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

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SMART IRB

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

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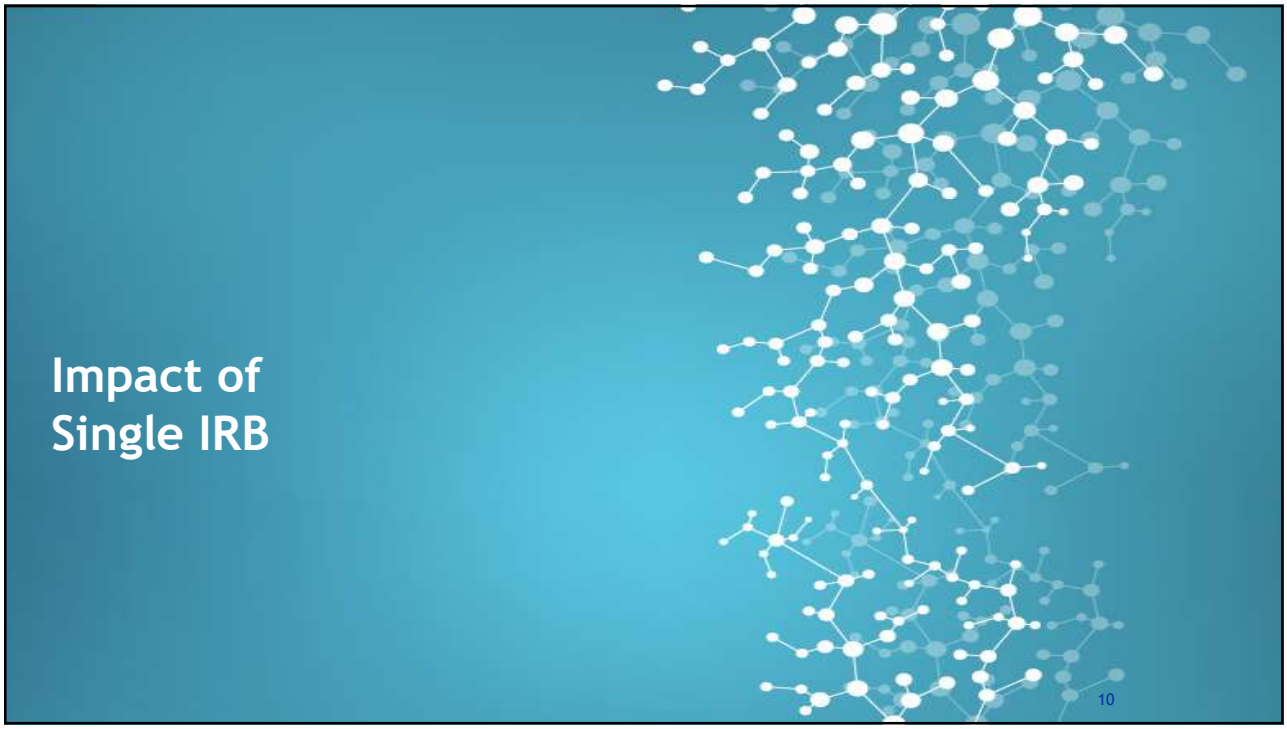

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What Is Single IRB Review?

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

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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.

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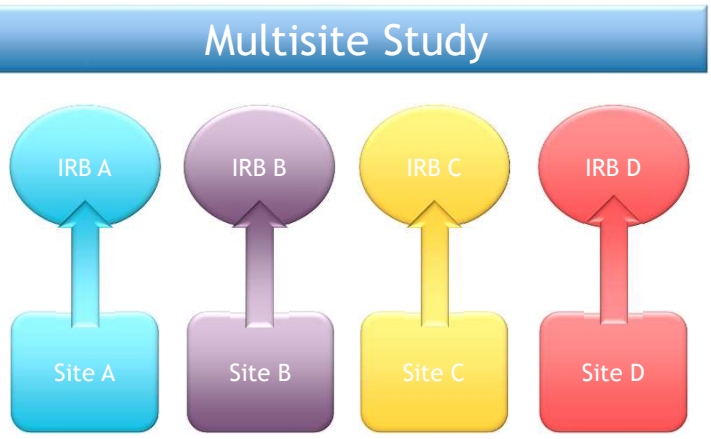
Before Single IRB Review

Each study team submits an application to their Local IRB to review



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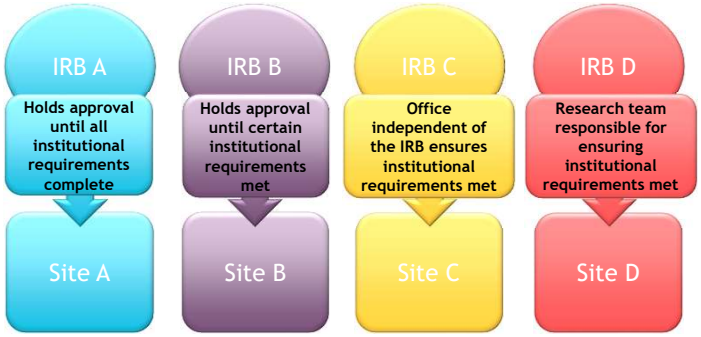
Before Single IRB Review

Multisite Study

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



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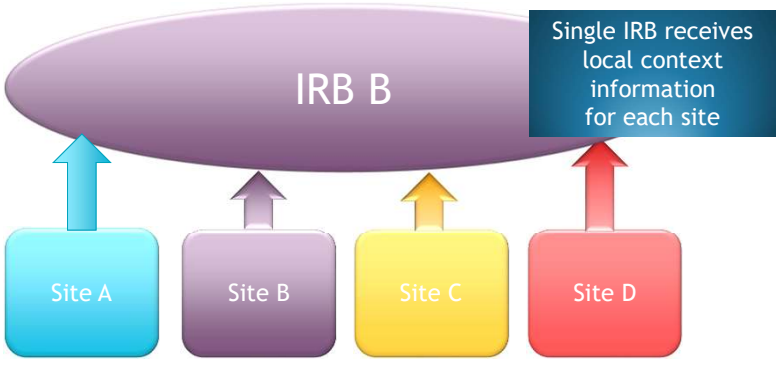
After Single IRB Review

Multisite Study



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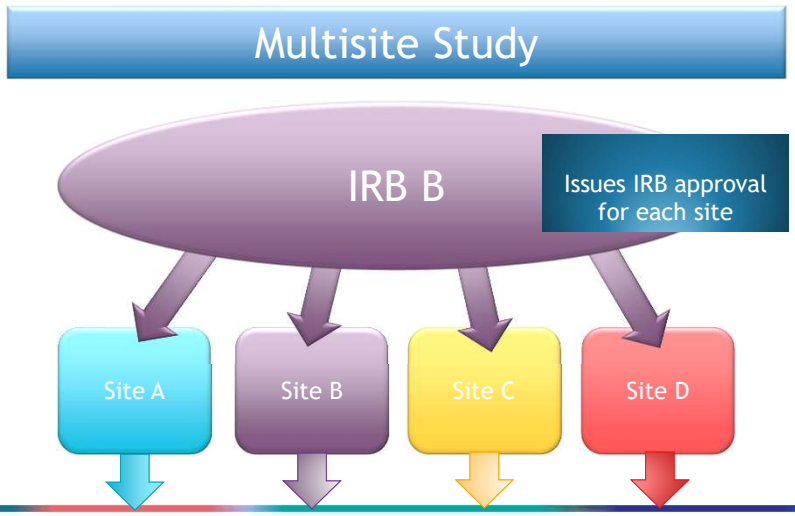
After Single IRB Review



Sites responsible are for ensuring institutional requirements completed before study activation

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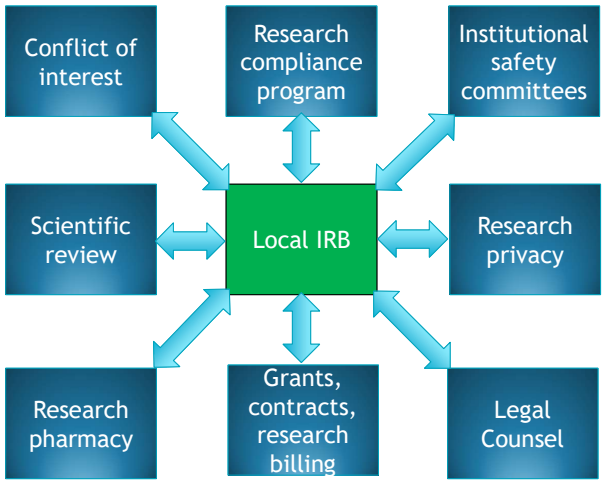
Monitoring & Communicating Institutional Requirements BEFORE Single IRB



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Monitoring & Communicating Institutional Requirements AFTER Single IRB

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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

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Key Study Team Roles

Overall Principal Investigator (PI)

Generally, the initiating or funding principal investigator

Site Investigator(s) (Site PIs)

Responsible for conduct of the research at their institution

Lead Study Team

Designated by the Overall PI

Provides key administrative and communication support for the study. May be a coordinating center.

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

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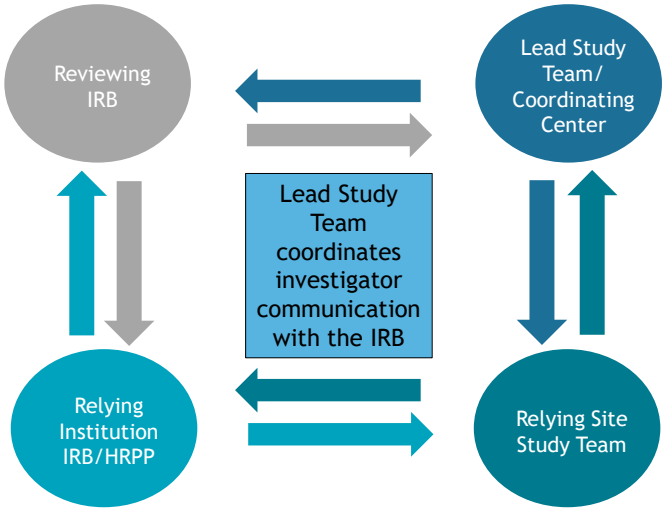
Common Single IRB Communication Model



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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

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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

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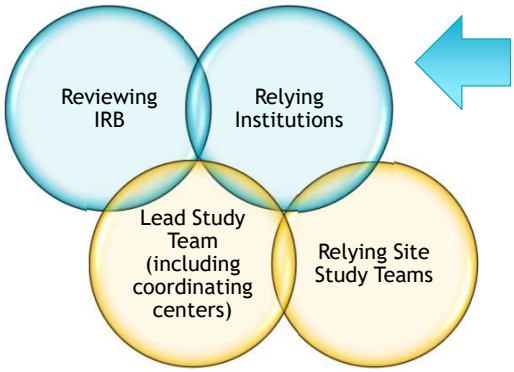
Communication Points of Contact

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

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The Reliance Process

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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.

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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.

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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

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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)

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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

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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

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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

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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

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SMART IRB resources that can help

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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

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Start Up Packages

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

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.**

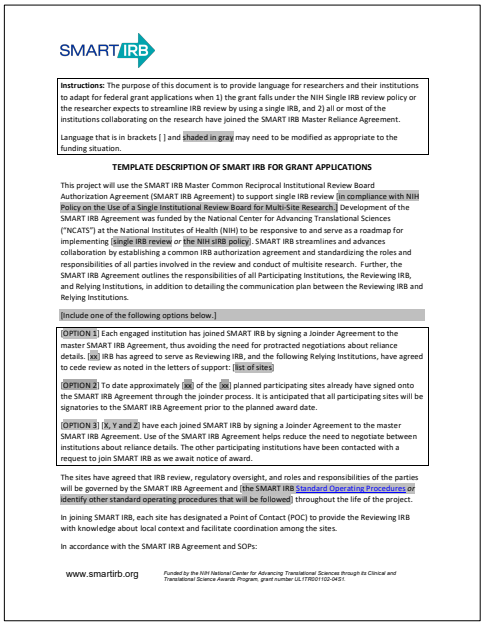
When to use? When you are . . .	What?	Why?
Identifying a Reviewing IRB and requesting a reliance arrangement	FAQs for Research Teams - Relying on an External IRB	Helpful hints for when your institution relies on an external IRB.
Understanding study team responsibilities related to Single IRB	Overall 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

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



SMART IRB

Instructions: The purpose of this document is to provide language for researchers and their institutions to adapt for federal grant applications when 1) the grant falls under the NIH Single IRB review policy or the researcher expects to streamline IRB review by using a single IRB, and 2) all or most of the institutions collaborating on the research have joined the SMART IRB Master Reliance Agreement.

Language that is in brackets [ ] and shaded in gray may need to be modified as appropriate to the funding situation.

TEMPLATE DESCRIPTION OF SMART IRB FOR GRANT APPLICATIONS

This project will use the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (SMART IRB Agreement) to support single IRB review [in compliance with NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research.] Development of the SMART IRB Agreement was funded by the National Center for Advancing Translational Sciences ("NCATS") at the National Institutes of Health (NIH) to be responsive to and serve as a roadmap for implementing [single IRB review or the NIH sIRB policy]. SMART IRB streamlines and advances collaboration by establishing a common IRB authorization agreement and standardizing the roles and responsibilities of all parties involved in the review and conduct of multisite research. Further, the SMART IRB Agreement outlines the responsibilities of all Participating Institutions, the Reviewing IRB, and Relying Institutions, in addition to detailing the communication plan between the Reviewing IRB and Relying Institutions.

[Include one of the following options below.]

[OPTION 1] Each engaged institution has joined SMART IRB by signing a Joinder Agreement to the master SMART IRB Agreement, thus avoiding the need for protracted negotiations about reliance details. [xx] IRB has agreed to serve as Reviewing IRB, and the following Relying Institutions, have agreed to cede review as noted in the letters of support: [list of sites]

[OPTION 2] To date approximately [xx] of the [xx] planned participating sites already have signed onto the SMART IRB Agreement through the joinder process. It is anticipated that all participating sites will be signatories to the SMART IRB Agreement prior to the planned award date.

[OPTION 3] [X, Y and Z] have each joined SMART IRB by signing a Joinder Agreement to the master SMART IRB Agreement. Use of the SMART IRB Agreement helps reduce the need to negotiate between institutions about reliance details. The other participating institutions have been contacted with a request to join SMART IRB as we await notice of award.

The sites have agreed that IRB review, regulatory oversight, and roles and responsibilities of the parties will be governed by the SMART IRB Agreement and [the SMART IRB Standard Operating Procedures or identify other standard operating procedures that will be followed] throughout the life of the project.

In joining SMART IRB, each site has designated a Point of Contact (POC) to provide the Reviewing IRB with knowledge about local context and facilitate coordination among the sites.

In accordance with the SMART IRB Agreement and SOPs:

www.smartirb.org

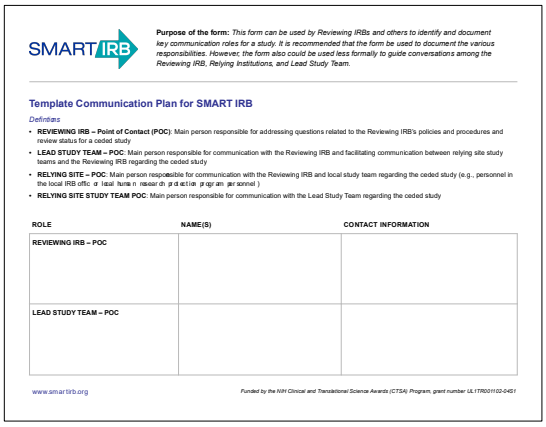
Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

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

Purpose of the form: *This form can be used by Reviewing IRBs and others to identify and document key communication roles for a study. It is recommended that the form be used to document the various responsibilities. However, the form also could be used less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team.*

Template Communication Plan for SMART IRB

Definitions

- **REVIEWING IRB – Point of Contact (POC)**: Main person responsible for addressing questions related to the Reviewing IRB's policies and procedures and review status for a ceded study
- **LEAD STUDY TEAM – POC**: Main person responsible for communication with the Reviewing IRB and facilitating communication between relying site study teams and the Reviewing IRB regarding the ceded study
- **RELYING SITE – POC**: Main person responsible for communication with the Reviewing IRB and local study team regarding the ceded study (e.g., personnel in the local IRB office or local human research protection program personnel)
- **RELYING SITE STUDY TEAM POC**: Main person responsible for communication with the Lead Study Team regarding the ceded study

ROLE	NAME(S)	CONTACT INFORMATION
REVIEWING IRB – POC		
LEAD STUDY TEAM – POC		

www.smartirb.org

Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR001102-04S1

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SMART IRB Online Reliance System

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

https://smartirb.org/reliance/

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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

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Discussion and Questions

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PI Perspectives

- ***Pooja Khatri, MD, MSc; University of Cincinnati***
- ***James Cnota, MD; Cincinnati Children's***

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IRB Perspectives

- ***Mike Linke, PhD; University of Cincinnati***
- ***Jeremy Corsmo, MPH; Cincinnati Children's***

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Questions

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

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