Single IRB Boot Camp:
A How-to Guide with SMART IRB

Day 2 - February 10, 2022

Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number 3 UL1 TR002541-04S2

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Welcome and Overview
Welcome!

You will gain a better understanding of:

- The single IRB (sIRB) review model and its impacts on IRBs/HRPPs, institutions, and investigators
- The SMART IRB platform and how it supports the implementation of sIRB review across the nation
- What HRPPs need in place for single IRB review
- Training and Preparing Study Teams for sIRB Review
- How and when to leverage SMART IRB resources & tools
Logistics

Please provide feedback by completing the survey - a link will be emailed following the session.

Presentation slides & recording will be posted on the SMART IRB website.

If you have any questions for the panelists, please use the Q&A function to submit them.
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<td>Barbara Bierer</td>
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Onward!
Smart IRB Bootcamp
Single IRB: Communication!!!
Communication!!! Communication!!!

Stacey C. Goretzka, CIP
IRB Manager, Medical University of South Carolina; SMART IRB Ambassador

Ada Sue Selwitz, MA
Executive Integrity/Compliance Advisor, Center for Clinical and Translational Science (CCTS), University of Kentucky; SMART IRB Ambassador
Acknowledgements

• Nichelle Cobb, Association for the Accreditation of Human Research Protection Programs
• John Heldens, University of Colorado-Denver
• Jennifer Hill, University of Kentucky
• Carissa Minder, Washington University-St. Louis
What we will discuss in this session

- Who are the key players in a Communication Plan?
- What are examples of Communication Models (Flow of communication)
- Who communicates what (Responsibilities)
- What to do when there are disagreements or miscommunications (Challenge)
Key Players

• Lead Institution
• Reviewing IRB
• Lead/Overall PI
• Relying PI
• Relying Institution

*Other players: Funding/Regulatory Agency or Coordinating Center, etc.
Two Popular Communication Models

• Lead PI Communication Model: All Study team information flows to the Reviewing IRB through the Lead/Overall PI; Relying PIs send information to Lead PI

• Relying PI Communication Model: Relying PIs work directly with Reviewing IRB and copy Lead/Overall PI

• Smart IRB Agreement allows either model, but the Smart IRB Resource documents are usually based on the Lead PI Communication Model
Lead PI Model (2 of 3)
Lead PI Model (3 of 3)
Relying PI Model (1 of 3)
Relying PI Model (2 of 3)
Relying PI Model (3 of 3)
Hint: Critical that you know what type of communication model will be used

- **Challenge:** The agreement may not specify type of flow. What do you do in that case?

- **Challenge:** The Reviewing IRB may not communicate their expectations for communication! What do you do in that case?
What do you do?

• If Relying (Institution or PI), ask the Reviewing IRB!

• If Reviewing IRB, work it out!
  – Have a mechanism in place
  – Be clear on expectations and communication flow
  – Be flexible

• To assist in developing communication plan, use Smart IRB Resources (e.g., Implementation Plan, Template Communication Plan, Overall and Relying Site PI Checklists)
• The basic communication responsibilities for single IRB are very similar to standard IRB practices.
• However, which Key Player is responsible depends upon the Communication Model being used.
• Reviewing IRB policies and Procedures
• Communication Plan (identifying flow of communication)
• Implementation Plan (confirming who does what regarding any standard issues not outlined specifically in the agreement such as HIPAA review etc.)
• Request for Local Context/Consideration Information (e.g., applicable state or local laws, regulations institutional policies, local factors)
• Request for Select Ancillary Reviews such as Conflict of Interest Management Plan
• Approved Consent Template including site-specific information/identified in customizable sections of the consent form such as compensation for research related injury, payment of research costs, local contact information

• Request documentation or Assurances for research personnel education, training, & qualifications
• IRB Determinations, Review Decisions for all types of review (initial, continuing, amendment etc.), Lapses of Approval and Applicable Corrective Action Plans
• IRB Findings and Actions related to reportable issues (e.g., unanticipated problems, serious or continuing noncompliance, suspension or termination, significant subject complaints, subject injuries, unanticipated problems involving risks to subjects or others, reports to federal, state or funding agencies)
RELYING INSTITUTION Communication Responsibilities:

Provide

• To Local Relying PI/Study Team
  – Relying Institution policies and procedures regarding use of an external IRB and the relying institution’s expectations for communication with them and with the reviewing IRB

• To Reviewing IRB promptly respond to requests for the following:
  – Local Context/Consideration Information such as state and local laws and regulations, institutional policies, local factors)
  – Consent Form with customized site-specific information addressed
  – If separate HIPAA authorization form is used, provide site-specific authorization language
  – Request for Ancillary Review information such as Conflict of Interest Management Plan
  – Documentation or Assurances for research personnel education, training, & qualifications
  – Ensures the Relying Study Team notifies the Reviewing IRB of unanticipated problems, potential noncompliance, suspension or restriction, significant subject complaints
• Contact their local Human Research Protection Program to identify local policies for single IRB
  – Provide home institution information required by its policies and procedures (including back and forth communication regarding selection of reviewing IRB)

• Communicate with Reviewing IRB to determine and document specific roles and responsibilities for communicating and coordinating key information to Relying Institutions & Relying PIs
  – Develop plan for communicating with Relying PIs and with the Reviewing IRB across lifetime of study (e.g., regular conference calls, site initiation procedures, training materials, etc.)
• Promptly respond to questions from Relying PI teams and Relying Institution HRPP staff

• Provides Relying Study Team with Reviewing IRB policies and procedures and the IRB determinations/actions for life of protocol (e.g., IRB approved versions of all study documents consent, authorization forms, protocol, recruitment, amendments, reports on unanticipated problems, serious or continuing noncompliance, subject complaints)

• Provides the Reviewing IRB with all required submissions (e.g., initial review, local context information for each site, local amendments, personnel updates, local reportable events, study wide information for continuing review and amendments)
  – Lead Study team should have mechanism for obtaining and collating information from Participation Site and/or Relying Site POC
• Contact their local Human Research Protection Program (HRPP) to identify local policies for single IRB
  – Provide home institution information required by its policies and procedures (including back and forth communication regarding selection of Reviewing IRB and requirements during life of study)
• Provide management plans for relevant HRPP personnel
• Collaborate with local HRPP personnel in identifying local context issues specific to the protocol and incorporate local required language into the consent template
Provide local reviews and signoffs such as coverage analysis, department approvals, data use agreements, material transfer agreement, ancillary committee reviews.

Promptly respond to questions from Lead/Overall PI Study Team and local Relying HRPP* personnel.

Provide Lead/Overall PI Study Team with all required submissions (e.g., local considerations, initial review, personnel updates, local reportable events, subject complaints, site continuing review request, etc. and any other issues required by Lead PI who will be forwarding on to the Reviewing IRB.)

If the institution does not have any assigned HRPP/IRB Reliance staff, then the Relying PI will have increased responsibilities for communication.
Smart IRB Resources for Lead/Overall PI & Relying PI and Study Team

- Overall Principal Investigator/Lead Study Team Guidance and Checklist
  https://smartirb.org/assets/files/PI_checklist.pdf

- Relying Site Investigator Guidance and Checklist
  https://smartirb.org/assets/files/Relying_institution_checklist.pdf

- Potential Relying Site Study Team Survey document
  https://smartirb.org/assets/files/Relying-Site-Team-Survey.pdf
Smart IRB Resources for all Key Players

- [https://smartirb.org/resources/](https://smartirb.org/resources/)
- [Implementation Checklist (pdf)](https://smartirb.org/resources/)
- [Communication Plan for Single IRB Review (pdf)](https://smartirb.org/resources/)
SMART IRB Agreement Implementation Checklist and Documentation Tool

**Purpose:** (1) to highlight the flexible provisions of the SMART IRB Agreement, and (2) to document which options institutions will implement as part of the Ceded Review. Some of the information documented in this form applies to IRB review while other determinations are at an institution-level.

While use of this tool is not required, Participating Institutions should document the selected options for each study in which they are involved. Both the Reviewing IRB and Relaying Institutions should maintain a copy of the completed tool or alternative documentation for a study (e.g., a standard operating procedure) that is covered by the SMART IRB Agreement.

**Instructions:**
1. The Reviewing IRB should complete the study-specific information in the box at the top of this page. Add, delete, or modify fields as needed. The Reviewing IRB can share this document with the proposed Relaying Institutions and discuss any points of disagreement, updating this form as necessary.
   a. To apply the same options to all studies involving the same Reviewing IRB and Relaying Institution(s), indicate “All” in the fields Institutions deem applicable; in that case, only one tool needs to be completed for the included studies.
   b. Additional notations can be included to clarify unique situations as long as they do not contradict the terms of the SMART IRB Agreement. For example, if IRB fees will only be assessed for some studies, this limitation could be noted in that section. If this document is used, it should be distributed by the Reviewing IRB Point of Contact (POC) to Relaying Institution POCs and maintained on file for each study.
2. For each provision identified below, Reviewing IRB POCs should work with relevant individuals at their institutions to identify and record the appropriate option and any sub-options as agreed upon by the involved institutions.
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.

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

### Communication Plan

<table>
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<tr>
<th>COMMUNICATION RESPONSIBILITY</th>
<th>RESPONSIBLE PARTY</th>
<th>NOTES</th>
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<tr>
<td><strong>COI:</strong> Providing applicable conflict of interest management plans for relying site study teams to the Reviewing IRB</td>
<td>Reviewing IRB, Lead Study Team, Relying Site Study Team(s), Relying Site(s) POC(s), Other, specify:</td>
<td></td>
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<td><strong>STUDY TEAM TRAINING &amp; QUALIFICATIONS:</strong> Providing confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research</td>
<td>Reviewing IRB, Lead Study Team, Relying Site Study Team(s), Relying Site(s) POC(s), Other, specify:</td>
<td></td>
</tr>
<tr>
<td><strong>LOCAL CONTEXT INFORMATION:</strong> Providing local context information to the Reviewing IRB regarding state laws and institutional requirements that pertain to the review of the ceded study</td>
<td>Reviewing IRB, Lead Study Team, Relying Site Study Team(s), Relying Site(s) POC(s), Other, specify:</td>
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<td><strong>IRB APPLICATION – STUDYWIDE:</strong> Preparing and submitting the studywide application for initial IRB review and studywide amendments to the Reviewing IRB</td>
<td>Reviewing IRB, Lead Study Team, Relying Site Study Team(s), Relying Site(s) POC(s)</td>
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Example
Communicating
Conflict of Interest
Determine who will perform the conflict of interest analysis

Relying Institution?

Reviewing IRB?
### Implementation Checklist

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<td>5.</td>
<td>Conflicts of Interest</td>
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<td></td>
<td><strong>OPTION 1 – Relying Institution(s) will perform conflict of interest analyses under their policies</strong>&lt;br&gt;The Relying Institution(s) will perform their own analyses under their relevant policy(ies) with respect to disclosure and management of their Research Personnel’s conflicts of interest in connection with the identified study(ies). The Relying Institution’s(s’) resulting determinations, prohibitions, management plans, and any updates will be provided to the Reviewing IRB. Note that the Reviewing IRB has the right to impose additional prohibitions or conflict management requirements.</td>
</tr>
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<td><strong>OPTION 2 – Reviewing IRB will perform conflict of interest analyses under its policies</strong>&lt;br&gt;The Reviewing IRB will apply its institution’s own policies with respect to disclosure and management of the Relying Institution’s(s’) Research Personnel’s conflicts of interest in connection with the identified study(ies). The Reviewing IRB will notify the Relying Institution(s) of the IRB’s resulting determinations, prohibitions, management plans, and any changes thereto. Note that the Relying Institution(s) may propose additional prohibitions or conflict management requirements to the Reviewing IRB for approval.</td>
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<td></td>
<td><strong>OPTION 3 – Relying Institution(s) and Reviewing IRB have agreed on an alternate plan for conflict of interest analyses</strong>&lt;br&gt;[DESCRIBE THE ALTERNATE PLAN]</td>
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# Communication Plan

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Relying Institution Responsibilities for Conflict of Interest

- The relying institution communicates their COI process to the relying site PI.
- The relying institution performs the COI analysis under their policies.
- The relying institution communicates the COI management plan to the relying site PI.
How does the Site PI’s conflict of interest management plan get communicated to the Reviewing IRB?
Reviewing IRB/Institution Responsibilities for Conflict of Interest

• The reviewing IRB communicates the process to receive information about COI and associated management plans from relying institutions.

• Examples of how reviewing IRBs collecting this information from relying sites might include the use of:
  – Local Context Forms
  – SMART IRB Protocol-Specific Document
Resource: Protocol-Specific Document

PROTOCOL-SPECIFIC DOCUMENT

To Collect Institutional Requirements from Relying Institutions

• https://smartirb.org/assets/files/Protocol-Specific-20180726.pdf
17. Did the organization determine there is a relevant individual or institutional financial conflicts of interest (COI) for this protocol?

- No
- Yes and the COI has been eliminated
- Yes and a management plan has been developed
- N/A organization does not have a COI review process

a. If yes, provide summary of conflict and management plan, or attach documentation.

b. If yes, provide the name and contact information for the appropriate POC for questions related to the determination and/or local management plan.
Lead PI Responsibilities for Conflict of Interest

• Using the example of the Lead PI Communication Model, the Lead PI:
  – Communication to the relying sites how the reviewing IRB will receive information regarding COI.
  – Communicates COI information from relying sites to the reviewing IRB.
• Reviews conflict of interest management plan from relying institution.

• If additional changes or strategies are needed, reviewing IRB communicates according to original plan established for communication.

  – Note! In the earlier example using the “Protocol Specific Document” to collect COI information, there is a designated area to provide the contact information for POC at the relying institution.
Conflict of Interest - Lead PI Model

Relying Site PI

Relying Institution

Lead Site PI

Reviewing

Institutional Review Board
• SMART IRB Harmonization Document
  – Conflict of Interest Review Process for sIRB Review (pdf)
https://smartirb.org/harmonization/

Harmonized Documents

**Recommendations for the Harmonization of Ancillary Reviews (NEW!)**
Best practices for defining ancillary reviews and recommendations for centralizing certain reviews as well as for the timing of reviews and allocation of responsibilities in an sIRB context. Zip file includes guidance as well as an implementation checklist for centralizing ancillary reviews.

**Conflict of Interest Review Processes for sIRB Review**
Guidance addresses the responsibilities of a Relying Institution and a Reviewing IRB/Reviewing IRB Institution in the COI review process, including specific guidance to assist in determining and managing COI, as well as answers to FAQs.

**Post-Approval Auditing for Studies Subject to Single IRB Review**
Identifies best practices and provides tools to support for-cause and not-for-cause audits of studies under a single IRB arrangement. Zip file includes guidance as well as checklists and a template report.
Communicate Early and Often!

Things have to be very clear from the beginning.

Tip
- Use and understand the agreement
- Use the implementation checklist
- Use the template communication plan
What to do when there are disagreements or miscommunications
He said / She Said - A Case Example

(1 of 2)

- Reviewing IRB sends out a template consent form with sections marked for site specific language.

- Relying Site Investigator sends back to the Reviewing IRB a consent form with lots and lots of changes and says her IRB requires all this. But the local context form submitted from the Relying Institution doesn’t mention it.....

What should the Reviewing IRB do?
What should Reviewing IRB do?

- Assume the PI is right?
  - Be confused?
  - Get mad?
  - Waste time wondering?
  - Read their minds?
- Shoot off an email or call the Relying Institution/IRB and Ask?
  - Be Calm
  - Be Flexible
  - Solve it!
Communication breakdown - A Case Example

• Early in the process the Reviewing IRB & Relying Institution agrees to pursue reliance

• Time goes by ...

• The Reviewing IRB inquires with the Lead PI if he has heard anything

• Lead PI contacts the Relying PI

• Relying PI produces a letter from 6 months prior from the Relying Institution indicating they have agreed to rely

• Nothing was documented between the Reviewing IRB and Relying Institution
Reviewing IRB Position

• Reach Out!
  – Get to the root of the issue
  – Don’t assume

• Be Flexible!
  – Can you accept something different?

• Be Nice!
  – It’s a small world

• Start and end on a positive note

John Heldens & Carissa Minder, PRIM&R AER 2019
Relying Institution Position

• Ask for options!
  – Can you provide the information another way?
  – Do we have to do reliance?

• Roll with it!
  – Sometimes, you just have to get through

• Be Nice!
  – It’s still a small world

• Start and end on a positive note

John Heldens & Carissa Minder, PRIM&R AER 2019
Pro Tips on Communication (1 of 2)

Be Willing to Talk
   To other IRBs, to PIs, to anyone.

Don’t be Shy
   Ask, Be responsive, Keep it short
Assume Good Intentions

- It’s for you, not for the other person
- Assume a friendly tone

Ask yourself, does this matter?

- Do you want to be right or do you want to be done?
- Stay flexible
Gratitude

• If you have a positive interaction with another IRB, a relying PI, anyone, let them know
• If you have a PI/Study Team that is really on top of sIRB procedures, share your appreciation
• If your IRB Chair and members have a terrific handle on sIRB, say thank you
In summary, what did we discuss today?

- Who are the key players in a Communication Plan?
- What are examples of Communication Models (Flow of Communication)
- Who communicates what (Responsibilities)
- What to do when there are disagreements or miscommunications (Challenge)
Training Study Teams

Nichelle Cobb, PhD
Senior Advisor, SMART IRB; Senior Advisor for Strategic Initiatives, Association for the Accreditation of Human Research Protection Programs (AAHRPP)

Kathy Lawry, MSSA, CIP
SMART IRB Ambassador; Senior Consultant, Association for the Accreditation of Human Research Protection Programs (AAHRPP)
What We Will Cover

- Overview the effect of single IRB on study teams and impact on training needs
- SMART IRB resources that can be leveraged to train study teams
- Strategies for study team training and education
Impact of Single IRB on the Funding Process
Funding Application Process Before the Single IRB Requirement

- Research team obtains input from budget and other fiscal experts as part of developing a funding proposal.
- Funding agency notifies institution that an award is likely and requests IRB approvals and other certifications.
- Agency releases funds upon provision of approval from prime awardee.

The institution’s sponsored programs office submits the proposal to the funding agency.

Prime awardee and subawardees each obtain IRB approval for the study.
Research team obtains input from budget and other fiscal experts as part of developing a funding proposal.

Funding application attests single IRB policy will be followed and includes budget for any IRB fees.

Funding agency notifies institution that an award is likely and requests single IRB approval and other certifications.

Agency releases funds upon provision of single IRB approval.

Contacts the IRB/HRPP office to select a Reviewing IRB, obtain a letter of support and input on budget.

The institution’s sponsored programs office submits the proposal to the funding agency.

Single IRB approves study for prime awardee and subawardees.
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Although NIH no longer requires the single IRB to be identified in the grant application, we recommend ensuring who will act as the Reviewing IRB is known before a grant application is submitted because of the potential effect on budget and to eliminate delays.
Resource: Grant Application Language

Grant Applications: Template Description of SMART IRB (docx):
Provides language for researchers and their institutions to adapt for federal grant applications.

https://smartirb.org/assets/files/Template_Description_SMART_IRB_for_grant_applications.docx
SMART IRB Resource: IRB Letter of Support for Grants

IRB Support Letter Model Language (docx): Provides language for IRBs/HRPPs to provide for grants that demonstrates support for single IRB review.

https://smartirb.org/assets/files/IRB-support-letter-model-language.docx
Budgeting for Single IRB Review

**IRB Fees**

NIH Single IRB Policy now permits institutions to charge for some components of IRB review when the institution either acts as the Reviewing IRB for the study or contracts with an independent (aka commercial) IRB to serve as Reviewing IRB.

**New Staff Roles**

May need to add staff who can manage communication between IRB and study teams across participating sites, especially when serving as a Lead Study Team.

**New Resources**

May need new platforms to disseminate documents to study teams.
SMART IRB Resource for IRB Fees and Costing Models

Points to Consider: Fees and Costing Models under the NIH sIRB Policy (pdf):
Points to consider regarding charging, structuring, and justifying fees for single IRB review, as well as federal regulations on direct/indirect costs.

Resource: How to find out who has joined SMART IRB

• Visit https://smartirb.org/ to find the full list of SMART IRB Participating Institutions.
• Once an institution’s joinder is activated, they are listed on the Participating Institutions page.
Impact of Single IRB on Protocol and Consent Form Preparation & Review Process
The protocol should be written in a way that it can be utilized across all sites:

- Describe procedures in a manner that all sites can be compliant
- Give choices of procedures that yield the same outcome when possible (e.g., CT vs MRI)
- Describe sections such as AE reporting and privacy/security of data as general as possible without compromising the integrity of the protocol (e.g., AE reporting according to FDA, or data will be stored in a secure manner and password protected)
The consent document should have portions that are exactly the same for each site as well as portions that allow local language.

- Lock down study specific information and allow customization only in certain sections for local context
- Another model: a 2-part consent that is merged after review into 1 document
SMART IRB Resource: Handling Consent Forms and Local Considerations

SMART IRB Guidance: Inserting “Local Context” Language in Informed Consent Documents (pdf)

Illustrates roles the Reviewing IRB, Overall PI, Relying Site Study Team, and Relying Institution POC may play in providing information and language for local consent forms.

https://smartirb.org/assets/files/Local_Context_Language_Guidelines.pdf
Inserting “Local Context” Language in Informed Consent Documents

SMART IRB Guidance: Inserting “Local Context” Language in Informed Consent Documents

Version date: December 14, 2017

Reviewing IRB
- Approves an informed consent template, identifying specific areas that can be revised to include appropriate local context information*
- Distributes informed consent template**

Overall Principal Investigator (or designee)
- Works with the Reviewing IRB to ensure relying site study teams are aware of the process to provide local context information for the consent form

Relying Site Study Team
- Works with the Overall Principal Investigator (or designee) to:
  - Obtain a copy of the appropriate consent form template
  - Ensure they understand the sections that can be revised to reflect local context language
  - Confirm the process through which the local context language for that site should be provided to the Reviewing IRB, once approved by the relying site’s SMART IRB POC

Relying Site SMART IRB Point of Contact (POC)
- If additional areas of the consent form must be updated to reflect state law or institutional requirements, contacts Reviewing IRB to discuss inclusion

*Template areas that can be changed are usually limited to:
- Contact information for local study team
- Costs that differ for the relying site
- Relying site’s language regarding the availability of and compensation for research-related injury

**The Reviewing IRB can distribute the template to the Overall Principal Investigator (or designee) AND/OR the Relying Site SMART IRB POC.

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Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, through grant number UL1TR002541-01S1.
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Managing Roles Related to Single IRB
Understanding Study Team Roles

Overall Principal Investigator
Generally, the initiating or funding principal investigator

Lead Study Team
Designated by the Overall PI
Ensure study coordination, communication, and routing of IRB submissions (in collaboration with Reviewing IRB)

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 Overall PI Responsibilities

Assumes leadership and has ultimate responsibility for conduct of the research study

Designates a Lead Study Team*
(can be a coordinating center)

*The Lead Study Team is often (but not always) the study team at the Reviewing IRB’s institution. In collaboration with the Reviewing IRB, the Lead Study Team ensures study coordination, communication, and the routing of IRB submissions.
Common Lead Study Team Key Responsibilities

Submit 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)

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

Ensure study teams are aware of Reviewing IRB policies and procedures

Provide IRB-approved materials/determinations to all site study teams
Common Responsibilities for Site PIs & Relying Site Study Teams

<table>
<thead>
<tr>
<th>Follow</th>
<th>Provide</th>
<th>Use</th>
<th>Obtain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow the policies and procedures of the Reviewing IRB (e.g., for reportable events, personnel changes)</td>
<td>Provide 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</td>
<td>Use the Reviewing IRB’s consent form template (excepting limited local language that can be added/changed)</td>
<td>Obtain authorization from their SMART IRB POCs in the case of personnel changes, COI updates, and/or changes that may be affected by State law or institutional requirements</td>
</tr>
</tbody>
</table>

*If the Lead Study Team is from an institution other than the Reviewing IRB Institution, the roles and responsibilities of the “Relying Site Study Team” also apply to the study team at the Reviewing IRB’s institution.*
Developing a Communication Plan

Extremely important to keep communications organized and consistent

Assign a Point of Contact (POC) for each group
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
SMART IRB Resource: 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.

Download the Communication Plan (pdf)

Download the Communication Plan (customizable Word document)

https://smartirb.org/assets/files/Communications_Plan_Form.pdf
Ongoing/Other Study Team Responsibilities
Institutional Requirements

Helping study teams understand and meet institutional requirements for study activation, such as:

- Ancillary committee approvals
- Expectations for any local reporting (e.g., reportable events)
Post-Reliance Requirements

Helping study teams understand:

What to report to the Reviewing IRB and adhering to the Reviewing IRB’s policies, such as for:

- Reportable events
- Personnel updates

What information to provide to the Reviewing IRB, such as:

- Site-specific amendments
- Continuing review (or providing information to a lead study team for the continuing review)
- Reportable events
Training Resources
Approach to Study Team Training

Should be on-demand, available when they need it

Should be targeted and practical
SMART IRB Resources for Study Teams

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

https://smartirb.org/study-teams/
Customizing the Training: Go to smartirb.org
Learning Center
for IRB and HRPP Administrators

The videos and companion resources below are designed to help IRB and HRPP administrators and staff successfully manage single IRB arrangements. Each 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 Packages

These packages contain a suite of resources to help you understand and fulfill your roles and responsibilities in a single IRB arrangement. Each package provides a guide describing how and when to use the included resource as well as links to online tools and further information.

See also: Start-up Packages for Study Teams.
Learning Center for IRB and HRPP Administrators

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See also: Start-up Packages for 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 training.

- 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.

<table>
<thead>
<tr>
<th>When to use? When you are...</th>
<th>What?</th>
<th>Why?</th>
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</thead>
<tbody>
<tr>
<td>Identifying a reviewing IRB and requesting a reliance arrangement</td>
<td>FAQs for Research Teams - Relying on an External IRB</td>
<td>Helpful hints when your institution relies on an external IRB.</td>
</tr>
<tr>
<td>Understanding study team responsibilities related to Single IRB</td>
<td>Overall PI (and Lead Study Team) Checklist</td>
<td>Helps an Overall PI (and Lead Study Team, where applicable) understand and fulfill their responsibilities under single IRB review.</td>
</tr>
<tr>
<td></td>
<td>Relaying Site Investigator Checklist</td>
<td>Helps site investigators and study teams understand and fulfill their responsibilities when a study has been ceded to an external institution.</td>
</tr>
<tr>
<td></td>
<td>Communication Plan for Single IRB Review</td>
<td>Helps IRBs, relying institutions, and study teams identify and assign key communication responsibilities for studies using a Single IRB.</td>
</tr>
<tr>
<td>Requesting and tracking single IRB arrangements</td>
<td>SMART IRB Online Reliance System</td>
<td>Allows study teams to work with their home institutions to propose a Single IRB arrangement.</td>
</tr>
<tr>
<td>Collecting and providing information for IRB review</td>
<td>Relaying Site Study Team Survey</td>
<td>The Overall PI/Lead Study Team may use this tool to obtain key information from relaying site study teams and determine whether particular regulatory or institutional requirements should be communicated to the Reviewing IRB.</td>
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<tr>
<td></td>
<td>Informed Consent Documents: Inserting Local Context Language</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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</table>

Learn more by watching the videos in the SMART IRB Learning Center.
SMART IRB Resource: Investigator Checklists

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

https://smartirb.org/assets/files/PI_checklist.pdf

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

https://smartirb.org/assets/files/Relying_institution_checklist.pdf
SMART IRB Resource: FAQs for Research Teams

FAQs for Research Teams - Relying on an External IRB (pdf): Provides helpful hints for study teams whose institutions have agreed to rely on an external IRB.

https://smartirb.org/assets/files/Relying_on_an_External_IRB_FAQs_for_Study_Teams.pdf

Customizable FAQ Template:
Institutions may download the FAQs for Research Teams Relying on an External IRB (docx) to create institution-specific guidance.
Questions
Goals of Single IRB Review

• NIH Single IRB policy
  – “enhance and streamline the IRB review process in the context of multi-site research so that research can proceed as effectively and expeditiously as possible.”

• Common Rule
  – “Mandated single IRB review would ultimately decrease administrative burdens and inefficiencies for investigators and institutions.”
Feedback from Investigators, Study teams & HRPPs

Challenges Encountered

- Differences across sites with sIRB makes things difficult
- Lack of harmonization at Relying Institutions
- Institutions only use SMART IRB Online Reliance System (ORS) for certain types of studies
- Not all sites use the ORS
- Institutions require significant/lengthy dual review
Harmonization

Harmonization Steering Committee (HSC)

• To promote a more strategic, effective, efficient and cooperative approach to policies, processes and procedures related to single IRB review of multisite studies

Co-chairs:
Barbara E. Bierer, MD
Director of Regulatory Policy, SMART IRB

Valery Gordon, PhD, MPH
Division of Clinical Innovation, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health

The HSC and its working groups follow an iterative development cycle guided by content experts, and responsive to public review and comment.
HSC: Iterative development cycle

**Finalized:**
- Institutional Profile
- Protocol-specific Document
- Fees & Costing Models Guidance
- Institution v. IRB Responsibilities Guidance
- Reportable Events
- Single IRB Review: Responsibilities Associated with the Review of Study Personnel
- Conflict of Interest Review
- Post-approval Auditing
- Single IRB Continuing Review Process
- Ancillary Reviews Harmonization

**In Progress:**
- Local Context

**Subcommittees’ focus:**
- Through “Emerging Issues Workshop” to HSC for selection
  https://smartirb.org/harmonization/
Harmonization Guidance:
https://smartirb.org/harmonization/

• Delineates Relying Institution and Reviewing IRB responsibilities for sIRB research
• Provides templates, checklists and forms to be edited and implemented locally
Harmonization Guidance: Post-Approval Auditing

As institutions apply diverse approaches to implementing single IRB review, new burdens and challenges emerge for investigators, collaborating institutions, and IRBs. One of the goals of SMART IRB is to harmonize these diverse approaches by promoting not only the alignment of policies and processes, but also the adoption of common terms and identification of common practices and workflows.

Harmonized Documents

Recommendations for the Harmonization of Ancillary Reviews
Best practices for defining ancillary reviews and recommendations for centralizing certain reviews as well as for the timing of reviews and allocation of responsibilities in an sIRB context. Zip file includes guidance as well as an implementation checklist for centralizing ancillary reviews.

Conflict of Interest Review Processes for sIRB Review
Guidance addresses the responsibilities of a偏离ing institution and a Reviewing IRB/Reviewing IRB institution in the CoI review process, including specific guidance to assist in determining and managing CoI, as well as answers to FAQs.

Post-Approval Auditing for Studies Subject to Single IRB Review
Identifies best practices and provides tools to support for-cause and not-for-cause audits of studies under a single IRB arrangement. Zip file includes guidance as well as checklists and a template report.

Single IRB Continuing Review Process
Recommendations for the roles and responsibilities of Reviewing IRBs, Relying Institutions, Overall PIs, and Relying Site Investigators as they relate to the continuing review process.

Single IRB Review: Responsibilities Associated with the Review of Study Personnel
Recommendations for ensuring study personnel are appropriately trained and qualified to conduct the research under review.

Reportable Events
- Recommendations for investigator-initiated multisite studies
- Reviewing noncompliance and unanticipated problems
- Ensuring prompt reporting

https://smartirb.org/harmonization/
Checklists and Templates

SMART IRB

CHECKLISTS AND TEMPLATES

SAMPLE FOR-CAUSE AUDIT NOTIFICATION CHECKLIST
FOR USE BY THE REVIEWING IRB REQUESTING THE AUDIT

STUDY TITLE:

PRINCIPAL INVESTIGATOR:

PARTICIPATING SITE FOR AUDIT:

SITE INVESTIGATOR:

RELYING INSTITUTION POINT OF CONTACT:

SPONSOR:

Funding Sources (check all that apply):

☐ Industry Sponsor
☐ Foundation
☐ Government/Grant
☐ Other:

Type of Study:

☐ Drug/Biologic
☐ Device
☐ Tissue/Sample Repository
☐ Genetics
☐ Questionnaire
☐ Chart Review/Database
☐ Other:

WHAT CONCERNS PROMPTED THE REQUEST FOR AN AUDIT:

☐ Reviewing IRB has reason to suspect serious or continuing noncompliance or unexplained problem involving others based on information received in a submission or an appeal of an investigator or another member of the institutional review board.

☐ Report of concerns from a third party (e.g., participant or sponsor complaints, institutional official request, government agency, etc. - FDA, NIH, CHRT).

☐ Reason to need verification that the Research is being conducted in accordance with the approved protocol (including known/suspected issues with study conduct, data integrity, etc.).

Comments and additional information:

DOCUMENTS AND INFORMATION THAT THE REVIEWING IRB REQUESTS TO BE REVIEWED IN ORDER TO ASSESS NON-COMPLIANCE (include relevant study selection and/or percent of records to be reviewed):

☐ Current Protocol
☐ In-use
☐ Investigator/Study Team Training Documentation
☐ Source Document
☐ Other:

COMMENTS:

www.smartirb.org

SMART IRB

SAMPLE AUDIT CHECKLIST
FOR USE BY INDIVIDUAL(S) CONDUCTING THE AUDIT

A. REGULATORY DOCUMENTATION

1. Is the approved protocol on file? (Original and all previously approved versions)

2. Is the IRB approval letter(s) on file?

3. Is this an FDA-regulated study? (Yes, go to 2)

4. Is there a signed ICA (127) on file?

5. Are all versions of the Investigator Brochure or package insert on file?

6. Are all versions of the package insert or device manual on file?

7. Are all correspondence to and from the FDA on file?

8. Are all CRs/IRCs or IRF on file and all study staff on file?

9. Are CRs on file, are they current in alignment with applicable requirements?

10. For all CRs on file, are they signed and dated, if required?

11. Is there a staff training log?

12. Is the staff training log complete and up-to-date?

13. Is there a subject enrollment?

14. Is there a subject enrollment log complete?

15. Is the site being monitored?

16. Is the site being monitored by:

17. Is there a site monitoring log?

18. Is there a site monitoring log complete?

19. Is there a site signature and delegation of responsibilities log?

20. Is the site signature and delegation log complete and up-to-date?

21. Are all correspondence to and from the sponsor on file?

22. Are lab tests required?

23. Are there a copy of normal lab values on file?

24. Is there a copy of the lab certification on file?

www.smartirb.org

https://smartirb.org/harmonization/
Recommendations for the Harmonization of Ancillary Reviews

- Challenges
- Recommendations
  - Ancillary Review Definitions
  - Centralizing Ancillary Reviews for sIRB
  - Timing of Ancillary Reviews
  - Allocating Ancillary Review Responsibilities
- Implementation Checklist
- Ancillary Reviews that may be centralized after sIRB approval

https://smartirb.org/harmonization/
Harmonization

• Significant work accomplished by leaders, operations, and compliance professionals

• Use whatever resources you find

• “If you see something, say something”
  - Polly Goodman at Polly_Goodman@hms.harvard.edu 😊

• Any challenges or ideas, please let us know
Implementing Harmonization
Implement SMART IRB Harmonized Guidance

- Review SMART IRB Guidances
  - Policy dependent:
    - Identify differences between local policies and SMART IRB guidance
    - Discuss changes with institutional stakeholders
    - Revise local and implement new, consistent policies
    - Educate research community on new policies
  - Procedurally dependent:
    - Try it, use the guidances, checklists, tools, and other resources
    - Never go back again...

https://smartirb.org/harmonization/
Discussion/Questions
Resources and Education to Support Institutions and Investigators

Mike Linke, PhD
Program Director, Education, SMART IRB; Chair, University of Cincinnati IRB and StrokeNet Central IRB; Adjunct Professor of Internal Medicine, University of Cincinnati
Resources (1 of 2)

- Standard operating procedures
- FAQs
- Checklists
- Templates
- Guidance
- Communication plans
- Startup packages
Resources (2 of 2)

**Topic**
- Joining SMART IRB
- Setting up Reliance
- Implementing the Agreement
- For Funding Applications
- About Single IRB Review

**Roles**
- Study Teams
- Reviewing IRBs
- Relying Institutions
- IRB/HRPP Staff
The Learning Centers

- Investigators/Study Teams
- IRB and HRPP Administrators
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.

Start-Up Packages

- Introduction to sIRB Review
- NIH sIRB Policy
- Selecting an sIRB

Developing an sIRB Plan

- Effects on Research Costs
- Study Team Roles
- Online Reliance System

https://smartirb.org/irb-admin/
Learning Center for IRB and HRPP Administrators

The videos and companion resources below are designed to help IRB and HRPP administrators and staff successfully manage single IRB arrangements.

[Diagram with links to various resources]

https://smartirb.org/study-teams/
SMART IRB Start-Up Packages

These packages contain a suite of resources to help you prepare NIH grant applications that require single IRB review and to ensure you understand and can fulfill your responsibilities related to single IRB arrangements. Each package provides a guide describing how and when to use the included resource as well as links to online tools and further information.

Download Study Team Package

Download NIH Grant Preparation Package
Download Start-up Packages

- Study Teams (zip)
- NIH Grant Preparation (zip)
- Reviewing IRBs (zip)
- Relying Institutions (zip)
https://smartirb.org/resources/
Please provide feedback by completing the survey - a link will be emailed.

Presentation slides & recording will be posted on the SMART IRB website.