2025 Single IRB Boot Camp:
A How-to Guide with SMART IRB

Day 1 - October 29, 2025

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Welcome and Overview

What Is SMART IRB?
The Streamlined, Multisite, Accelerated Resources for Trials IRB Reliance platform

SMART IRB is…

A federally funded project to support institutions and researchers in the implementation of single IRB

SMART IRB provides…

An IRB reliance agreement

Reliance System to initiate and track reliance

Other resources free to institutions and researchers

SMART IRB is NOT…

An IRB

An electronic system for Reviewing IRBs to receive studies for review

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

The presentations will be recorded and posted on the SMART IRB Website along with the slides

If you have technical difficulties, please reach out through the chat for help.

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

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

Day 1 Overview

Time	Presentation Topic	Presenter
12:00 – 12:05 pm	Welcome and Objectives	Barbara Bierer/Mike Linke
12:05 - 12:30 pm	Reliance Requests	Polly Goodman
12:30 - 1:15 pm	Using the SMART IRB Agreement	Nichelle Cobb Carissa Minder
1:15-1:25 pm	Break	
1:25 - 1:55 pm	What Institutions Need in Place for Single IRB review	Jeremy Lavigne Mike Linke
1:55 - 2:55 pm	Reliance System Overview	Polly Goodman Jeremy Lavigne
2:55 - 3:00pm	Wrap Up & Day 2 Preview	Mike Linke

Onward!

Reliance Requests

Workflows, Roles, Tracking, and Resources Needed

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

In this session we will discuss:

Workflows	• SMART IRB Reliance Systems • Other models
Roles	• Reviewing IRB • Relying Institution • Study Teams
Tracking Reliance Requests	• IRB/HRPP System • Spreadsheet • Reliance System • IREx • Other
Institutional Resources Needed	• IRB/HRPP Staff • IRB/HRPP Systems • IRB/HRPP SOPs for sIRB

Workflows

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

- For what types of studies will the institution execute reliance arrangements?
- What are the procedures to be followed by the research teams?
- How is the reliance submission submitted?
- Who is reviewing the request?
- Which reliance agreement will be used?

Reliance submission process (1 of 2)

- How does your institution receive reliance requests
  - Via email
  - Via IRB system
  - SMART IRB 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)
  - Type of IRB institution
  - 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 Reliance Agreement
  - Reliance System
  - Letter of Acknowledgement
  - IREx (IRB Exchange)
- An existing agreement
  - institution-specific
  - consortium-specific
- Negotiate a new agreement

What procedures are followed by the research team?

- Set up a consult?
- Email?
- Submission?
- Sponsored Program Office alerts the HRPP?

SMART IRB Reliance System

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 www.smartirb.org/.

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

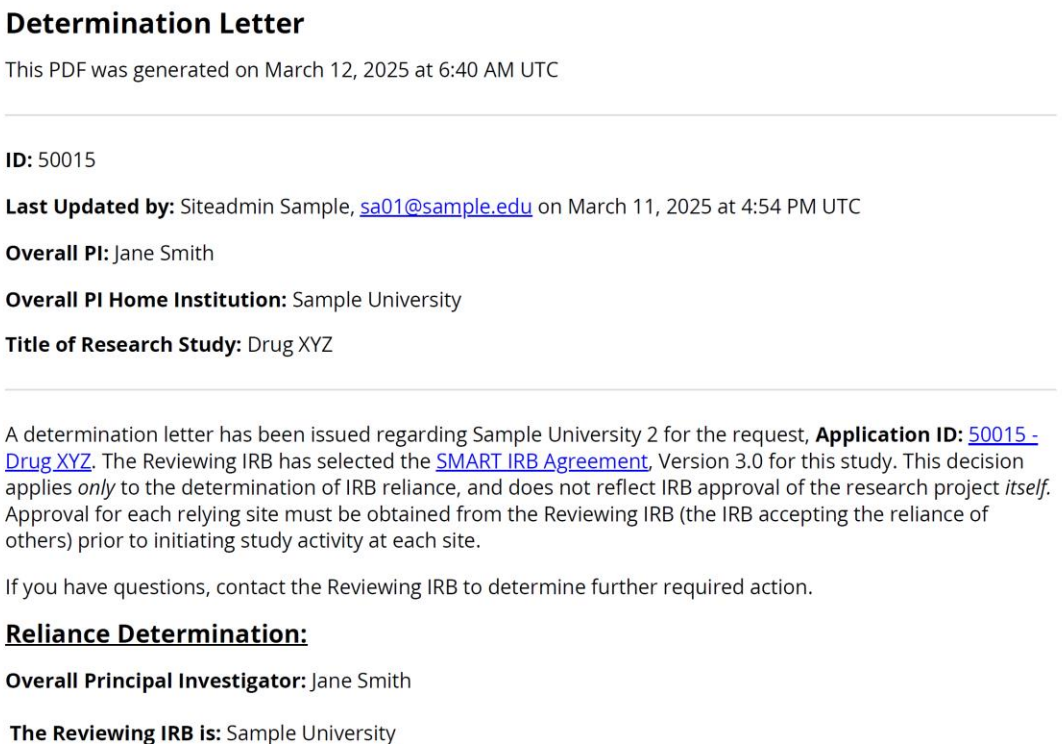
Provides a centralized place to record and track reliance arrangements on a study-by-study basis

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



Determination Letter

This PDF was generated on March 12, 2025 at 6:40 AM UTC

ID: 50015

Last Updated by: Siteadmin Sample, sa01@sample.edu on March 11, 2025 at 4:54 PM UTC

Overall PI: Jane Smith

Overall PI Home Institution: Sample University

Title of Research Study: Drug XYZ

A determination letter has been issued regarding Sample University 2 for the request, **Application ID:** 50015 - Drug XYZ. The Reviewing IRB has selected the SMART IRB Agreement, Version 3.0 for this study. This decision applies *only* to the determination of IRB reliance, and does not reflect IRB approval of the research project *itself*. Approval for each relying site must be obtained from the Reviewing IRB (the IRB accepting the reliance of others) prior to initiating study activity at each site.

If you have questions, contact the Reviewing IRB to determine further required action.

Reliance Determination:

Overall Principal Investigator: Jane Smith

The Reviewing IRB is: Sample University

- 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 considerations survey
- Develop a communication plan
- Notification of review findings and expired studies

Relying Institution – Responsibilities

- Complete local considerations 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 - Responsibilities

- Facilitate communication between sites
- Assist with completion of local considerations survey
- Understand Relying Institution's requirements
- Provide study personnel list

Tracking Reliance Requests

Methods for Tracking Reliance Requests

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

Institutional Resources Needed

Institutional Resources

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

Questions?

Using the SMART IRB Agreement

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

Carissa Minder, BSN, MS, CIP
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

How to use the SMART IRB Agreement and Documenting Reliance

Nature of the SMART IRB Agreement

The Agreement is a "common" 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 or studies covered by the Agreement

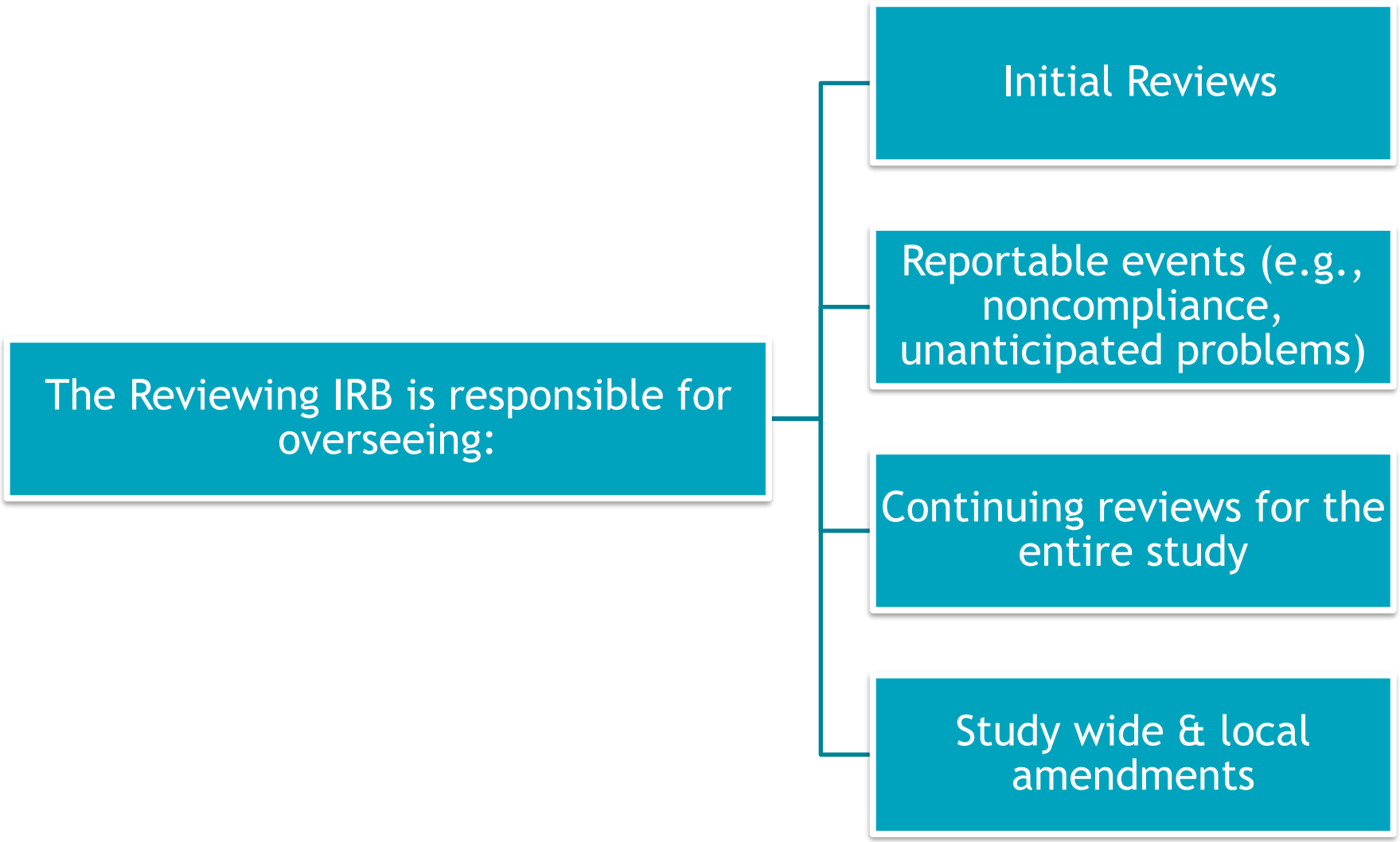
Documentation of Reliance Arrangements

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

No supplemental agreements are required

SMART IRB Agreement Division of Responsibilities

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 and Other Considerations
(1 of 2)

The Reviewing IRB considers communicated local considerations, such as:

- **Local Considerations: 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.
- **Other Considerations:** The requirements of any applicable federal laws or regulations or of relevant federal departments or agencies that are not readily apparent from the IRB submission for the research or that are specific to the Relying Institution that would affect the conduct or approval of the research at the Relying Institution.
- **Consent Forms/Scripts**: Site-specific customizations to the consent form(s)/script(s) to address legal or regulatory issues, federal department- or agency-specific requirements, or institutional requirements.
- **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 Institution communicates:

- Local Considerations that would affect the conduct or approval of the research at the Relying Institution, such as:
  - Applicable state and local laws & regulations or standards
  - Institutional policies
  - Local factors (Ancillary reviews)
  - Federal laws not readily apparent or specific to relying institution
- Information or documentation regarding its research personnel's education, training, and qualifications as requested

Conflicts of Interest(COI)

(1 of 2)

The Reviewing IRB:

- Will consider any applicable conflict of interest assurances received from Relying Institutions that are Federal Institutions and any applicable conflict of interest determinations and associated management plans provided by non-federal Relying Institutions
- 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 non-federal 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

Federal Institutions

- Provide Assurance that permissible under federal law

Consent Documents
(1 of 2)

The Reviewing IRB:

- Provides or distributes to Relying Institutions and Site Investigators (or other personnel) with informed consent forms or consent scripts (when informed consent required)
- Permits Relying Institution/Site Investigator (or other personnel) to customize limited site-specific sections of the form or script to address legal or regulatory issues, federal department or agency-specific requirements, or institutional requirements
- Provides final consent form(s) or script(s) to Relying Institutions/Site Investigators (or other personnel)

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 consistent with contract
  - Variations in costs
  - Local contact information
  - Additional items to address legal, regulatory, federal agency or institutional requirements

Policies & Procedures

The Reviewing IRB:

- Ensures that the SOPs to be followed are identified and documented (e.g., the SMART IRB SOPs will be used)
- Makes its policies and procedures policies and procedures relevant to its review and oversight of research available to Relying Institutions, when applicable and upon request

Role of Covered Entity Relying Institution

- Nothing in the agreement shifts regulatory responsibility for HIPAA compliance away from the Covered Entity Relying Institution
- Focus of HIPAA provisions is on which party will perform specific tasks required for the Relying Institution's compliance
- Relying Institution (not Reviewing IRB) drives that decision

HIPAA Privacy Rule

The Reviewing IRB:

- Provides authorization form/language (only) if Relying Institution does not
- May merge authorization and ICF unless the Relying Institution requires separate forms
- If it is responsible for providing the authorization to Relying Institutions, it ensures the authorization contains the required elements and statements and permits the use and disclosure of PHI as necessary for the research

HIPAA Privacy Rule

The Relying Institution:

- Retains regulatory responsibility for HIPAA Privacy Rule compliance
- May require its own authorization form/language to be used (does not need the agreement of Reviewing IRB/Reviewing IRB Institution)
- May identify Local Considerations mandating authorization be separate from the ICF
- If the it provides the authorization, the Relying Institution ensures the authorization contains the required elements and statements and permits the use and disclosure of PHI as necessary for the research

Authorization Forms/Language

- Relying Institution may require its own authorization form/language to be used (does not need the agreement of Reviewing IRB/Reviewing IRB Institution)
  - Reviewing IRB/Reviewing IRB Institution provides authorization form/language (only) if Relying Institution does not
- Relying Institution may identify Local Considerations mandating authorization be separate from the ICF
  - Reviewing IRB/Reviewing IRB Institution may merge authorization and ICF (only) in absence of such considerations
- The party providing the authorization ensures it contains the required elements and statements and permits the use and disclosure of PHI as necessary for the research

HIPAA Privacy Rule: Waivers of Authorization

The Reviewing IRB:

- Only reviews waiver requests if Relying Institution does not
- If responsible for reviewing HIPAA waivers, the Reviewing IRB must take any Local Considerations provided by the Relying Institution that may prevent them from granting a waiver

HIPAA Privacy Rule: Waivers of Authorization

The Relying Institution:

- Only reviews waiver requests if the Reviewing does not
- If the Reviewing IRB is responsible for reviewing HIPAA waivers, communicates any Local Considerations that may prevent the Reviewing IRB from granting a waiver of authorization

Waivers of Authorization

- Relying Institution may perform/provide waiver of HIPAA authorization (does not need agreement of Reviewing IRB)
  - Reviewing IRB reviews waiver requests (only) if Relying Institution does not
- Relying Institution may identify Local Considerations preventing approval of a waiver
  - Reviewing IRB may approve a waiver (only) in absence of such considerations
- The party performing/providing the waiver does so in accordance with HIPAA's waiver criteria

Reviewing IRBs/Reviewing IRB Institutions That Do Not Address HIPAA

- Reviewing IRBs/Reviewing IRB Institutions that are federal departments or agencies, that are not HIPAA Covered Entities, or that otherwise do not provide HIPAA authorizations or waivers (for any reason) are not obligated to do so
- This is a somewhat broader exception than earlier versions of the agreement, which expected Reviewing IRBs/Reviewing IRB Institutions to perform these tasks unless they have policies prohibiting them from doing so

HIPAA Privacy Rule: Agreement Default Position

- Reviewing IRB will provide a HIPAA authorization form/section as necessary to permit the use and disclosure of Protected Health Information ("PHI") for the research.
- Reviewing IRB Institution may (but is not required to) merge the HIPAA authorization form/section into the consent documents unless this is contrary to Relying Institution policy.
- If a Reviewing IRB Institution identifies concerns about the content of a HIPAA authorization form/section provided by a Relying Institution that may affect the rights or welfare of research participants, the Relying Institution will work with the Reviewing IRB/Reviewing IRB Institution to address such concerns.
- A Reviewing IRB Institution is under no obligation to review the content of a HIPAA authorization form/section provided by a Relying Institution.
- Unless a Relying Institution provides documentation that it has obtained or will obtain a HIPAA waiver/alteration of authorization, a Reviewing IRB will review requests for a HIPAA waiver/alteration of authorization.
- Flexibility is allowed and must be communicated

If a Relying Institution provides HIPAA authorization language, they will ensure:

- The accuracy of the language
- Compliance of the language with the HIPAA Privacy Rule

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
- Significant Complaints
- Potential noncompliance
- Suspension or restriction of study team personnel authority to conduct study

External Reporting (1 of 2)

The Reviewing IRB:

Default Procedure

- 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
- will draft the report and provide the Relying Institution the opportunity (no fewer than five (5) business days, whenever possible, to review and comment on the draft Report before sending the final report to the external recipients.

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

Relying Institution will notify the Reviewing IRB/Reviewing IRB Institution in advance if the Relying Institution determines that a Report is required.

Additional notifications the Reviewing IRB is required to make

- lapses in IRB approval of the research and any applicable corrective action plans
- communications regarding unanticipated problems, suspension or termination of IRB approval, serious and/or continuing noncompliance, and/or other regulatory compliance concerns received by the Reviewing IRB from, or made by the Reviewing IRB, to, federal human subjects research regulatory agencies

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

Default vs. Flexible Options

SMART IRB is FLEXIBLE!

Agreement has default terms for:

SOPs	Payment for Services
HIPAA Determinations	QA/ QI
HIPAA Language	Insurance
COI Review	Indemnification
IRB Notification	Reporting
Reporting	Grant Congruence

Option 1

Letter of Acknowledgement – Basic

SMART IRB

Reviewing IRB for the research noted below; and the following Relying Institution has agreed to cede IRB review to the Reviewing IRB listed below.

Letter of Acknowledgement

IRB Review will be ceded under the **SMART IRB Agreement Version 3.0**. Questions regarding this reliance arrangement should be directed to SMART IRB institutional Points of Contact.

Reviewing IRB Institution	
Relying Institution	
Research Study Title(s):	
Reviewing Institution PI	
Relying Institution Site Investigator	
SMART IRB Terms	☐ Default Implementation Applies (per Implementation Checklist) ☐ Flexible Implementation Applies (per Implementation Checklist)
This Letter of Acknowledgment was completed by the following institutional representatives (Name, Role, Date):	
Reviewing Institution POC/Designee	
Relying Institution POC/Designee	

Option 2

Letter of Acknowledgement – Default Implementation

Reviewing IRB Institution	
Relying Institution	
Research Study Title(s):	
Reviewing Institution PI/IRB#	
Relying Institution Site Investigator/IRB#	
This Letter of Acknowledgment was completed by the following institutional representatives (Name, Role, Date):	
Reviewing Institution POC/Designee	
Relying Institution POC/Designee	

Default Implementation Applies

1. Standard Operating Procedures: SMART IRB SOPs Will Apply

The Participating Institutions will follow the SMART IRB SOPs with respect to the identified research.

2. (If HIPAA Applies) HIPAA Determinations and Actions: Relying Institution Will Provide Determination

The Relying Institution or a third party named by Relying Institution will make any HIPAA determinations or perform any HIPAA Actions in connection with the research.

Option 3 Letter of Acknowledgement- Flexible Implementation

Flexible Implementation Apply

[please outline terms as mutually agreed and delete the options that do not apply; we recommend the reviewing IRB POC and relying institution POC work together to agree on flexible implementation]

1. Standard Operating Procedures:
(Default) SMART IRB SOPs Will Apply

The Participating Institutions will follow the SMART IRB SOPs with respect to the identified research.

Reviewing IRB SOPs Will Apply

The Participating Institutions will follow the Reviewing IRB SOPs *[Insert link here]* with respect to the identified research.

Other Mandated SOPs Will Apply

The Participating Institutions will follow the *[Insert SOP here]* with respect to the identified research.

2. HIPAA Determinations and Actions:
(Default if HIPAA Applies) Relying Institution or Third Party Will Provide Determination

The Relying Institution or third party will make any HIPAA determinations or perform any HIPAA Actions in connection with this research on behalf of the Relying Institution.

SOPs

Mandated Policies

- Some institutions may be subject to one or more federal department or agency-specific policies and procedures governing the conduct of the reliance relationship once it is established
- In such instance, the Mandated Policies will apply

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 Content

- Responsibilities
- Establishing a Reviewing IRB
- Establishing and Adding Sites
- Conducting Reviews
- Record Keeping
- HIPAA
- COI
- Reportable Events
- SOP 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 to make them available
- Familiarity for IRB Staff
- Institution specific
- Not harmonized

PI Education on SOPs

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

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 Institutions Need in Place for sIRB Review

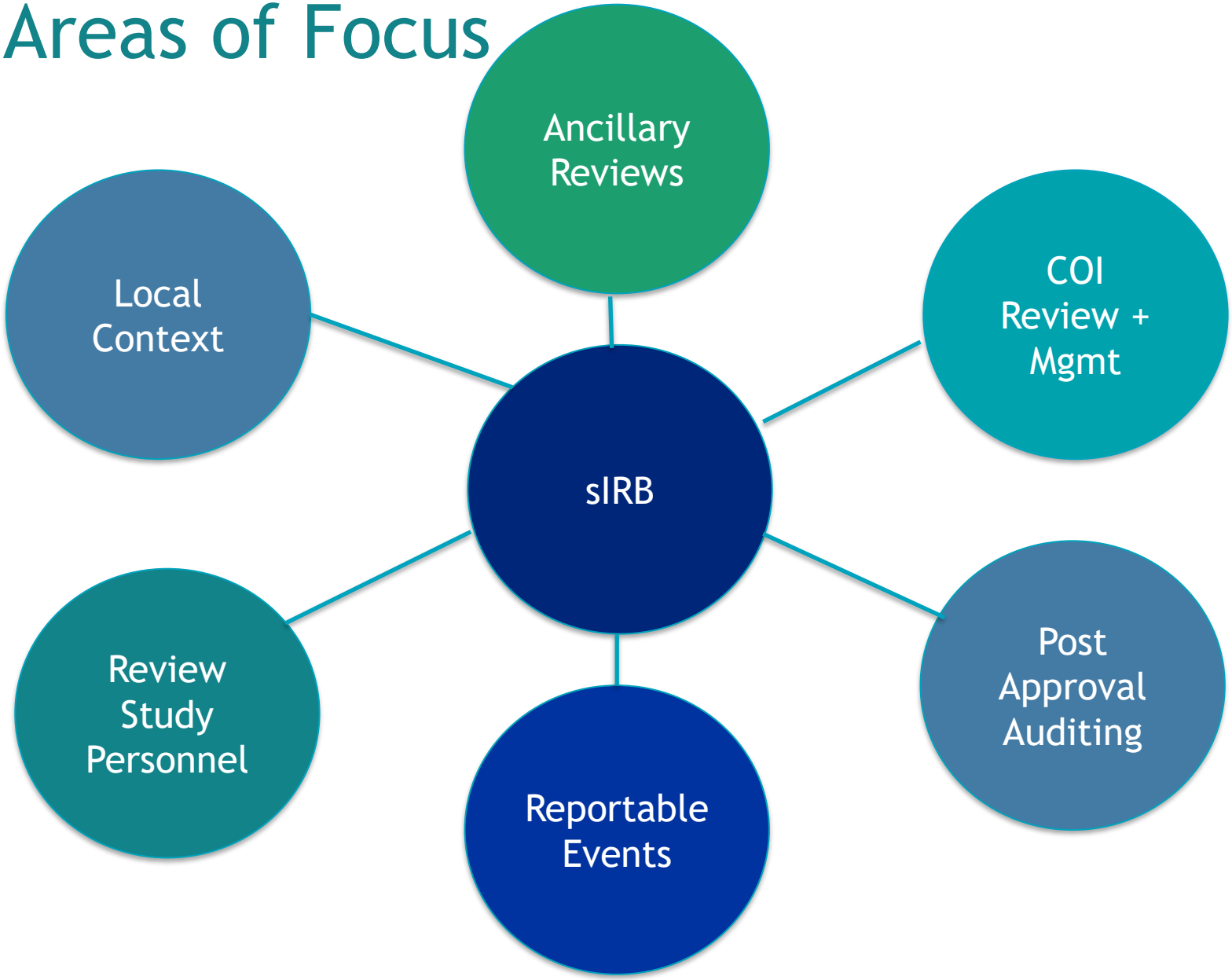
Michael Linke, PhD
Program Director, Education, SMART IRB; Chair, StrokeNet Central IRB; Adjunct Professor of Internal Medicine, University of Cincinnati

Jeremy Lavigne, MA, CIP
Senior SMART IRB Officer, SMART IRB, Harvard Catalyst | The Harvard Clinical and Translational Science Center

The sIRB world: the historical context

- Reliance has been around as long as there have been IRBs, as the exception rather than the norm
- sIRB saw a meteoric rise in the US resulting from federal mandates (NIH 2018, OHRP 2020, FDA date TBD)
- This shift in the research regulatory landscape present opportunities and challenges that continue to be grappled with to this day
- Today we will focus on 6 key challenge areas faced by HRPPs across the US in light of the new regulatory landscape

Key Areas of Focus



Recommendations for the Harmonization of Ancillary Reviews

Ancillary Reviews Working Group of the SMART IRB Harmonization Steering Committee

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

Challenges with Ancillary Reviews

- 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

Ancillary Review Process

- 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

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

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

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

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

Single IRB Review: Reportable Events

Review of Reportable Events Working Group of the SMART IRB Harmonization Steering Committee

What the Guidance Contains

- Definitions of key types of reportable events (e.g., noncompliance, unanticipated problems)
- Considerations for Reviewing IRBs, Relying Institutions, and Research Teams
- Recommended List of Events that Likely Constitute Serious Noncompliance
- Recommended List of Events that Likely Constitute Continuing Noncompliance

Challenges
Variability Observed Amongst Organizations

- Definitions of noncompliance, serious noncompliance, and continuing noncompliance
- Which events must be promptly reported to the Reviewing IRB
- Timeframe for reporting to the Reviewing IRB
- Responsible party for submitting reports to the Reviewing IRB
- Who triages and assesses reports of noncompliance

Considerations for Reviewing Institutions

- Aligning policy definitions with federal regulations
- Disseminating policies for reportable events.
- Event-reporting mechanisms.
- Limiting the events reported/triaging events.
- Notifying study teams and relying site HRPPs.
- Reporting to OHRP, FDA, and other entities.

Considerations for Relying Institutions

- Develop a policy and process for reporting on sIRB studies
- Ensuring site events are reported to the Reviewing IRB.
- Promptly providing feedback on external reports.
- Providing input on corrective action plans.

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

Recommendations for the Harmonization of Local Considerations

Local Considerations Working Group of the SMART IRB Harmonization Steering Committee

Not Yet Published

Local Considerations Challenges

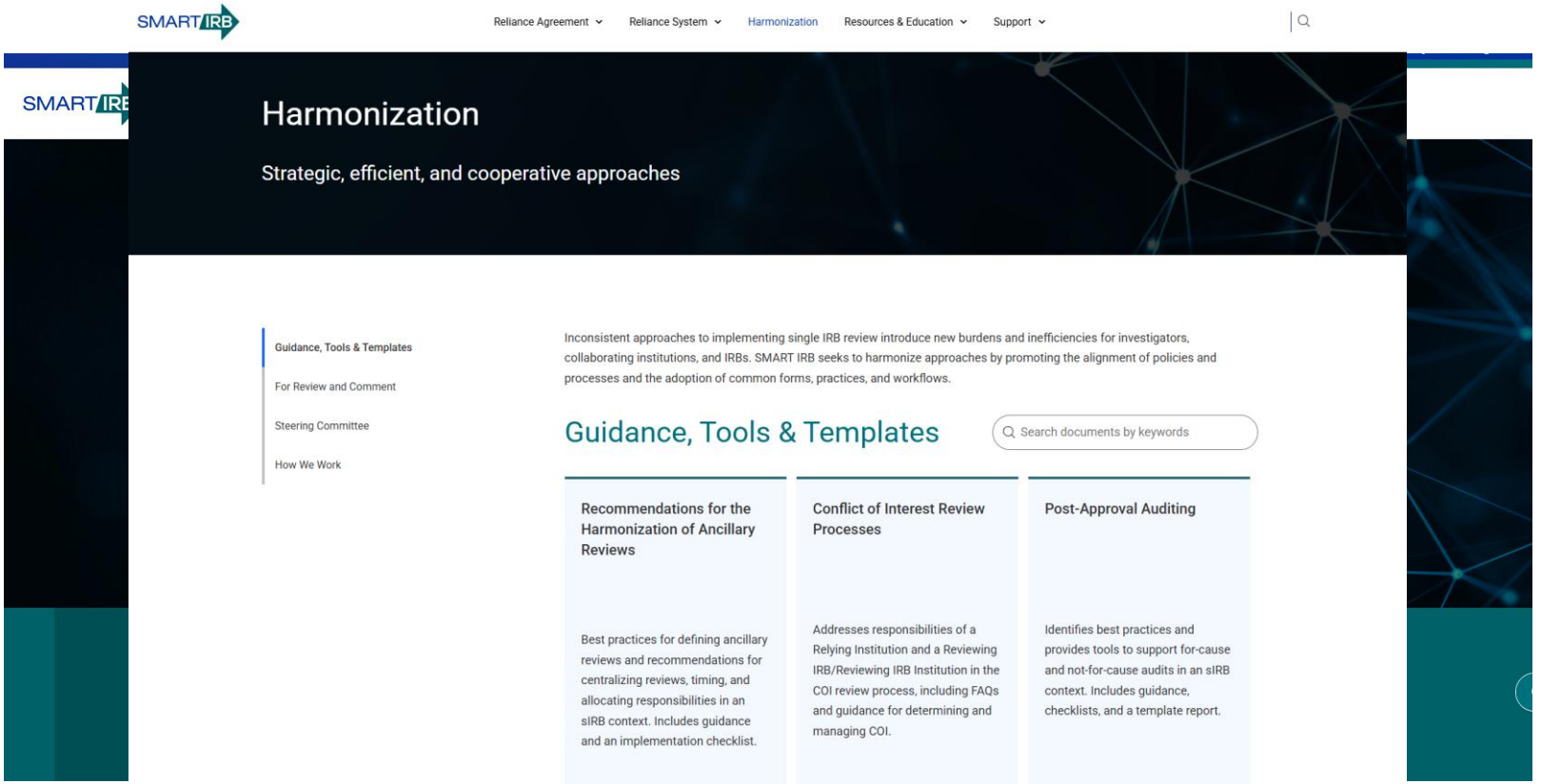
- Defining 'local context' or 'local considerations'. What information should you provide to the Reviewing IRB?
- Who is responsible for completing, verifying, and sharing this information with the reviewing IRB?
- For Reviewing IRBs: How to manage variations in local study practice throughout the life of a study?
- For Relying institutions, how to ensure local requirements are maintained?

Local Considerations Opportunities

- Standardize institutional information (profile) and adopt universal forms/questionnaires
- Create or reframe local considerations guidance for the life of the study, educate study teams on expectations
- Harmonization: common workflow for local considerations (study development initial review, after initial IRB approval)
- More to follow!

Harmonization Guidance

All Harmonization materials referenced here can be found at https://smartirb.org/harmonization/



Questions? We are here to help!

Reliance System Overview

Polly Goodman, CIP
Senior Associate Director, SMART IRB, Harvard Catalyst | The Harvard Clinical and Translational Science Center

Jeremy Lavigne, MA, CIP
Senior SMART IRB Officer, SMART IRB, Harvard Catalyst | The Harvard Clinical and Translational Science Center

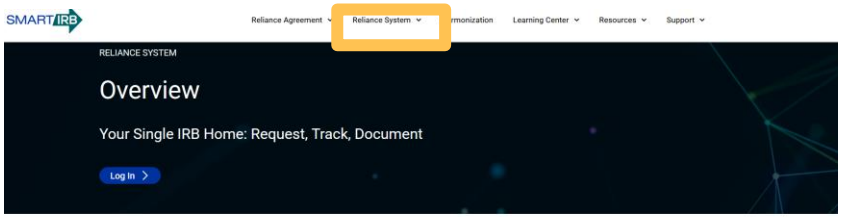
SMART IRB Reliance System

- Reliance System is your home to document, manage, and track reliance requests for your institution(s)
- Launched March 2025 alongside Version 3.0
- Replaced the previous ‘Joinder’ and ‘Online Reliance System’ with a single federated platform
- Includes increased security and much-requested features like management of multiple institutions, permissions, and much more!

What does the Reliance System do?

- Assign user roles and permissions to meet the needs of your institution
- Allows seamless management of numerous institutions with one single platform
- When using Reliance System, no need to use LOA or IREx
- Use of Reliance System is optional; work with your institution to determine which mechanism of reliance works best for you

Reliance System Overview



Reliance System Overview

With the SMART IRB Reliance System, seamlessly request, track, and document reliance arrangements with other Participating Institutions*.

Join SMART IRB & Manage Institutional Details

(for Institutional Leadership and IRB/HRPP Administrators/ Staff only)

- Join SMART IRB Reliance Agreement V3.0
- Sign the optional Indemnification Addendum
- Manage Institutional Profile(s)
- Establish user permissions
- Access institutional sIRB activity reports

Request, Track, & Document Single IRB Arrangements

(for Investigators/Study Team Members and IRB/HRPP Administrators/Staff)

- Simplify selection of a single IRB
- Manage communication with institutions & investigators
- Clearly request edits & identify next steps
- Track reliance details for your studies
- Add new sites at any time

Download Video Transcript

Video Chapters

- Introduction to the Reliance Request Process (0:00
- Who can submit requests (0:46)
- Creating a New Request (1:07)
- Adding a New Site to a Request (3:57)
- Providing Site Details (5:34)
- Reliance Pre-check (7:47)
- Reviewing IRB Decision (8:37)
- Tracking Request Status (9:07)
- Entering a Site's Reliance Decision (9:27)
- Issuing Determination Letter (9:57)

Step-by-step guidance to support Reliance System users.

Study Teams

Learn how investigators and study team members can centrally request, track, and document reliance arrangements for their studies.

View Guides >

Points of Contact (POCs)

Learn how IRB/HRPP administrators or staff and/or institutional leadership can join the SMART IRB Agreement, manage institutional information and user permissions, and track and document their institution's reliance arrangements.

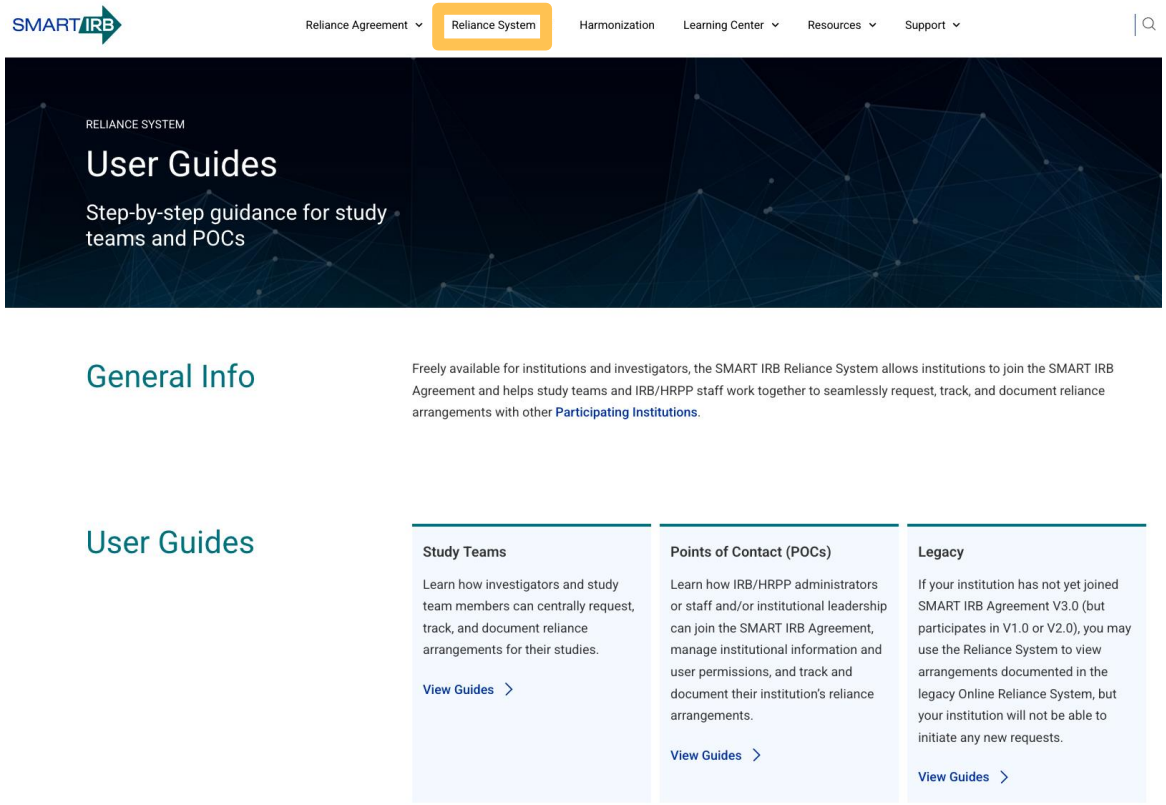
View Guides >

Legacy

If your institution has not yet joined SMART IRB Agreement V3.0 (but participates in V1.0 or V2.0), you may use the Reliance System to view arrangements documented in the legacy Online Reliance System, but your institution will not be able to initiate any new requests.

View Guides >

User Guides


SMART IRB
Reliance Agreement
Reliance System
Harmonization
Learning Center
Resources
Support
RELIANCE SYSTEM
User Guides
Step-by-step guidance for study teams and POCs
General Info
Freely available for institutions and investigators, the SMART IRB Reliance System allows institutions to join the SMART IRB Agreement and helps study teams and IRB/HRPP staff work together to seamlessly request, track, and document reliance arrangements with other Participating Institutions.
User Guides
Study Teams
Learn how investigators and study team members can centrally request, track, and document reliance arrangements for their studies.
View Guides
Points of Contact (POCs)
Learn how IRB/HRPP administrators or staff and/or institutional leadership can join the SMART IRB Agreement, manage institutional information and user permissions, and track and document their institution's reliance arrangements.
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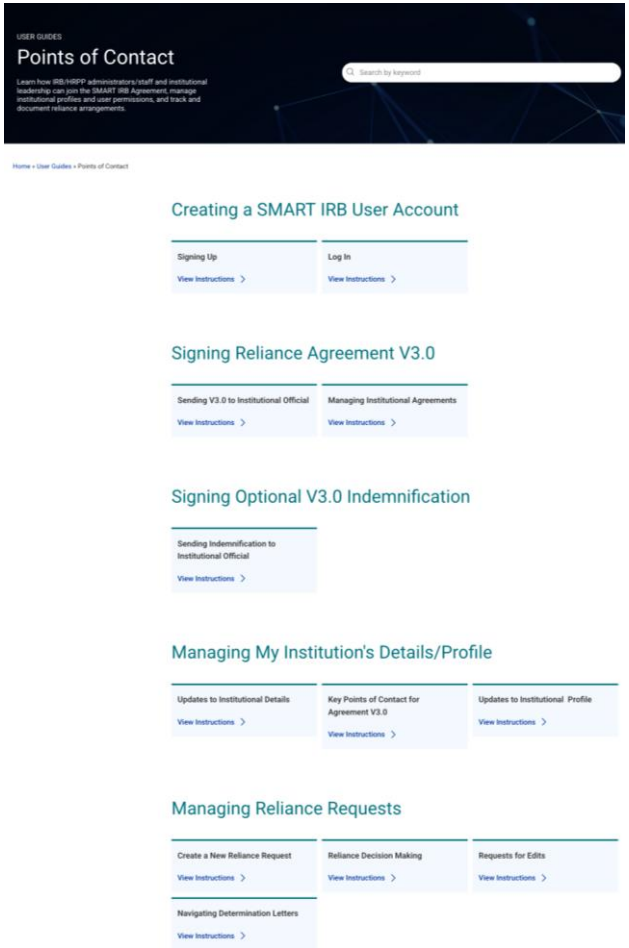
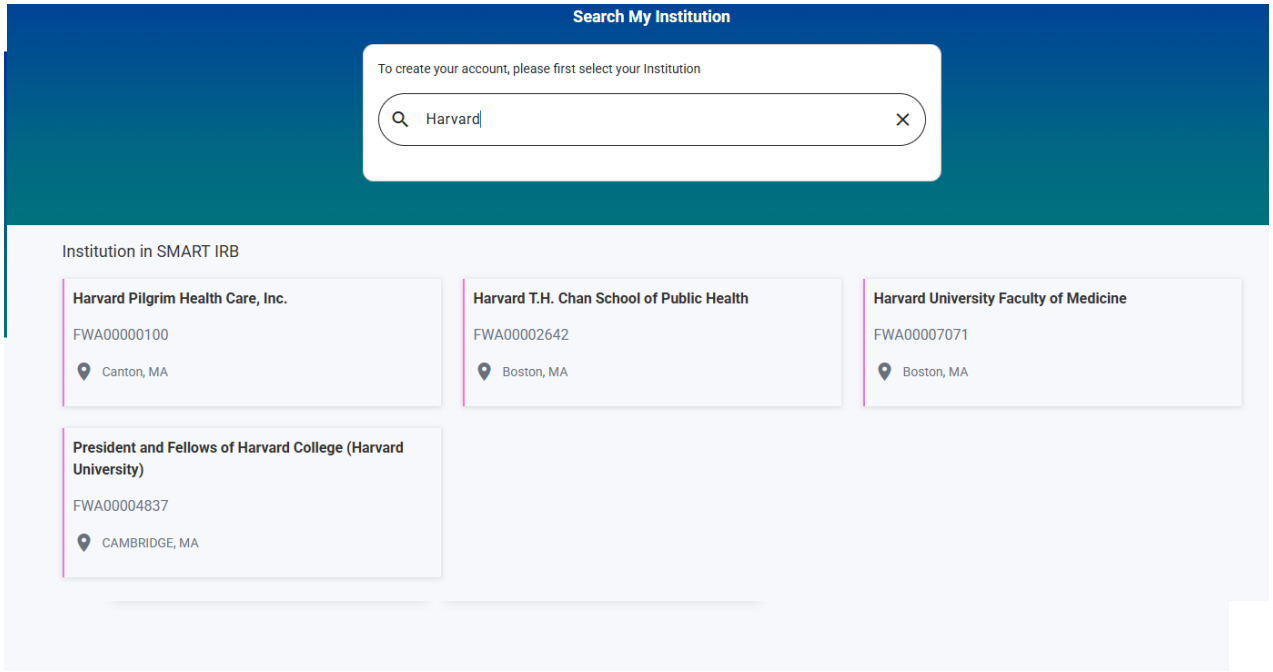
View Guides


USER GUIDES
Points of Contact
Creating a SMART IRB User Account
Signing Up
View Instructions
Log In
View Instructions
Signing Reliance Agreement V3.0
Sending V3.0 to Institutional Official
View Instructions
Managing Institutional Agreements
View Instructions
Signing Optional V3.0 Indemnification
Sending Indemnification to Institutional Official
View Instructions
Managing My Institution's Details/Profile
Updates to Institutional Details
View Instructions
Key Points of Contact for Agreement V3.0
View Instructions
Updates to Institutional Profile
View Instructions
Managing Reliance Requests
Create a New Reliance Request
View Instructions
Reliance Decision Making
View Instructions
Requests for Edits
View Instructions
Navigating Determination Letters
View Instructions

Registration, Login, and Identity Access Management Systems

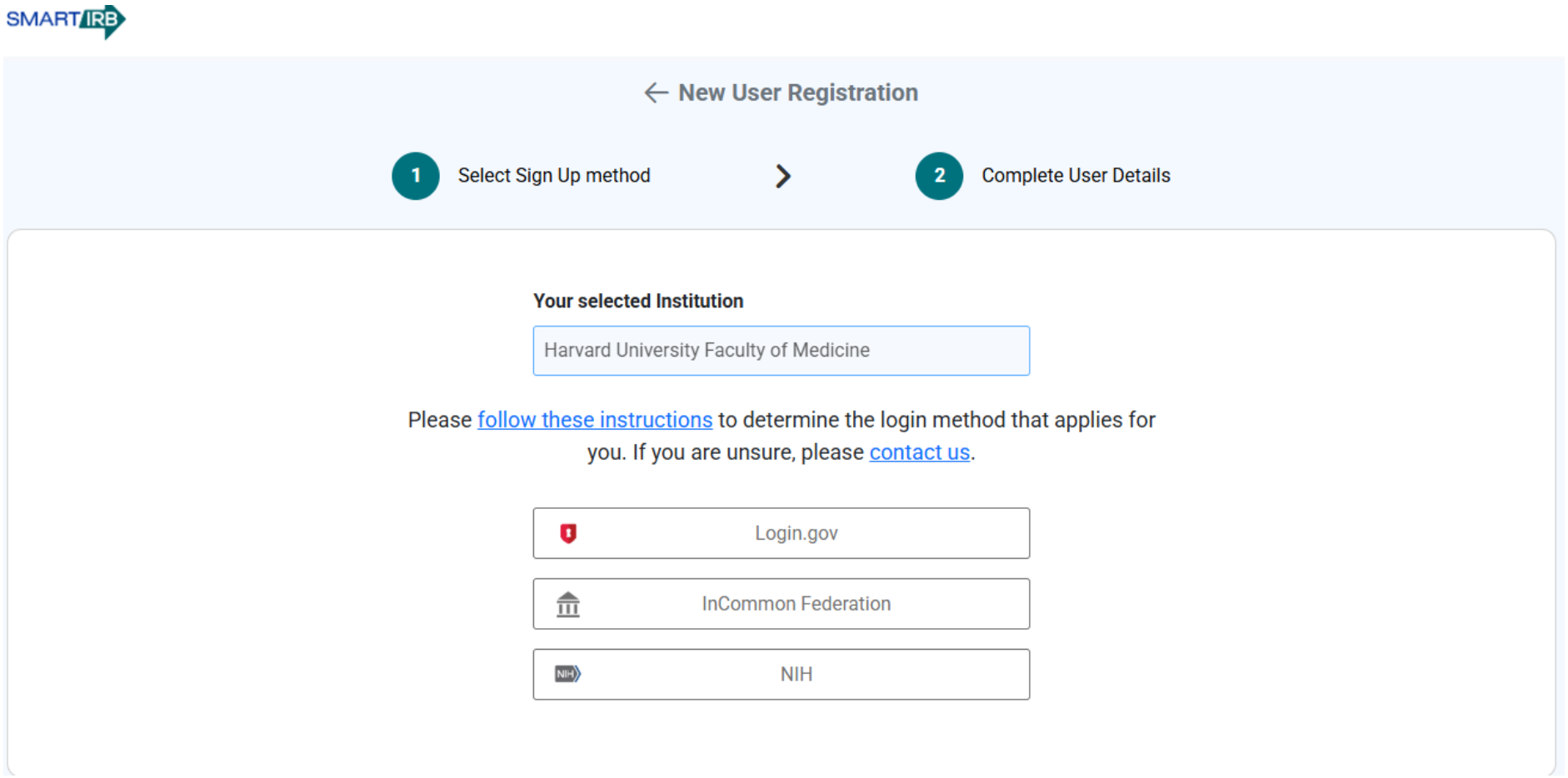
- **Log In** – Users with an active account in the old Joinder or Online Reliance System
- **Register** – Users that did not have an active account previously in a SMART IRB system

How to register as a new user

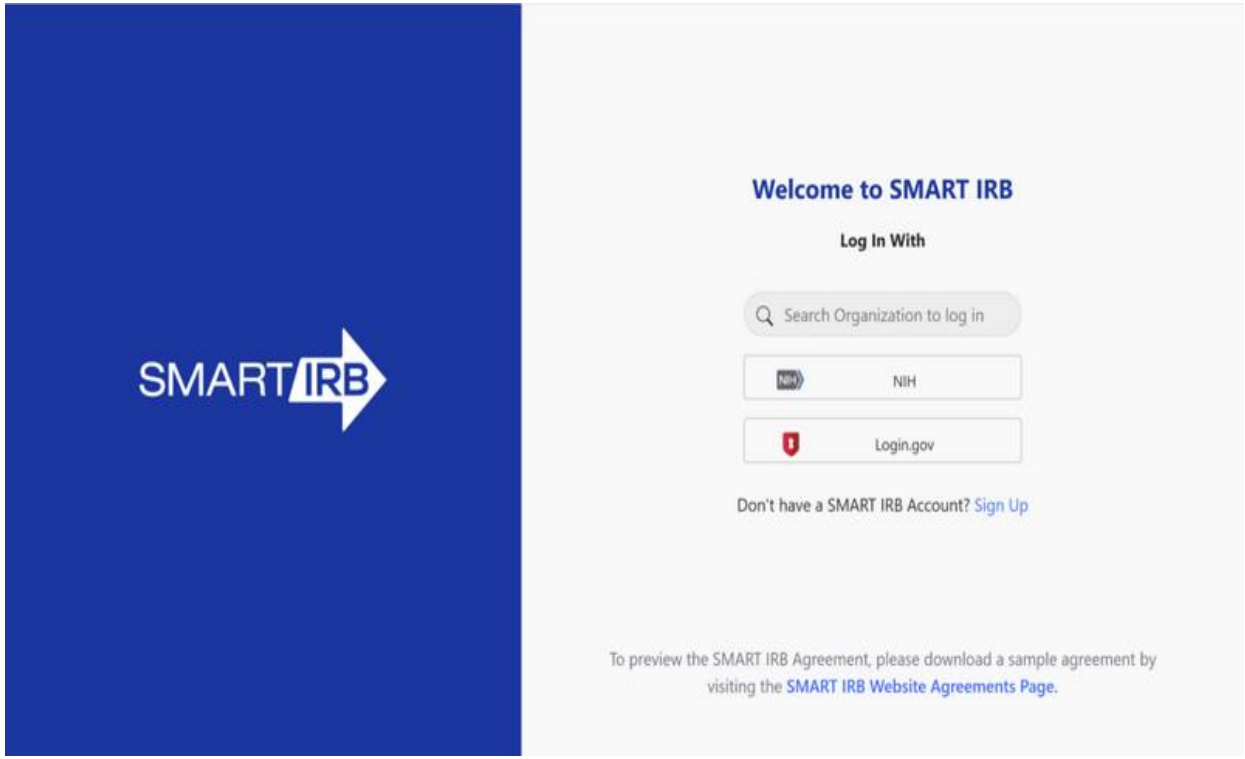


- Enter Institutional Name or Assurance
- Select the Institution that applies for you
- If your institution does not appear in the drop down:
  - Check the SMART IRB Participating Institutions List
  - If institution is not a signatory to any SMART IRB Agreement, contact Help@smartirb.org

Registration, continued



Log In Options

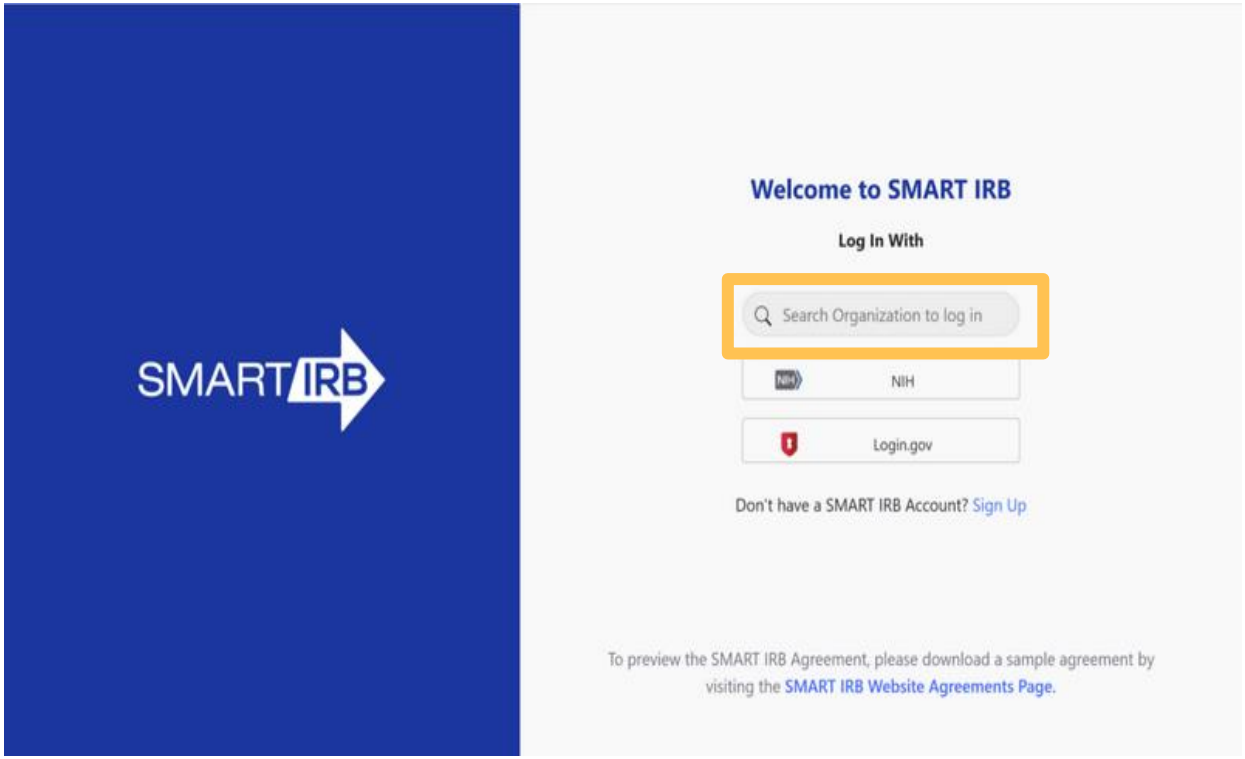


SMART IRB Reliance System has 3 Options to Log In

- **Single Sign On (SSO)**
- **NIH**
- **Login.gov**

Why? Each option meets federal requirements as **Identity & Access Management Systems (IAMS)** for secure access to sensitive information.

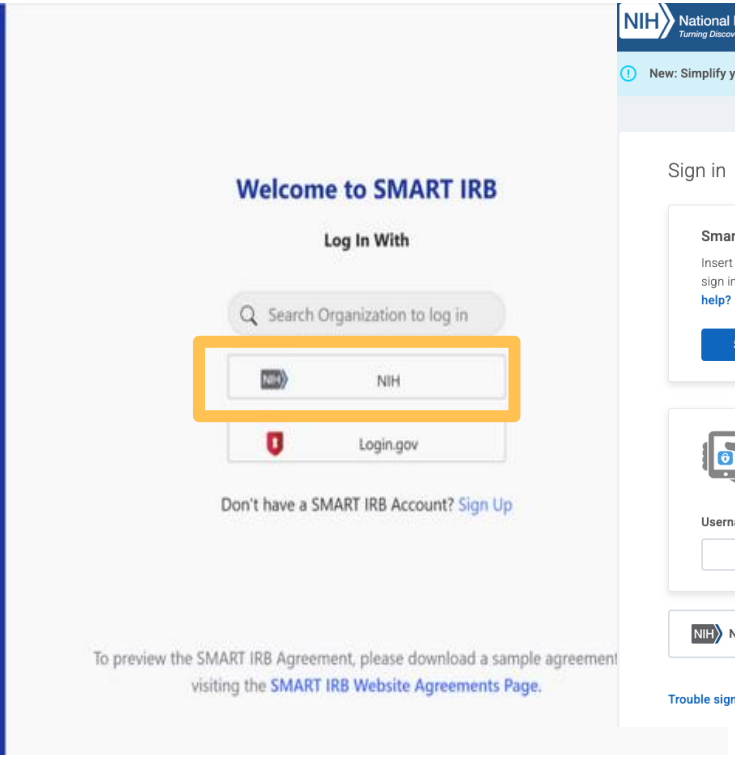
Registration and Login: SSO

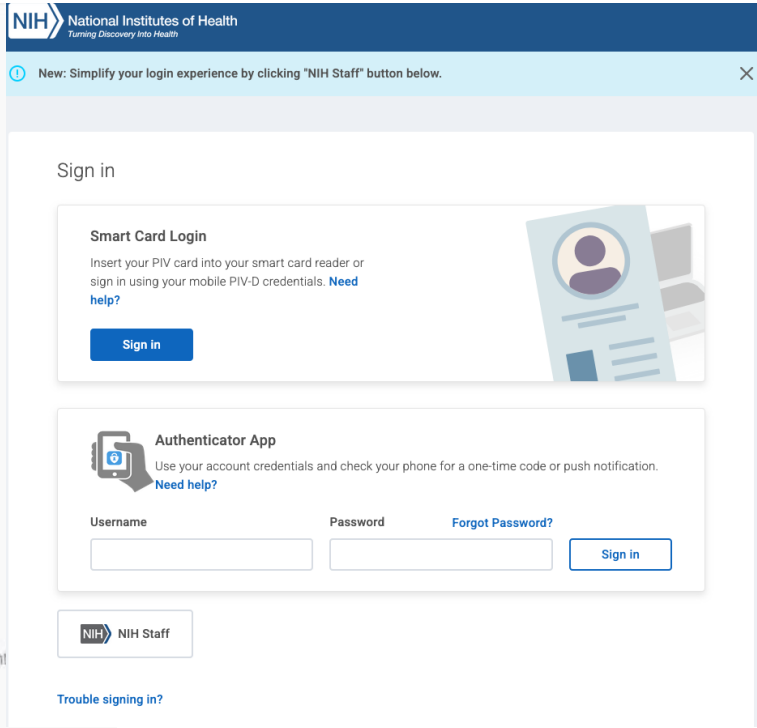


Log In with SSO

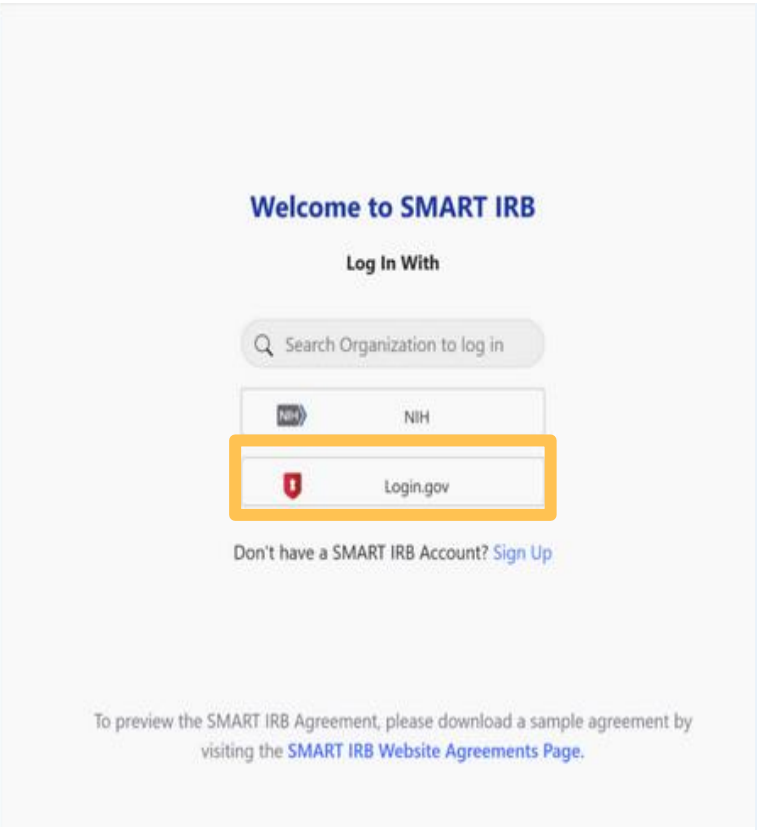
- Find Institution in search box
- List is generated from InCommon Federation network database
- All SSO may be not available
- If SSO email does *not* match your SMART IRB system email, please contact the Help desk for assistance.

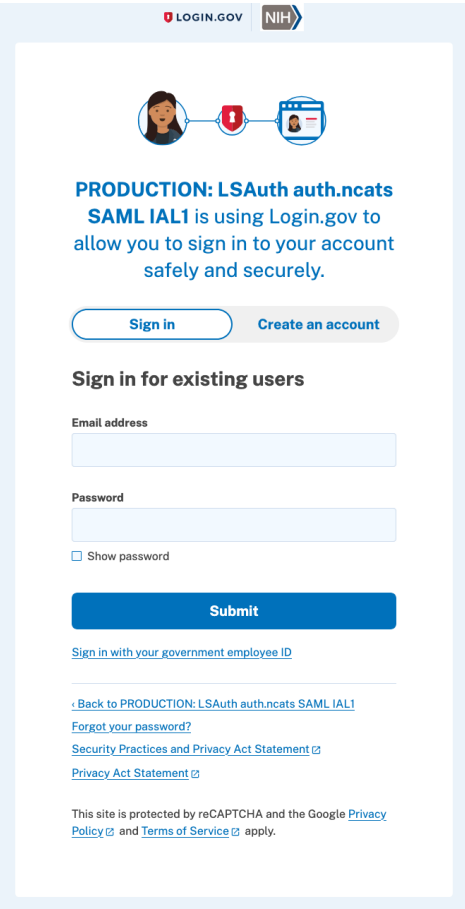
Registration and Login (NIH)





Registration and Login (Login.gov)





Troubleshooting? Reach Out!

- If you run into any difficulties along the way, we are happy to be of assistance. Reach us at the helpdesk at help@smartirb.org or via the Support Center pathway

SMART IRB Reliance System Demo

Common Reliance System Questions

- How do I know whether my institution is part of InCommon?
- I or another user is receiving an ‘Unauthorized’ message when logging in. What does this mean?
- Can I activate user accounts at my institution?
- Can I add reliance requests for V2.0 institutions?
- Who can edit a Reliance System submission?
- At what point can a submission be edited?

Common Reliance System Questions

- Can I (HRPP professional) submit reliance requests on behalf of study teams?
- Does my PI or site investigator need to have a Reliance System account to be listed on a request?
- Who should be assigned as POC and Alt POC?
- What is ‘Contact for Notices’, and who should be listed there?
- Can I update documents throughout the life of the study in the Reliance System?

Reliance System Questions, continued

- What permissions should I give my general users?
- If my institutional official changes, do I need to re-submit a V3.0 Joinder agreement in the Reliance System?
- What is the benefit of completing the institutional profile?
- My study has closed, or a site's participation has ended. Do I need to take any steps in the reliance system?
- I am experiencing an issue or have a system enhancement. Who should I contact?

Questions? We are here to help!

Day 2 Thursday, October 30, 2025 12:00 PM-3:00 PM

Time	Presentation Topic	Presenter
12:00 – 12:05 pm	Welcome	Mike Linke
12:05 – 1:05 pm	Communication	Ada Sue Selwitz Stacey Goretzka
1:05 - 1:50 pm	Training Study Teams	Nichelle Cobb Mike Linke
1:50 – 2:00 pm	Break	
2:00 – 2:25 pm	Harmonization Guidance Review	Nichelle Cobb
2:25 - 2:55 pm	Resources Recap and Frequently Asked Questions	Polly Goodman Jeremy Lavigne
2:55 - 3:00pm	Final Questions & Wrap Up	Mike Linke