met
Site B

IRB C: Office independent of the IRB ensures institutional requirements met
Site C

IRB D: Research team responsible for ensuring institutional requirements met
Site D

After Single IRB Review

Single IRB receives local context information for each site.

IRB B

Site A
Site B
Site C
Site D
After Single IRB Review

Multisite Study

IRB B

Issues IRB approval for each site

Site A  Site B  Site C  Site D

Sites responsible are for ensuring institutional requirements completed before study activation

Monitoring & Communicating Institutional Requirements BEFORE Single IRB

Local IRB

Conflict of interest  Research compliance program  Institutional safety committees

Scientific review  Grants, contracts, research billing

Research pharmacy  Research privacy  Legal Counsel

Institutional safety committees  Research pharmacy
Monitoring & Communicating Institutional Requirements AFTER Single IRB

- Conflict of interest
- Research compliance program
- Institutional safety committees
- Scientific review
- Research privacy
- Grants, contracts, research billing
- Research pharmacy
- Legal Counsel

Single IRB Review is a team sport

The Players
- Reviewing IRBs
- Relying Institutions
- Lead Study Team
- Relying Site Study Teams

Keys to success: Know your role and responsibilities as part of the team

Work together and communicate to ensure success
Key Study Team Roles

Overall Principal Investigator (PI)
Generally, the initiating or funding principal investigator

Lead Study Team
Designated by the Overall PI
Provides key administrative and communication support for the study.
May be a coordinating center.

Site Investigator(s) (Site PIs)
Responsible for conduct of the research at their institution

Relying Site Study Team(s)
Study team(s) whose institution has ceded review to the Reviewing IRB
Includes Site Investigator and local personnel who carry out communication, coordination, and administrative procedures

Common Single IRB Communication Model

Reviewing IRB
Lead Study Team/Coordinating Center
Relying Institution IRB/HRPP
Lead Study Team coordinates investigator communication with the IRB
Relying Site Study Team
Common Key Responsibilities: Lead Study Team

Educating relying site study teams about Reviewing IRB processes, requirements and policies (e.g., regarding reportable events)

Submitting materials to the Reviewing IRB for all sites, including study-wide and site-specific changes of protocol, continuing reviews, and reportable events (e.g., unanticipated problems, noncompliance, and new information)

Providing draft study materials to all site study teams, including any proposed consent form template

Distributing IRB-approved materials and determination letters to all site study teams

Common Key Responsibilities: Site PIs & Relying Site Study Teams

Following the policies and procedures of the Reviewing IRB (e.g., for reportable events, personnel updates)

Providing the Lead Study Team information about study progress for continuing review and local events (e.g., unanticipated problems, noncompliance) so that it can be reported to the Reviewing IRB

Providing information to include in the informed consent document (e.g., study team contact information and unique study costs) and using the Reviewing IRB’s consent form template

Obtaining authorization from their local institutions, such as reliance Point of Contacts (POCs), in the case of personnel changes, conflict of interest updates, and/or changes that may be affected by State law or institutional requirements
Communication Points of Contact

Extremely important to keep communications organized and consistent

- A Point of Contact (POC) should be identified for each group
- Institutions should have a designated reliance Point of Contact, who can advise regarding reliance arrangements and requirements

The Reliance Process
Single IRB Agreements

To use a single IRB for a multi-site research study, institutions must enter into formal arrangements called reliance agreements to document which institution will serve as the Reviewing IRB and which will cede IRB review to that institution.

A reliance agreement, sometimes called an IRB authorization agreement, is an agreement between institutions, not between IRBs or between researchers and IRBs.

SMART IRB Master Reliance Agreement

The SMART IRB Agreement is a national agreement, with almost 800 Participating Institutions, and eliminates the need to negotiate a reliance agreement.

Many institutions only accept the SMART IRB Agreement to document single IRB arrangements.

Because NIH requests certification of IRB approval as part of the just-in-time process, using the SMART IRB Agreement can reduce the time to IRB approval and release of funding.
Single IRB Process: Initiating a Reliance Arrangement

Overall PI/Lead Study Team identifies the need for single IRB review

Overall PI/Lead Study Team reaches out to the potential reviewing IRB to confirm interest & ability to serve in that role

If the reviewing IRB is not at the Overall PI’s institution, the Overall PI/Lead Study Team consult with local IRB/HRPP personnel to confirm use of the proposed reviewing IRB

Overall PI/Lead Study Team submits a formal request for a reliance arrangement following the process required by the Overall PI’s home institution that includes identifying participating sites

Single IRB Process: Executing a Reliance Arrangement

Lead Study Team works with participating sites to reach out to their local reliance points of contact (POCs) to discuss the need for reliance arrangements

Reviewing IRB and relying institutions execute a reliance arrangement, which may include using a master agreement (e.g., SMART IRB)

Reviewing IRB and relying institutions document the study-specific reliance arrangement (e.g., using the SMART IRB Online Reliance System or template acknowledgement letter)
Single IRB Process:
Initial Review

Reviewing IRB requests institutional and study-specific local context information from relying institution POCs

Relying institution POCs work with their local study teams to provide local context information to the reviewing IRB

Lead Study Team collects information from relying site study teams to prepare and submit an initial review application to the reviewing IRB

After initial IRB approval obtained, the Lead Study Team disseminates the IRB notification and approved documents to the relying site study teams

Examples of local context information

- Qualifications of investigators/study staff
- Ancillary reviews that may need to be completed before IRB review (e.g., conflict of interest; feasibility; scientific review)
- Differences in locally available resources that should be considered by the Reviewing IRB
- Additional state laws and/or local requirements that should be considered by the Reviewing IRB (e.g., mandatory reporting to state health authorities, child abuse reporting, child pregnancy results)
- Drug and device storage requirements and processes
- Institutional approach to HIPAA Privacy Rule requirements and language
Single IRB Process: After Initial Review

Relying site study teams inform the Lead Study Team of any local amendments required and reportable events, provides information relevant to continuing review, and relevant updates to study personnel (including changes in conflicts of interest)

The Lead Study Team submits amendments, continuing reviews, and reportable events to the IRB on behalf of relying site study teams

Relying site study teams communicate to their institutions of any information, documents, or events required by institutional policy on an ongoing basis

The relying institutions maintain responsibility for ensuring their local study teams comply with IRB determinations and institutional requirements throughout the life of the study

Summary: Effects of Single IRB on Responsibilities

Shift in responsibilities for academic IRBs
- Reviewing IRBs: consideration of local context issues for each site
- Relying Institutions: monitoring for compliance (institutional requirements, federal regulations, & with IRB determinations)

Increase in responsibility for Overall PIs/Lead Study Teams
- Managing regulatory submissions for and additional communication responsibilities with relying sites throughout the life of a study

Decrease in regulatory responsibility for Relying Site Study Teams?
- Eliminates the need to prepare IRB submissions; however, must provide information to the Lead Study Team
SMART IRB resources that can help

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.

- **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.

*Go to SMARTIRB.ORG, click on the Resources or Learning Center tabs*
Start Up Packages

Download key documents and explains how and when to use them and provide links to other resources (e.g., training modules)

Resource: Grant Application Language

Template Description of SMART IRB: Provides language for researchers and their institutions to adapt for federal grant applications.

Available at https://smartirb.org/sites/default/files/Template_Description_SMART_IRB_for_grant_applications_11-17-2017.docx
Resource: Communication plan for single IRB review

Document key communication roles, such as responsibilities for:

- submitting initial and continuing reviews, amendments, and reportable events
- providing conflict of interest management plans
- distributing IRB-approved documents and communicating Reviewing IRB determinations

Communication Plan available at https://smartirb.org/sites/default/files/Communications_Plan_Form.pdf

SMART IRB Online Reliance System

Helps investigators and institutions request, track, and document reliance arrangements for each study.

https://smartirb.org/reliance/
Short Training Modules for Investigators

• Overview of the NIH Single IRB Policy
• Selecting a Single IRB
• Developing a Single IRB Plan
• Single IRB review and SMART IRB
• Managing Roles Related to Single IRB
• Potential Effects of Single IRB on Research Costs
• Reliance Walkthrough Video: Using the SMART IRB Online Reliance System

Discussion and Questions
PI Perspectives

• Pooja Khatri, MD, MSc; University of Cincinnati
• James Cnota, MD; Cincinnati Children’s

IRB Perspectives

• Mike Linke, PhD; University of Cincinnati
• Jeremy Corsmo, MPH; Cincinnati Children’s
Questions

• To submit a question for our presenter or panelists, please email to mina.busch@cchmc.org.

• Open microphones.

Single IRB Presentation & Panel Discussion

Featuring: Nichelle Cobb, PhD; University of Wisconsin-Madison; Smart IRB Director
And Panelists: James Cnota, MD; Cincinnati Children’s
Jeremy Corsmo, MPH; Cincinnati Children’s
Pooja Khatri, MD, MSc; University of Cincinnati
Mike Linke, PhD; University of Cincinnati