SMART TALK
A Community Forum to Explore Issues Surrounding Single IRB Review

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number 3UL1TR002541-01S1.
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

Open and free to anyone with interest
Upcoming sessions

June: Practical Issues and Pragmatic Solutions for the IRB Reliance Process

July: Single IRB and the Review of Research Involving Children

Future: NIH’s Approach to the Implementation of the NIH Single IRB policy
Key SMART IRB Resources at SMARTIRB.ORG

- Master Reliance Agreement
- Implementation Checklist for use of the SMART IRB Agreement
- Online Reliance System (Helps investigators and institutions request, track, and document reliance arrangements for each study)
- SMART IRB SOP Manual
- Communication Plan for Single IRB Review
- Reviewing IRB Instructions for Relying Institution Point(s) of Contact
- Reviewing IRB Instructions for Relying Site Study Teams
- FAQs for Research Teams - Relying on an External IRB
- Overall PI (and Lead Study Team) Checklist
- Relying Site Investigator Checklist
- Grant Applications: Template Description of SMART IRB
- Local Considerations: Institutional Profile
- Local Considerations: Protocol-specific Document
Join us for the next SMART Talk
June 17, 2020
2:00-3:30 pm EDT

Practical Issues and Pragmatic Solutions for the IRB Reliance Process

Questions?
Contact
help@smartirb.org

Register at smartirb.org
Sign up for our mailing list to be notified of future offerings
Roadmap to Single IRB Review

Training & Education Resources for Investigators and their Study Teams

Nichelle Cobb
University of Wisconsin-Madison & SMART IRB Director of Operations

Kathy Lawry
SMART IRB Ambassador
Senior Consultant, AAHRPP
What We Will Cover

- Overview of training topics and SMART IRB training resources
- Strategies for study team training and education
- Additional information for Overall Principal Investigators (PIs) and Lead Study Teams
Approach to Study Team Training

Should be on-demand, available when they need it

Should be targeted and practical
New SMART IRB Resource

Learning Center
for Investigators and Study Teams

The videos and companion resources below are designed to help investigators and study teams successfully plan for and navigate single IRB review arrangements for their studies. Questions about local processes and policies are best addressed by your institution’s SMART IRB Point of Contact.

- Introduction to Single IRB Review and SMART IRB
- Overview of the NIH Single IRB Policy
- Selecting a Single IRB
- Developing a Single IRB Plan
- Potential Effects of NIH Single IRB Policy on Research Costs
- Study Team Roles Related to Single IRB
- Using the SMART IRB Online Reliance System

On-demand, short videos and key resources aid in planning and implementation of single IRB arrangements.

https://smartirb.org/study-teams/
Introduction to Single IRB Review and SMART IRB

• What single IRB is with a brief history of policies & regulations
• Roles related to single IRB
• Why reliance agreements are needed/required
• What SMART IRB is and is not
• Using the SMART IRB agreement
Overview of the NIH Single IRB Policy

- Describes the NIH policy, when the policy does and does not apply
- Policy effective dates
- Differences between NIH policy and the Common Rule
Selecting a Single IRB

- Discusses who selects the single IRB when a specific IRB is not required
- Shows a tool to identify institutions who have joined SMART IRB and how to find the institution’s SMART IRB Point of Contact
Developing a Single IRB Plan

- Describes the NIH single IRB plan requirement
- Discusses the need to determine which sites need a reliance agreement (i.e., are engaged in human subjects research)
- Explains the exceptions to the NIH policy that might need to be addressed in the single IRB plan
- Addresses how to leverage the SMART IRB Agreement for grants
Potential Effects of NIH Single IRB Policy on Research Costs

• Explains the potential need for study teams to address IRB fees for NIH-funded research, variation in what IRBs charge and how fees are assessed (i.e., direct vs. indirect costs)

• Discusses staffing needs due to new roles for managing communication between sites and with the IRB as well as new resource requirements (e.g., systems to store and share documents related to IRB review)

• Describes how SMART IRB can help
Study Team Roles Related to Single IRB

• Explains key study team roles and responsibilities that are a result of change in communication model between study teams and IRBs
  – Overall PI and Lead Study Team
  – Site Investigators and Relying Site Study Teams
• Describes the need for communication points of contact and who they are and a SMART IRB resource for documenting communication roles (Communication Plan)
• Identifies where Study Teams can find other SMART IRB resources, such as FAQs for relying on an external IRB, investigator checklists
Customizing the Training

SMART IRB

Supporting single IRB review
Advancing collaborative research

SMART IRB is a platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH Single IRB Review policy (effective date: January 25, 2018). Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation, regardless of funding status.

NIH Proposed Revisions to the SMART IRB Agreement

Review the NIH’s proposed revisions and provide feedback.
The videos and companion resources below are designed to help IRB and HRPP administrators and staff successfully manage single IRB arrangements.

- Implementing the SMART IRB Agreement
- Serving as a Reviewing IRB
- Responsibilities of Relying Institutions
- Online Reliance System Walkthrough
- Getting Started with SMART IRB and the Online Reliance System
- SMART IRB Resources for IRB and HRPP Personnel
- SMART Talk Monthly Community Forum
- Training for Investigators and Study Teams
Training for Investigators and Study Teams

Use this suite of training videos and resources as is, or customize to reflect local processes and policies.

Visit the Investigator and Study Team Learning Center to view available materials; send investigators here for self-guided learning.

- Download presentations (no audio) to use for local training sessions or customize to reflect local processes.

To download the presentations with embedded audio, please use the links below:

- Developing a Single IRB Plan
- Overview of the NIH Single IRB Policy for Researchers
- Potential Effects of Single IRB on Research Costs
- Selecting a Single IRB
- Single IRB review and SMART IRB
- Study Team Roles Related to Single IRB
## 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.

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<th>When to use? When you are...</th>
<th>What?</th>
<th>Why?</th>
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<td>Identifying a Reviewing IRB and requesting a reliance arrangement</td>
<td><strong>FAQs for Research Teams - Relying on an External IRB</strong></td>
<td>Helpful hints for when your institution relies on an external IRB.</td>
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<td>Understanding study team responsibilities related to Single IRB</td>
<td><strong>Overall PI (and Lead Study Team) Checklist</strong></td>
<td>Helps an Overall PI (and Lead Study Team, where applicable) understand and fulfill their responsibilities under single IRB review.</td>
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<td><strong>Relying Site Investigator Checklist</strong></td>
<td>Helps site investigators and study teams understand and fulfill their responsibilities when a study has been ceded to an external institution.</td>
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<td><strong>Communication Plan for Single IRB Review</strong></td>
<td>Helps IRBs, relying institutions, and study teams identify and assign key communication responsibilities for studies using a Single IRB.</td>
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<td>Requesting and tracking single IRB arrangements</td>
<td><strong>SMART IRB Online Reliance System</strong></td>
<td>Allows study teams to work with their home institutions to propose a Single IRB arrangement.</td>
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<td>Collecting and providing information for IRB review</td>
<td><strong>Relying Site Study Team Survey</strong></td>
<td>The Overall PI/Lead Study Team may use this tool to obtain key information from relying site teams and determine whether particular regulatory or institutional requirements should be communicated to the Reviewing IRB.</td>
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<td><strong>Informed Consent Documents; Inserting Local Context Language</strong></td>
<td>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.</td>
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Learn more by watching the videos in the [SMART IRB Learning Center](https://www.smartirb.org).
Addressing the Changes in Roles & Responsibilities and the need for a new Communication Model

• SMART IRB developed resources to recognize and facilitate this change
  – Communication plan for single IRB review
  – Checklists for Lead Investigators and study teams
  – Checklists and FAQs for Investigators Relying on an External IRB
  – Survey of the Relying Site team and the Informed Consent Document Inserting Local Context Language
Communication plan for single IRB review

Document key communication roles, e.g., submitting initial and continuing reviews, amendments, and reportable events; providing conflict of interest management plans; and providing IRB-approved documents and communicating Reviewing IRB determinations.

### 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.

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<tr>
<th>ROLE</th>
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<td>REVIEWING IRB – POC</td>
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*www.smartirb.org*

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

Overall PI (and Lead Study Team) Checklist: Helps Overall PIs (and Lead Study Teams) understand and fulfill their responsibilities.

Relying Institution PI Checklist: Helps site investigators and study teams understand and fulfill their responsibilities when a study has been ceded to an external IRB.

Purpose of form: The Home Institution for the Overall Principal Investigator and/or Lead Study Team can use this form to provide them with guidance regarding the additional responsibilities accrued in assuming that role, particularly when the SMART IRB Standard Operation Procedures are followed. Language in this document should be adapted to reflect local processes.

Overall Principal Investigator/Lead Study Team Guidance and Checklist

As the Overall Principal Investigator for a study overseen by a single IRB for all or most sites, you should review this guidance to make sure you have agreed to collaborate with investigators from other institutions as follows:

You should contact the IRB administration at your institution to:
- Discuss whether your home institution will participate in this study or whether another external IRB will do so (both). The Lead Study Team should be involved in this discussion.
- Provide them with details about the study protocol and template consent document(s), which will help them understand the nature of the study.
- Identify all sites that will be participating in this study or whether another external IRB would be appropriate.
- If your institution agrees to single IRB oversight, you will need to ensure the Lead Study Team:
  - Provides a reliance request to the Overall PI's home institution using the process required by that institution.
  - Provides participating Relying Site Study Teams with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).
  - Participates in conference calls regarding a study as requested.
  - Provides the Site Investigators with the names and roles of all key study personnel on the local study team.
  - Provides participating Relying Site Study Teams with the names and roles of all key study personnel on the local study team.
  - Prepare and submit IRB application updates, local reportable events, and updates.
  - As part of preparing the IRB application, the Lead Study Team (or designee) must:
    - Have a mechanism in place to obtain and collate information from Relying Site Study Teams.
    - Work with the Lead Study Team and the IRB/HRPP POC from your institution to incorporate locally required language into the consent template to be used by the local study team, such as institutionally required material transfer agreements, ancillary committee reviews (e.g., radiology, nursing, and pharmacy).

Purpose of form: Relying institutions can use this form to provide their local study teams with guidance regarding the investigator's responsibilities when a study is under the oversight of an IRB external to their institution, particularly when the SMART IRB Standard Operation Procedures are followed. Language in this document should be adapted to reflect local processes.

Relying Investigator Guidance and Checklist

As Principal Investigator at the Relying Institution for a study that may be overseen by an external IRB, you should be aware of your responsibilities. Once you have agreed to collaborate with an investigator at another institution and intend to use an external IRB for oversight of this study:

You should contact the IRB administration or relevant Human Research Protection Program (HRPP) personnel at your institution to:
- Discuss whether ceding IRB oversight to an external IRB is appropriate.
- Provide them with details about the study (including your study team's role), the proposed reviewing IRB, and the lead investigator's name and institution.
- Obtain a copy of the studywide protocol and template consent document(s), which will help facilitate the discussion with your local IRB/HRPP.
- If your institution agrees to cede review to an external IRB, you will be asked to provide the IRB administration or relevant HRPP personnel at your institution with:
  - The names and roles of all key study personnel on the local study team.
  - Any management plans for potential conflicts of interest (COI) relevant to the study that will be overseen by the external IRB, including any new or altered management plans put in place throughout the lifespan of the study.
- Register the study at your institution according to local processes, such as creating a shell study in the local electronic system and uploading documents received.
- Promptly respond to questions or requests for information from the Lead Study Team (or their designee) as well as from the Reviewing IRB.
- Participate, as required, in conference calls regarding a study as requested by the Lead Study Team, Reviewing IRB, or your local IRB/HRPP.
- Become familiar with the reportable event policy of the Reviewing IRB to ensure that you appropriately report protocol deviations, noncompliance, significant subject complaints, subject injuries, unanticipated problems, or other events required by the Reviewing IRB to be reported and within the timeframes required.
- Ensure all local reviews and sign-offs that, in addition to IRB approval, are in place before a study is activated, such as coverage analysis, department approvals, data use agreements, material transfer agreements, ancillary committee reviews (e.g., radiology, nursing, and pharmacy).

Purpose of form: The Home Institution for the Overall Principal Investigator and/or Lead Study Team can use this form to provide them with guidance regarding the additional responsibilities accrued in assuming that role, particularly when the SMART IRB Standard Operation Procedures are followed. Language in this document should be adapted to reflect local processes.

For externally funded studies, provide your sponsored programs office with documentation that IRB oversight for a study has been ceded to and approved by an external IRB.

Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR001102-04S1
FAQs for Research Teams - Relying on an External IRB: Provides helpful hints for study teams whose institutions have agreed to rely on an external IRB.

Also available in a customizable Word Template: Institutions may use this template to create institution-specific guidance for study teams whose research study is ceded to an external IRB.
Information for IRB Review

Relying Study Team Survey: This survey template allows the Overall Principal Investigator/Lead Study Team to obtain information from the relying site study team to determine whether particular regulatory or institutional requirements should be communicated to the Reviewing IRB.
Informed Consent Form Documents: Inserting Local Context Language

Provides guidance to IRB’s, relying institutions, and study teams regarding the different roles that may be involved in inserting local context language in informed consent documents.
Roadmap to Single IRB Review

Training & Education Resources for Investigators and their Study Teams

• Carey Gorden, MetroHealth
• Sarah Mumford, University of Utah
• Ada Sue Selwitz, University of Kentucky & SMART IRB Ambassador
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Practical Issues and
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