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

Day 1 - February 7, 2023

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Chair, University of Cincinnati IRB and StrokeNet Central IRB
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Welcome and Overview

Welcome!

Today 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
- SMART IRB resources and how to leverage them when:
  - Serving as a Reviewing IRB
  - Serving as a Relying Institution
  - Training and Preparing Study Teams for sIRB Review

Logistics

Please join us both today, 2/7 and Thursday, 2/9.

Please provide feedback by completing the survey – a link will be posted in chat and emailed.

Presentation slides will be posted on the SMART IRB website.

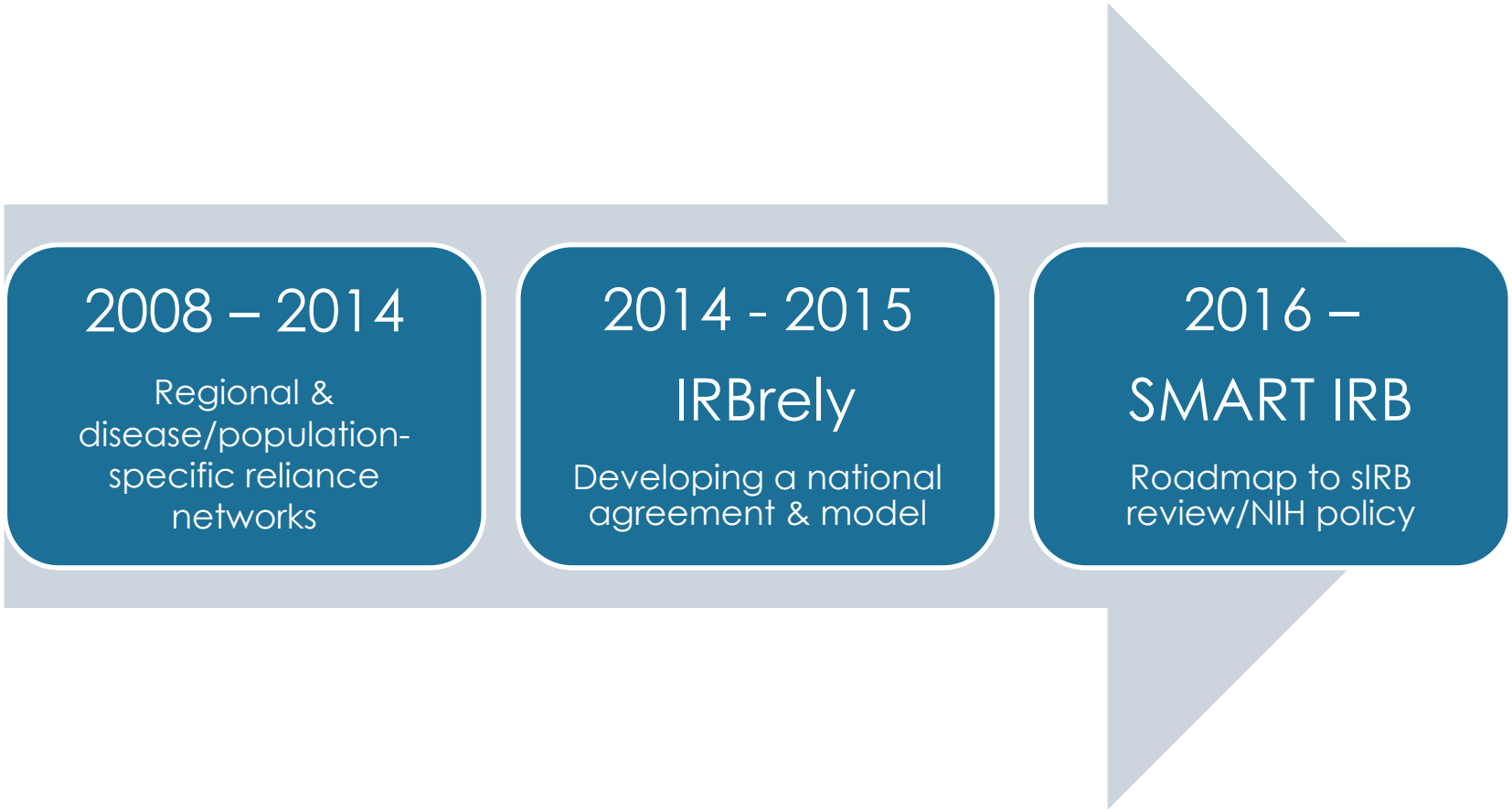
If you have any questions for the panelists, please use the chat or Q&A function to submit them.

Day 1 Overview

Time	Presentation Topic	Presenter
12:00 – 12:10 pm	Welcome and Objectives	Mike Linke
12:10 - 12:45 pm	Reliance Requests	Polly Goodman Lubabah Helwani
12:45 - 1:30 pm	Using the SMART IRB Agreement	Nichelle Cobb Carissa Minder
1:30 - 2:25 pm	What HRPPs need in place for single IRB review	John Bauman Mike Linke
2:25 - 2:55pm	Online Reliance System Demonstration	Polly Goodman
2:55 - 3:00pm	Wrap Up & Day 2 Preview	Mike Linke

Background

Single IRB Review: Evolution



Working Together to Develop a National IRB Reliance Agreement

8 CTSAs came together to develop a national IRB reliance agreement

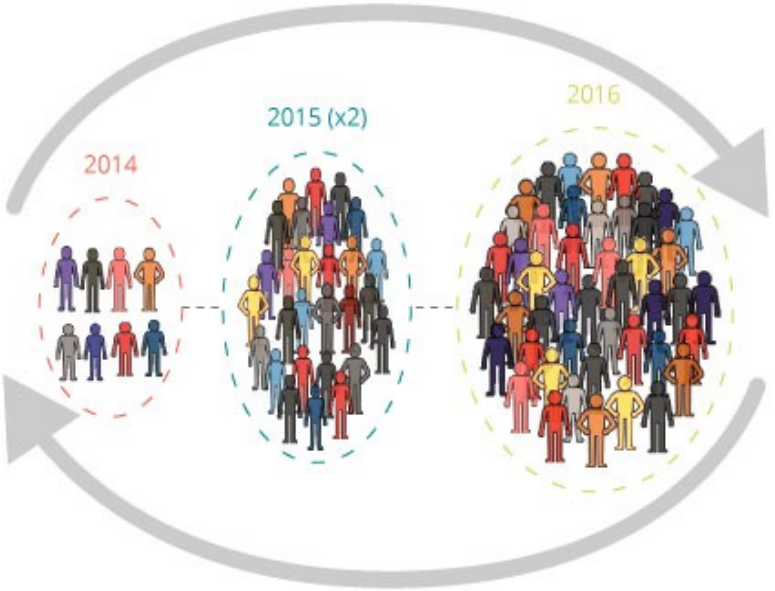
- Public & private universities
- Academic healthcare centers

Shared with 72 Institutions

+ 25 CTSAs in 19 states
+ Community hospitals
+ Independent/commercial IRBs

Shared with 115+ Institutions

+ 64 CTSAs in 33 states
+ NIH agencies



Since 2016

SMART IRB

More than 1000 institutions have joined the SMART IRB Agreement

Supporting single IRB review

Informatics

SMARTIRB.org
Resources and supportive services freely available to support sIRB review

Joinder platform
Allows institutions to join the SMART IRB Agreement

Online Reliance System
Provides a central system and process to request, track, and document reliance arrangements for each study

SMART IRB Agreement

Single IRB Authorization Agreement

Sign once and implement

SOPs

Clear roles and responsibilities for investigators and institutions

Flexibility to use other SOPs as agreed upon or required

Expertise Across the Nation

Ambassadors
Help institutions join and implement SMART IRB

Education & Training
Tools, templates, FAQs, checklists, guidance, peer consultations, and webinars support adoption of SMART IRB

Harmonization Steering Committee
Leaders in the field promote best practice

Building Community

A monthly email newsletter

- Announcements, news
- Resources, education
- 4900+ subscribers

SMART Talk - Monthly forums

- Best practices, emerging issues
- Ask the experts


SMART IRB

SMART IRB: The Essentials
The "Fall, Leaves, Fall" Edition.

All things being equinox.
Balancing apples with single IRB review.
Who's on first? Who's doing what? Reporting to federal agencies? Ensuring personnel training? Identifying COI? We've got it all mapped out in our Institution v. IRB Responsibilities guide for reviewing IRBs and relying institutions (thanks to the Harmonization Steering Committee for navigating the corn maze!).

Take a hint.
Helpful tips for study teams, at your service.
Looking to get investigators and study staff up to speed on what it really means to rely on an external IRB? Send them our FAQs for Research Teams. Or, use our template to customize the FAQs to reflect your institution's extra special particularities. But wait, there's more to fall for at smartirb.org/resources - one-stop shopping for tools, templates, and checklists to help with single IRB review at prices you can't beat.

Immediate gratification.
Data at your finger tips.
When your institution uses SMART IRB's Online Reliance System to document reliance arrangements, you can pull on-demand reports with information about all reliance requests involving your institution. Just log in and click on the "Reports" tab. Note: this feature is only available to an institution's Reliance POC and POC Backups. On-demand

Class picture perfect
(Awkwardly) smile if you're one of our Participating Institutions. Take a look at our big, beautiful, and ever-expanding reliance network. Be a pal and let us know if we have any apple crisp between our teeth.

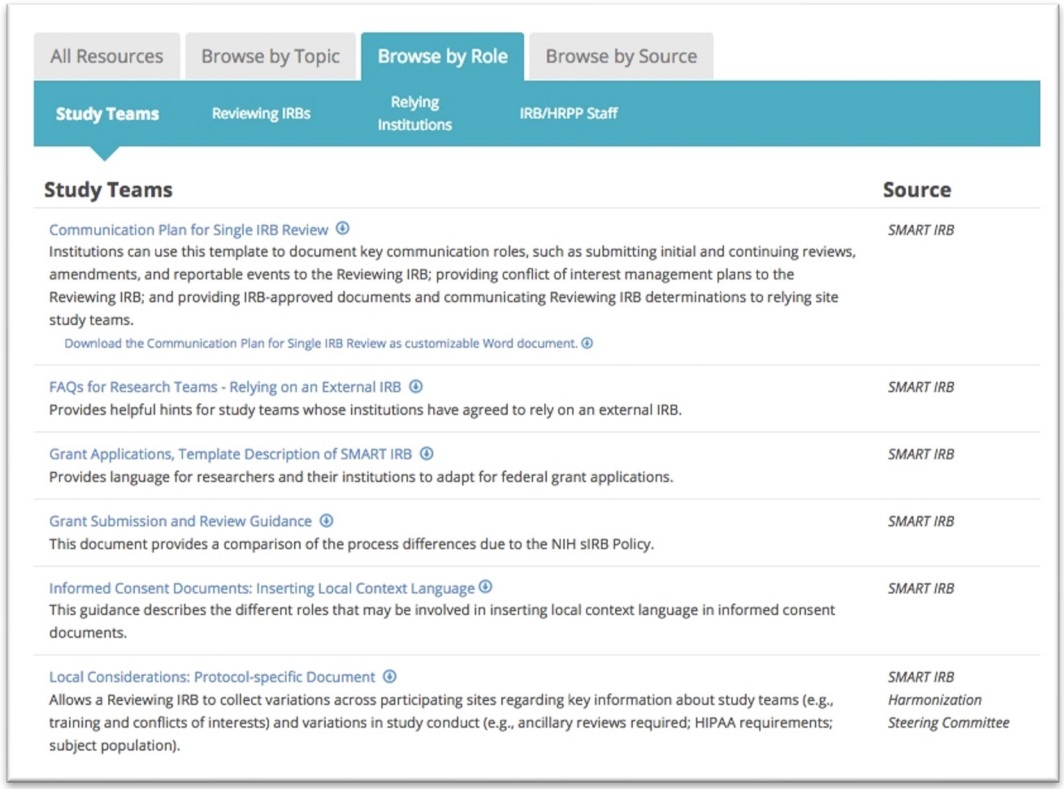
Fall fashion trend.
Voted Vogue's #1 accessory for '18.
Once you've joined, sport a SMART IRB badge on your website.

SMART IRB Participating Institution

Rolling admissions.
The time has never been better to join SMART IRB. Lend your affiliates a helping hand by sharing this guidance...and forward them the signature element of our press kit, the SMART IRB newsletter.

Resources & Guidance

A library for IRBs, institutions, investigators, and study teams: smartirb.org/resources


All Resources | Browse by Topic | Browse by Role | Browse by Source

Study Teams | Reviewing IRBs | Relying Institutions | IRB/HRPP Staff

Study Teams	Source
Communication Plan for Single IRB Review Institutions can use this template to document key communication roles, such as submitting initial and continuing reviews, amendments, and reportable events to the Reviewing IRB; providing conflict of interest management plans to the Reviewing IRB; and providing IRB-approved documents and communicating Reviewing IRB determinations to relying site study teams. Download the Communication Plan for Single IRB Review as customizable Word document.	*SMART IRB*
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.	*SMART IRB*
Grant Applications, Template Description of SMART IRB Provides language for researchers and their institutions to adapt for federal grant applications.	*SMART IRB*
Grant Submission and Review Guidance This document provides a comparison of the process differences due to the NIH sIRB Policy.	*SMART IRB*
Informed Consent Documents: Inserting Local Context Language This guidance describes the different roles that may be involved in inserting local context language in informed consent documents.	*SMART IRB*
Local Considerations: Protocol-specific Document Allows a Reviewing IRB to collect variations across participating sites regarding key information about study teams (e.g., training and conflicts of interests) and variations in study conduct (e.g., ancillary reviews required; HIPAA requirements; subject population).	*SMART IRB* *Harmonization Steering Committee*

But… the shift to a single IRB review model is not without its challenges.

- Culture shift underway
- Requires education, training, and support for HRPP staff and study teams
- Cooperation, alignment, and harmonization of policies, processes, and procedures is key

Successful implementation of sIRB review is a *community effort* - we're (required to be*) in this together!

*NIH sIRB mandate: effective Jan 2018

*Revised Common Rule sIRB requirement: effective Jan 2020

Onward!

Reliance Requests

Workflows, Roles, Tracking, and Resources Needed

Polly Goodman
Associate Director of Regulatory Affairs Operations, SMART IRB, Harvard Catalyst

Lubabah Helwani
University of California Los Angeles, SMART IRB West and Pacific Ambassador

In this session we will:

Workflows	• SMART IRB Online Reliance Systems (ORS) • Other models
Roles	• Reviewing IRB • Relying Institution • Study Teams
Tracking Reliance Requests	• IRB/HRPP System • Spreadsheet • Online Reliance System • IREx • Other
Institutional Resources Needed	• IRB/HRPP Staff • IRB/HRPP Systems • IRB/HRPP SOPs for sIRB • Investigator & Study team resources

Workflows

An investigator wishes to execute reliance(s) for their multi-site research. Now what?

- How is the reliance submission submitted?
- Who is reviewing the request?
- Which reliance agreement will be used?
- What are the procedures to be followed by the research teams?

Reliance submission process (1 of 2)

- How does your institution receive reliance requests
  - Via email
  - Via IRB system
  - SMART IRB Online Reliance System
- Do those processes differ depending on the study specifics?
  - Type of study (ex. NCI CIRB)
  - Type of IRB review (expedited or full board)
  - Institutions involved

Reliance submission process (2 of 2)

Who is processing vs. reviewing/approving sIRB requests?

- IRB Chair, IRB members
- Institutional/Signatory Official
- IRB office staff

How are reliance requests evaluated? What information is needed to make a reliance decision?

- Specific criteria for Reviewing IRB/Relying Institution
- Engagement
- Is single IRB review required?

Which Reliance Agreement will be used?

- SMART IRB master agreement
  - Online Reliance System
  - Letter of Acknowledgement
  - IREx (IRB Exchange)
- An existing agreement
  - institution-specific
  - consortium-specific
- Negotiate a new agreement

Institutions need to decide under what circumstances which reliance agreement(s) will be utilized.

What procedures are followed by the research team? (Reviewing IRB)

- Set up a consult?
- Email?
- Submission?
- Alert the IRB office – grants team to do this? How does the IRB get notified?

SMART IRB Online Reliance System (ORS)

SMART IRB Online Reliance System

Launched in May 2017

Single point of entry standardizes reliance processes

Communication portal eliminates tracking via email or other methods

Guided workflow makes clear when action is required

The system works for institutions:

1. With and without significant reliance experience
2. Familiar or unfamiliar with one another
3. With limited or substantial infrastructure to support single IRB review

Allows SMART IRB Participating Institutions to work together to establish reliance arrangements on a study-by-study basis

Get started at smartirb.org/reliance.

Benefits for INVESTIGATORS

Clarity and Guidance

The system guides you through the request process, collecting the information institutions need to determine an appropriate arrangement for your study

Automatic Notifications

Email notifications ensure you are informed at key points in the decision-making process

Reliance Tracking

The system gives you a window into the decision-making process and provides a single place to track reliance arrangements for your studies

Benefits for INSTITUTIONS

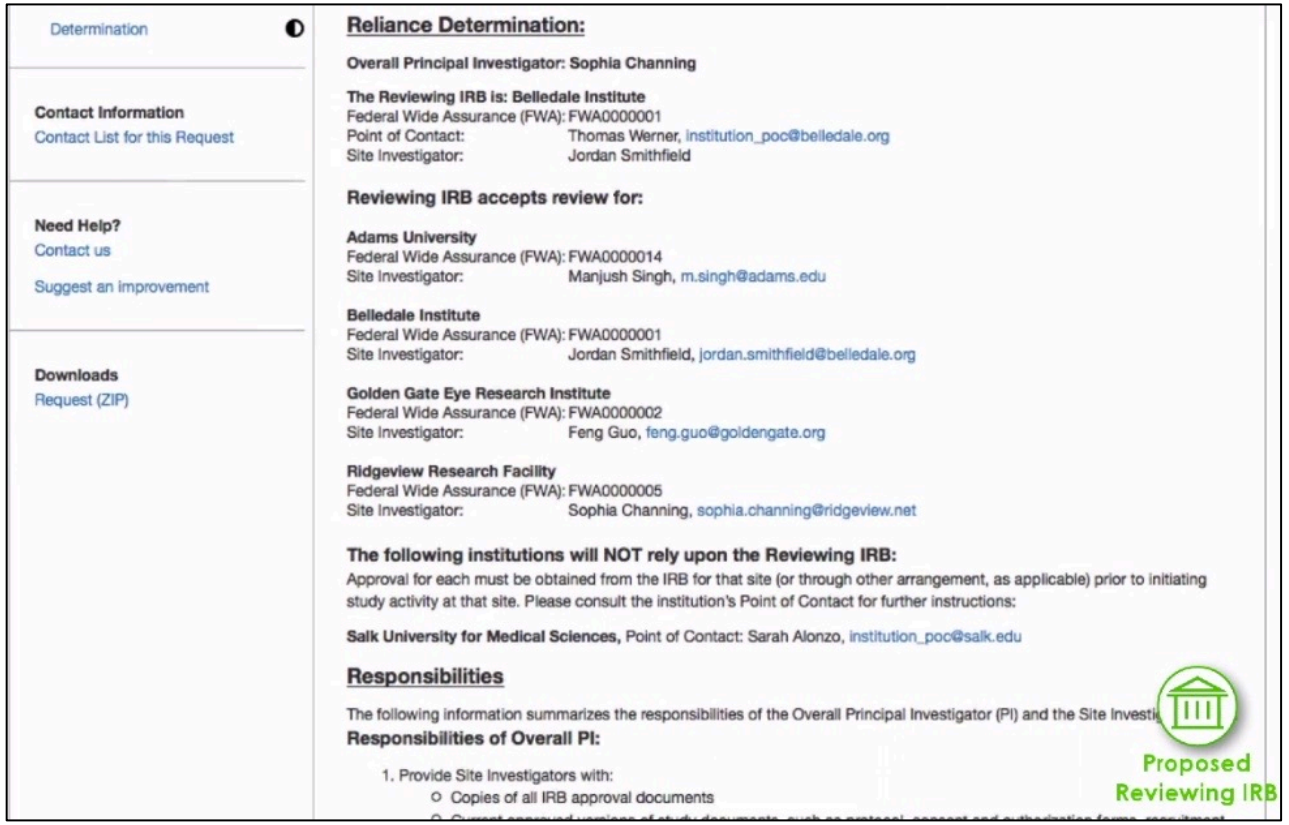
Provides a centralized place to record and track reliance arrangements on a study-by-study basis

Connects you with the appropriate POC for each site, eliminating the need to track down their information

Guides you through the decision-making process, making clear when your action is required

Provides a central, transparent platform to communicate local context issues

System-generated Determination Letter



- Sent to Overall PI, Site Investigators, and designated contacts for all engaged sites; stored in the system.
- Documents the Reviewing IRB and Relying Institution(s).
- Describes responsibilities of the Overall PI and Site Investigators.

Roles

Reviewing IRB – Responsibilities

- Evaluate sites
- Open communication with the relying site PIs:
  - Will sites be added on initially or an amendment?
- Provide Approved Study Documents
  - Template consent forms
- Develop local context survey
- Develop a communication plan
- Notification of review findings and expired studies

Relying Institution

- Complete local context survey and provide Institutional profile
- Review study documents for required local language or adherence to institutional policies
- Perform Ancillary Reviews
- Review Study Personnel
- Disclose Conflict of Interest

Study Teams

- Facilitate communication between sites
- Assist with completion of local context survey
- Submit reliance request to Relying Institution
- Provide study personnel list

Tracking Reliance Requests

Methods for Tracking Reliance Requests

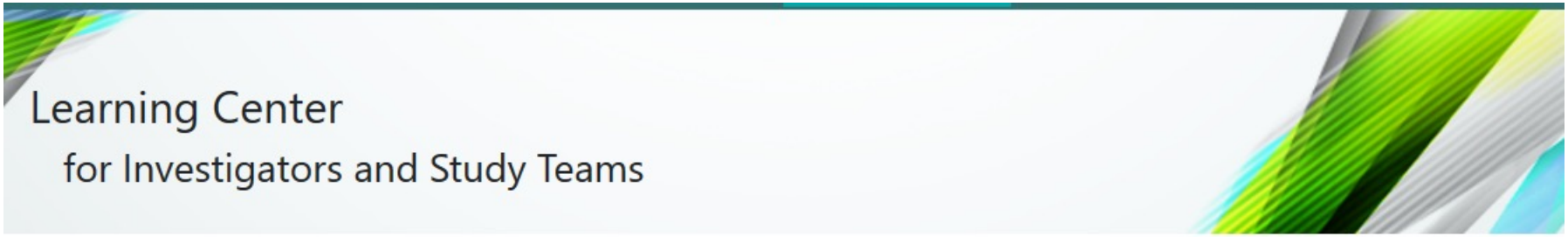
- Track studies in local IRB/HRPP system
- Spreadsheet
- Online Reliance System

Institutional Resources Needed

Institutional Resources

- IRB/HRPP Staff
  - SMART IRB Point of Contact
- IRB/HRPP Electronic Submission System
- IRB/HRPP SOPs for sIRB
- Investigator & Study team resources
  - Checklists

Start-Up Packages at smartirb.org/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

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

Customized Learning

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

https://smartirb.org/irb-admin/

Questions?

Using the SMART IRB Agreement

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

Carissa Minder, RN, BSN, MS, CIP, CCRP
SMART IRB Ambassador; Associate Director, Human Research Protection Office, Washington University in St. Louis

What We Will Cover

- How to use the SMART IRB Agreement and document reliance
- SMART IRB Agreement Responsibilities
  - All Participating Institutions
  - Reviewing IRB
  - Relying Institution
- Addressing the flexible terms of the agreement
- SOPs
- Addenda to the agreement
- Working with institutions that have not joined SMART IRB

How to use the SMART IRB Agreement and Documenting Reliance

Nature of the SMART IRB Agreement

The Agreement is a “master” agreement which means:	
No additional IRB authorization agreements required to enable reliance among institutions that have joined SMART IRB	Reliance arrangements, however, need to be documented for each study

Documentation of Reliance Arrangements

When using the SMART IRB Agreement, an additional IRB authorization agreement is not required for institutions that have joined, but use of the agreement needs to be documented

The documentation that the SMART IRB agreement will be used for a reliance arrangement does NOT require signature

No supplemental agreements are required

Resources: SMART IRB Online Reliance System or download a Template Letter of Acknowledgement (docx)

SMART IRB Agreement Division of Responsibilities

Responsibilities of All Institutions that Join SMART IRB

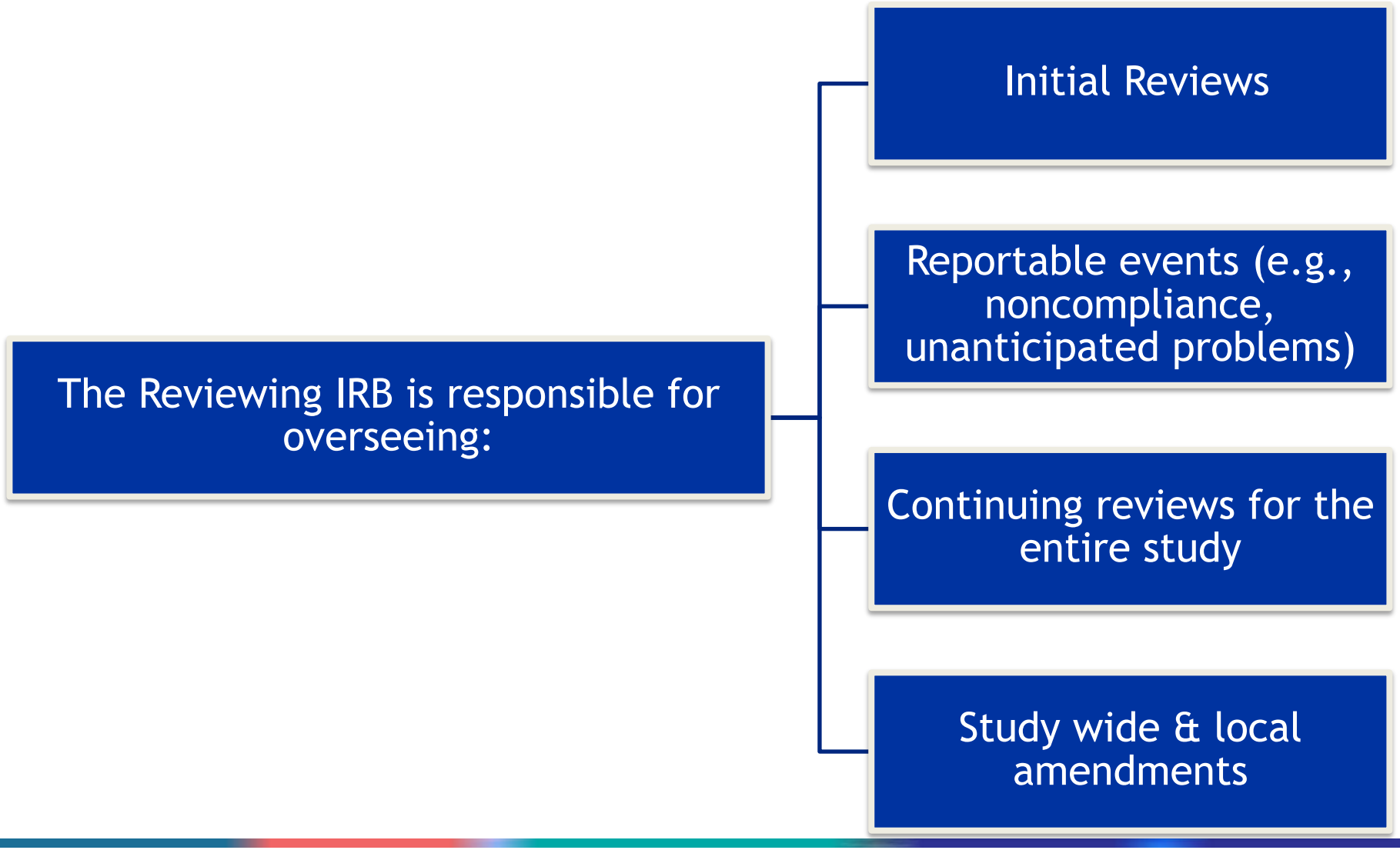
Maintain, implement, or have access to a human subjects research QA/QI process/function/program/ service that can conduct and report to the Participating Institution the results of for-cause and not-for-cause audits

UNLESS the Reviewing IRB waives this requirement

Maintain sufficient insurance coverage (includes self-funded liability coverage in the case of state institutions) to cover their activities related to the reliance arrangement

UNLESS the Reviewing IRB waives this requirement

Nature of the SMART IRB Model



Relying Institutions Must Ensure Study Teams:

Do not initiate any study or changes of protocol* without approval from the Reviewing IRB

(*except those to eliminate an apparent immediate hazard)

Provide the Reviewing IRB with information about local study conduct for continuing review

Maintain research records (e.g., consent forms, HIPAA authorization)

Local Considerations
(1 of 2)

The Reviewing IRB considers communicated local requirements, such as:

- **Applicable state or local laws, regulations, institutional policies, standards, or other local factors**, including ancillary reviews, relevant to the research that would affect the conduct or approval of the research at the Relying Institution
- Site-specific information requested/identified in the customizable sections of the Reviewing IRB's **consent form**
- **Conflict of interest** determinations, prohibitions, and management plans
- **Local requirements and restrictions on use and disclosure of PHI** that could prevent the Reviewing IRB from approving a request for waiver of HIPAA authorization with respect to the Relying Institution

Local Considerations
(2 of 2)

The Relying IRB Institution communicates:

- Local context that would affect the conduct or approval of the research at the Relying Institution, such as:
  - State and local laws & regulations
  - Institutional policies
  - Local factors
  - Ancillary reviews
- Information or documentation regarding its research personnel's education, training, and qualifications as requested

Conflicts of Interest (1 of 2)

The Reviewing IRB:

- Ensures any COI management plan is incorporated into its initial or other deliberations, as applicable, such as including disclosures to subjects in consent forms
- Retains the authority to impose additional prohibitions or conflict management requirements more stringent or restrictive than proposed by a Relying Institution
- Will not modify or change any management plan or mandated disclosure to subjects without discussion with and acceptance by the Relying Institution

Conflicts of Interest (2 of 2)

The Relying Institution:

- Maintains & shares COI policies
- Performs COI analysis (unless alternate arrangement agreed upon with Reviewing IRB)
- Communicates COI determinations (e.g., management plans, restrictions) to the Reviewing IRB
- Abides by Reviewing IRB COI determinations

Consent Documents

(1 of 2)

The Reviewing IRB:

- Provides Relying Institutions and Site Investigators with approved informed consent templates (when informed consent required)
- Permits Relying Institution/Site Investigator to customize limited site-specific sections of the form
- Provides final approved consent form(s) to Relying Institutions/Site Investigators (either directly or through a designee, such as a Lead Study Team)

Consent Documents

(2 of 2)

The Relying Institution:

- Provides site-specific information in the customizable sections of the Reviewing IRB's consent form, such as:
  - Compensation for injury language
  - Variations in costs
  - Local contact information

Policies & Procedures

The Reviewing IRB:

- Makes its policies and procedures available to Relying Institutions, when applicable and upon request

HIPAA Privacy Rule: Agreement Default Position

- Expectation for the Reviewing IRB to serve as the Privacy Board for Relying Institutions, when a study falls under the HIPAA Privacy Rule
- Reviewing IRB and Relying Institutions can make alternate arrangements, such that some or all Relying Institutions can perform Privacy Board determinations instead of the Reviewing IRB
- The Relying Institution may obtain agreement from the Reviewing IRB to use a separate authorization form

If a separate HIPAA authorization form will be used, the Relying Institution will ensure:

The accuracy of the information within the form

Compliance of the form with the HIPAA Privacy Rule

That the form permits PHI to be used by and disclosed to the Reviewing IRB, the Reviewing IRB Institution, and all Relying Institutions as necessary for conducting, reviewing and overseeing the Research (including investigation and evaluation of events)

Reportable Events (1 of 2)

The Reviewing IRB promptly notifies Overall PI, Site Investigators and Relying Institution(s) about findings of and actions related to:

- Apparent serious and/or continuing noncompliance
- Serious and/or continuing noncompliance, including any steps it deems necessary for remediation of the noncompliance at the Relying Institution
- Unanticipated problems involving risks to subjects or others
- Subject injuries related to research participation
- Significant subject complaints (e.g., those that could affect the conduct of the research)
- Suspension or termination of IRB approval of the research

Reportable Events (2 of 2)

The Relying Institution ensures the Reviewing IRB is notified of:

- Unanticipated problems
- Potential noncompliance
- Suspension or restriction of study team personnel authority to conduct study

External Reporting (1 of 2)

The Reviewing IRB notifies a Relying Institution in advance if it determines that a report is required to a regulatory agency (e.g., OHRP, FDA), sponsor, funding agency, and/or other oversight authority of:

- Unanticipated problems involving risks to human subjects or others
- Serious and/or continuing noncompliance
- Any suspensions or terminations of IRB approval

External Reporting (2 of 2)

When a Reviewing IRB makes a determination or takes an action that requires reporting to a regulatory agency, the Relying Institution:

- Promptly provides any comments on any draft report from the Reviewing IRB/Reviewing Institution
- If the Reviewing IRB/Reviewing IRB Institution requests the Relying Institution make the report, promptly prepare the draft report and provide the Reviewing IRB/Reviewing IRB Institution with the opportunity to review and comment on the draft report
- If the Relying Institution elects to make its own additional report, provides a copy to the Reviewing IRB/Reviewing IRB Institution

Audits (1 of 2)

The Reviewing IRB can:

- Conduct audits of the research;
- Request a Relying Institution conduct an audit/investigation and report its findings to the Reviewing IRB; OR
- Work cooperatively with a Relying Institution to conduct an audit/investigation

When a Relying Institution conducts the audit/investigation, the Reviewing IRB will reasonably cooperate with the institution by:

- Providing research review records and related information
- Meeting with representatives from the Relying Institution
- Helping implement corrective actions, as applicable

Audits (2 of 2)

The Relying Institution cooperates when the Reviewing IRB/ Reviewing Institution requests an audit by:

- Providing research records and related information
- Meeting with representatives from the Reviewing IRB/ Reviewing IRB institution
- Helping to carry out corrective action(s), as applicable
- Reporting its findings to the Reviewing IRB/ Reviewing IRB Institution within a reasonable timeframe in the case of its own or a joint investigation
- Complying with all corrective actions required by the Reviewing IRB/ Reviewing IRB Institution

Flexible Terms

Flexibility in the SMART IRB Agreement

The SMART IRB Agreement provides for flexibility related to:

- The Reviewing IRB serving as a Privacy Board
- Requiring insurance or indemnification agreement
- Requiring an auditing mechanism or who performs audits
- Whether HIPAA authorization language will be included in consent form
- Who performs COI analyses
- Responsibilities for reporting events/actions to federal agencies/sponsors

Resource: download SMART IRB Implementation Checklist (pdf) at smartirb.org/resources/

SOPs

What is Required?

- Participating Institutions are **strongly encouraged** to use and follow the SMART IRB Standard Operating Procedures (SOPs) with respect to Research covered under this Agreement. Download SMART IRB SOPs (pdf)
- Participating Institutions **may opt to use their own policies and procedures for the reliance relationship** if doing so would not render the Participating Institutions in violation of any term of the Agreement.

SMART IRB SOP

- The SMART IRB SOPs will be publicly posted
- The SMART IRB SOPs will be reviewed periodically and may change from time to time.
- Material changes will be open for written comments

SMART IRB SOP Content

- Responsibilities
- Selecting a Reviewing IRB
- Adding Sites
- Conducting Reviews
- Record Keeping
- HIPAA
- COI
- Reportable Events
- Agreement Management

To Use or Not to Use?

Use SMART SOPs

- Already done
- Available to Everyone
- Training of IRB Staff
- High Level
- Harmonized

Use Other SOPs

- Have to make or Update them
- Have make them Available
- Familiarity For IRB Staff
- Institution Specific
- Not Harmonized

Communication

- SMART IRB Communication Plan
- Other Communication Plan
- Master Communication Plan
- Addendum
- Email

PI Education on SOPs

- Important no matter what SOPs are used
- Relying Institution and Reviewing IRB share responsibility
- Site PIs and Lead PIs

Addenda to the SMART IRB Agreement

What is an Addendum?

- Legal Document Adding to the SMART IRB Agreement (Not Amending)
- Can cover multiple things
  - Indemnification
  - Flexible Terms (including which SOPs)

How to make life easier

- Limit to certain types of studies
- Master Addenda
- As few terms as possible
- Determine up front if there are easier ways to review (Relying Site)
- Determine up front if there are requests that can be accepted (Reviewing IRB)

Working with Sites that have not Joined SMART IRB

Joining SMART IRB

- You want me to do WHAT?
- Know your audience
- Think about the “investment”—can you present it as a future time saver
- Ask about specific areas they are worried about
- Talk about it—it’s overwhelming
- Contact your Ambassador—particularly about the Joinder Process
- It’s not for everybody! Have an option B.

Questions?

What HRPPs Need in Place for sIRB Review

Michael Linke, PhD
Program Director, Education, SMART IRB; Chair, University of Cincinnati IRB and StrokeNet Central IRB; Adjunct Professor of Internal Medicine, University of Cincinnati

John R. Bauman, PhD
SMART IRB Ambassador; Associate Vice President for Research Compliance, Office of Research Compliance, Office of Vice President for Research, Indiana University

The New sIRB World

- On the one hand
  - Not such a new idea
    - We have always deferred to other IRBs
      - Institutional agreements
      - Reliance on independent IRBs
- On the other hand
    - A whole new ballgame
      - Qualitatively and quantitatively different

sIRB Process

- Thus requiring
  - Adjustments to policy, process, staff roles/responsibilities
- Leading to the question:
  - What should HRPPs have in place for entering the world of sIRB?

Process Changes

What has the sIRB process changed?

- At the end of the day….
  - sIRB may perform as promised
    - Reduces multiple reviews by multiple committees
    - Thus reducing the workload of the committee(s)
  - But will result in workload shifts
    - Not a reduction in work for all parties
    - Introduces different types of work
    - Differential impact on each of the three domains: Institution, IRB, Researcher

What To Do

- First and foremost, decisions
  - What will be the roles and responsibilities of HRPP and research teams be, respectively, in the sIRB process?
  - And, given the institutionalization of these new processes, how will the HRPP remain an integrated whole?
  - How will the different components of HRPP (writ large) keep working together as a systematic, integrated whole?
- Now turn to some of the major connections in question
  - Ancillary Reviews
  - COI reviews and management
  - Post approval monitoring
  - Review of study personnel

Recommendations for the Harmonization of Ancillary Reviews

Ancillary Reviews Working Group of the SMART IRB Harmonization Steering Committee

Ancillary Reviews

- Relying institutions may need to change their processes for managing ancillary reviews.
  - many IRBs/HRPPs are responsible for identifying which ancillary reviews apply to a study and ensuring they are completed
  - most sIRBs are unwilling to take responsibility for ensuring Relying Institution ancillary reviews are completed

Ancillary Review Definition

- signs-offs or approvals that are in addition to IRB approval of human subjects research
- required by institutional or funding entity policy(ies) or by regulation, statute, or law.
- may occur before, during, or after IRB review
- most must be completed before site activation

Ancillary Review Examples

- Scientific Review
- Institutional Biosafety Committee (IBC) Review
- Radiation Safety
- Information Technology (IT) Security
- Clinicaltrials.gov
- Coverage Analysis

ANCILLARY REVIEWS THAT MAY BE TRIGGERED AFTER SIRB APPROVAL

- HIPAA-related events
- Personnel Changes
- Administrative Study Procedures
- Pharmacy Support
- Radiation Safety

Challenges with Ancillary Reviews
(1 of 2)

- Affect the efficiency of sIRB review
- Delay sIRB submission and study activation
- Inflexibility of IRB systems
- Confusion on which reviews are required
- Defining roles and responsibilities

Challenges with Ancillary Reviews
(2 of 2)

Four areas that represent opportunities to increase the efficiency of study activation:

1. Variations in the definition of ancillary reviews and identification of which reviews are relevant to sIRB review
2. Centralization of certain ancillary reviews for multisite studies
3. Timing of ancillary review requirements, particularly in relation to IRB review
4. The responsibilities of Reviewing IRBs, Relying Institutions, and study teams related to ancillary reviews

A New Approach

Reassessing how HRPPs approach Ancillary Reviews

- The role of the IRB as the “gatekeeper”
- Identifying which reviews are required
- Ensuring reviews are completed
- Implementation of centralized ancillary review

Download Recommendations for the Harmonization of Ancillary Reviews (zip)

Guidance: Conflict of Interest (COI) Review Processes for Single IRB Review

Conflict of Interest Working Group of the SMART IRB Harmonization Steering Committee

Roles and Responsibilities of the Relying Institution

- Have polices that define which interests require disclosure and which are considered a significant financial interest (SFI)
- Have processes and policies to identify conflicts of interest at initial review as well as during a study
- Have a process through which any identified COI is resolved
- Communicate the presence of any COI and management plan to the Reviewing IRB at initial review and if a new COI is subsequently identified

Roles and Responsibilities of the Reviewing IRB/Institution

- Have a process to receive information about COI and management plans from Relying Institutions at initial review and if a new COI is subsequently identified
- Determine if the management plan is sufficient or if additional management strategies are needed
- If additional changes are needed, communicate with the Relying Institution to reach an agreement on what additional strategies are required
- Accept assurance from a federal Relying Institution that all federal investigator COI policies have been met

Download Guidance: COI Review Processes for Single IRB Review (pdf)

Post-Approval Auditing for Studies Subject to Single IRB Review

Post-Approval Auditing Working Group of the SMART IRB Harmonization Steering Committee

Post-Approval Auditing: Institutional Responsibilities

- Maintain, implement or have access to a human subjects research QA/QI process function
- If an institution does not have a QA/QI process, it must have an alternate means of monitoring the research
- May agree to waive the requirement to have access to a QA/QI process

Post-Approval Auditing: Reviewing IRB Responsibilities

- Communicate to Relying Institution the concerns that prompted a for-cause audit request
- Determine who will perform a for-cause audit
- Establish time frame for completion of audit
- Communicate a process for sharing study documents
- Review and approve of, or modify, the Relying Institution's proposed corrective action plan

Post-Approval Auditing: Relying Institution Responsibilities

- Conduct for-cause audits as requested by the Reviewing IRB
- Comply with audits conducted by the Reviewing IRB Institution
- Provide relevant study documents and policies to the Reviewing IRB
- Provide a written report of all for-cause audits to the Reviewing IRB
- Ensure the Overall PI and Site Investigators communicate any issues of potential serious and continuing noncompliance with the Reviewing IRB
- Provide feedback to the Reviewing IRB and Investigator(s) on the corrective action plan
- Regularly conduct not-for-cause audits as part of their post-approval monitoring program

Download Guidance: Post-Approval Auditing for Studies Subject to Single IRB Review (zip)

Single IRB Review: Responsibilities Associated with the Review of Study Personnel

Review of Study Personnel Working Group of the SMART IRB Harmonization Steering Committee

Review of Study Personnel: Joint Responsibilities

- Ensuring study personnel are adequately trained is a joint responsibility
- HHS and FDA regulations do not stipulate how IRBs must ascertain these qualifications
- SMART IRB Agreement obligates Institutions to ensure their research personnel have adequate education, training, and qualifications to perform the research and safeguard the rights and welfare of research subjects.

Review of Study Personnel: Reviewing IRB Responsibilities

- sIRBs must evaluate the qualifications of PIs
- Implement processes to ensure other study personnel are qualified to conduct the research

Review of Study Personnel: Relying Institutions Responsibilities

- Study personnel are appropriately trained and qualified
- Study personnel have met institutional requirements related to their role
- COI determinations, prohibitions, and management plans are monitored and communicated to the sIRB
- Study personnel follow the requirements of the sIRB

Meeting Obligations

Relying Institutions may meet these obligations in a variety of ways:

- Delegating responsibilities to a coordinating center
- Requiring local site PIs to track personnel updates
- Leveraging credentialing or human resources processes

Download Single IRB Review: Responsibilities Associated with the Review of Study Personnel (pdf)

We're Here to Help

Expert Advice and Guidance

https://smartirb.org/support/

Preparing to serve as a Reviewing IRB or Relying Institution? We'll connect you with other IRBs experienced in the conduct, review, and oversight of multisite research.

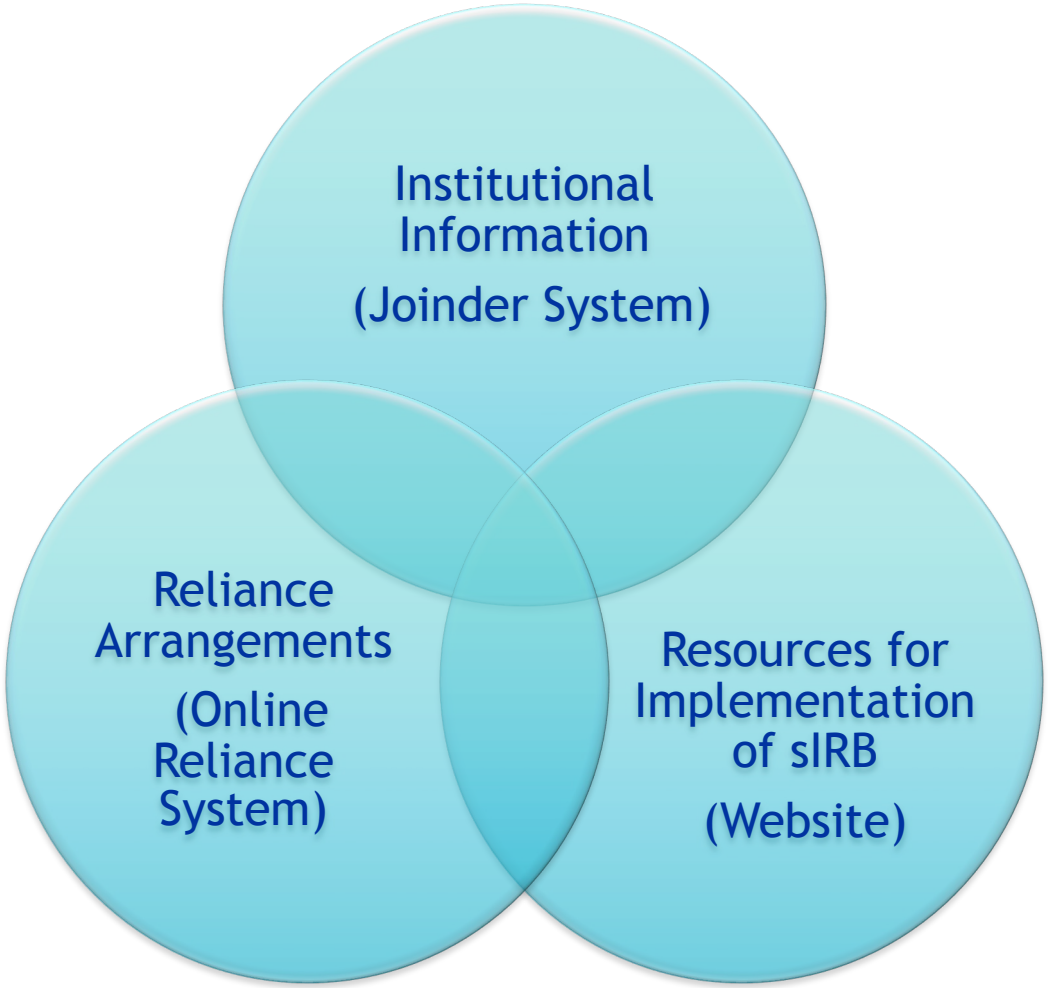
consultation@smartirb.org

Discussion/Questions

Online Reliance System Demonstration

Polly Goodman
Associate Director of Regulatory Affairs Operations, SMART IRB, Harvard Catalyst

Summary of SMART IRB Components



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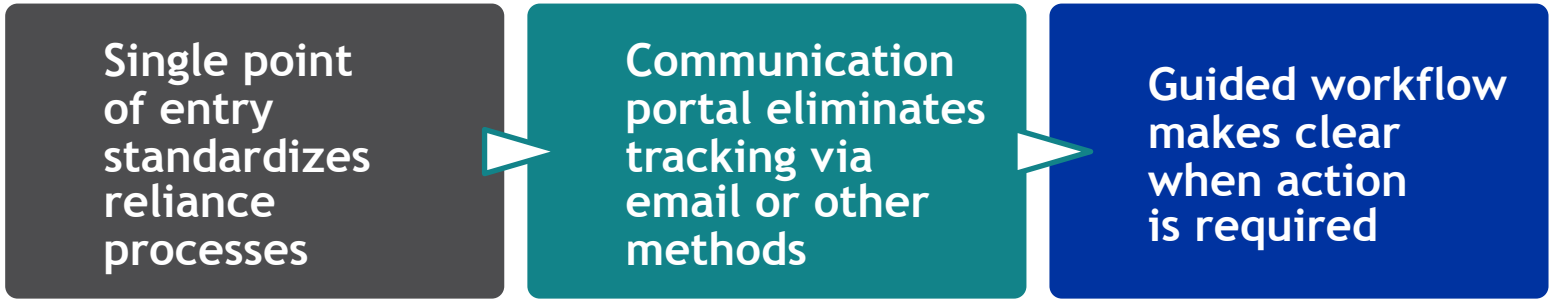
SMART IRB Online Reliance System

Allows investigators and institution POCs to request, track, and document reliance arrangements for each study



The system works for institutions:

1. With and without significant reliance experience
2. Familiar or unfamiliar with one another
3. With limited or substantial infrastructure to support single IRB review

smartirb.org

SMART IRB Online Reliance System

Benefits for **INVESTIGATORS**

Clarity and Guidance

The system guides you through the request process, collecting the information institutions need to determine an appropriate arrangement for your study

Automatic Notifications

Email notifications ensure you are informed at key points in the decision-making process

Reliance Tracking

The system gives you a window into the decision-making process and provides a single place to track reliance arrangements for your studies

smartirb.org

SMART IRB Online Reliance System **Benefits for INSTITUTIONS**

Provides a centralized place to record and track reliance arrangements on a study-by-study basis

Connects you with the appropriate POC for each site, eliminating the need to track down their information

Guides you through the decision-making process, making clear when your action is required

Provides a central, transparent platform to communicate local context issues

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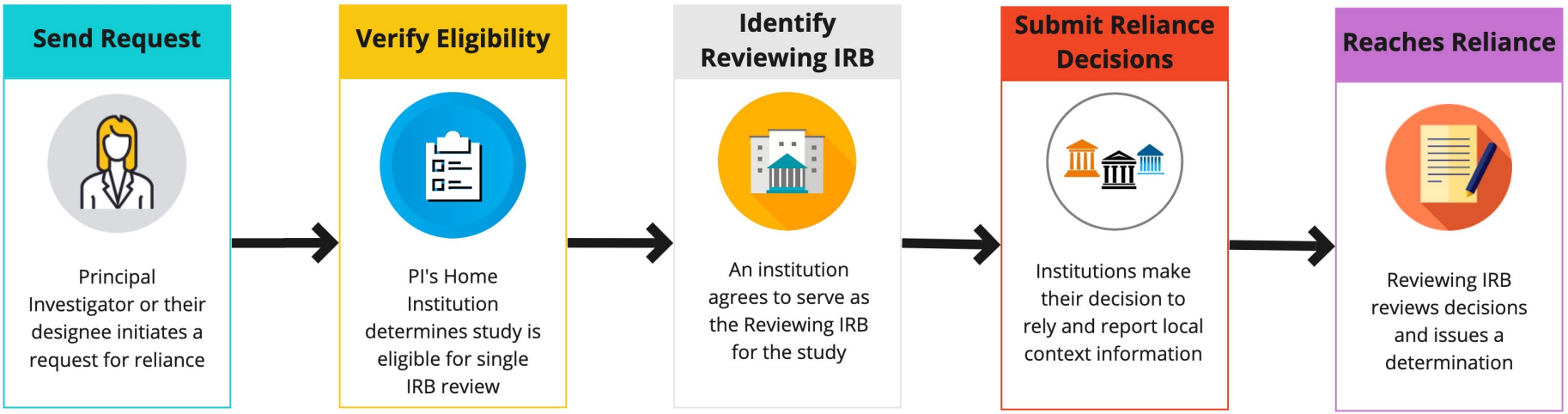
The SMART IRB Online Reliance System

Request, track and document reliance arrangements



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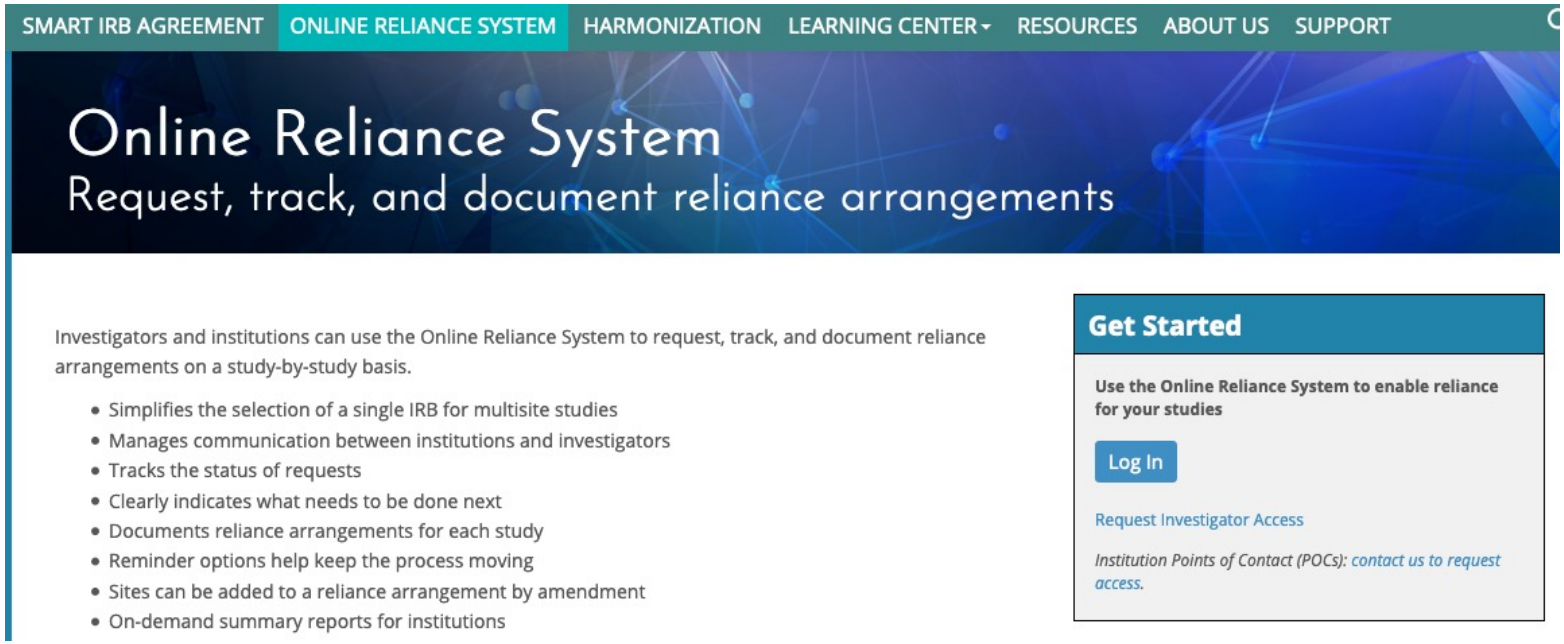
Online Reliance System Demo



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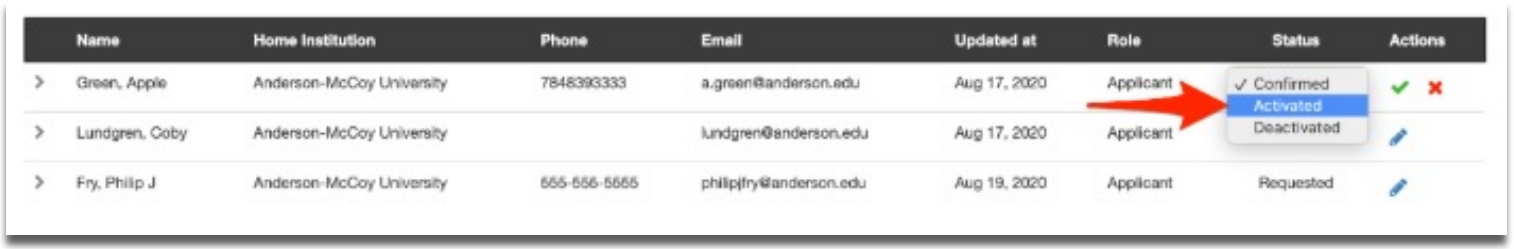
Tips and Tricks: User Status

There are 4 statuses that a user account can have:

- **User Status definition:**
- **Requested:** The user has requested for access and has NOT verified their email.
- **Pending:** The user has verified their email and is awaiting POC approval.
- **Activated:** The user has been approved by the POC and now has access to the System.
- **Deactivated:** The user has been deactivated by a POC and can no longer access the System.

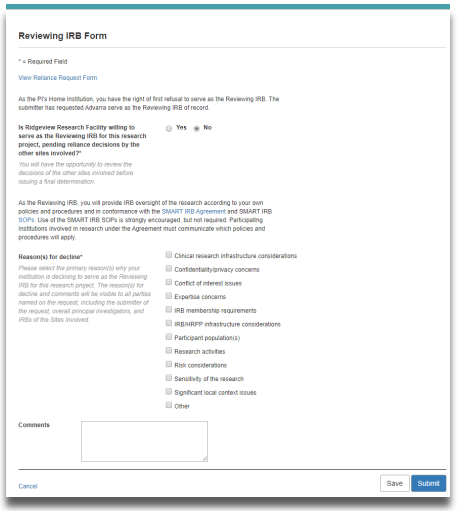


Tips and Tricks: Right of First Refusal - Reviewing IRB

- The Overall PI's Home Institution has the right of first refusal to be the Proposed Reviewing IRB. Regardless of which institution is listed as the Requested Reviewing IRB, the PI's Home Institution must first indicate their willingness to be the Reviewing IRB.

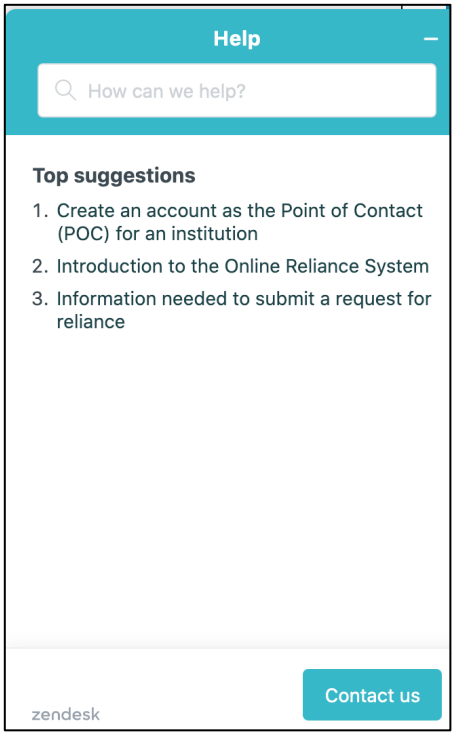
- Once Pre-Check is completed, the Overall PI's Home Institution Point of Contact (POC) indicates if their IRB is willing to be the Proposed Reviewing IRB. The request point of contact (submitter) may have designated a different institution to be the Requested Reviewing IRB.

- If the POC enters the decision that,
  No, they are not willing to serve as the Reviewing IRB, they next have the right to choose the next Proposed Reviewing IRB. **The POC must complete both steps (declining to be the Reviewing IRB, and selecting the next Proposed Reviewing IRB) before the request can continue.**



Help Desk

- Help button on bottom right of every page
  - Clicking brings up our Help Center, where you can access knowledgebase articles and search for answers
- You can also contact us directly at Help@SMARTIRB.org



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Join us for Day #2
Thursday, Feb. 9 @12pm ET

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

Day 2 Overview

Time	Presentation Topic	Presenter
12:00 – 12:10 pm	Welcome	Barbara Bierer
12:10 – 1:10 pm	Communication	Ada Sue Selwitz Stacey Goretzka
1:10 - 1:55 pm	Training Study Teams	Nichelle Cobb Kathy Lawry
1:55 - 2:25 pm	Harmonization	Barbara Bierer
2:25 - 2:50pm	SMART IRB Resources Recap	Mike Linke
2:55 - 3:00pm	Final Questions & Wrap Up	Barbara Bierer