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

Day 2 - October 30, 2025

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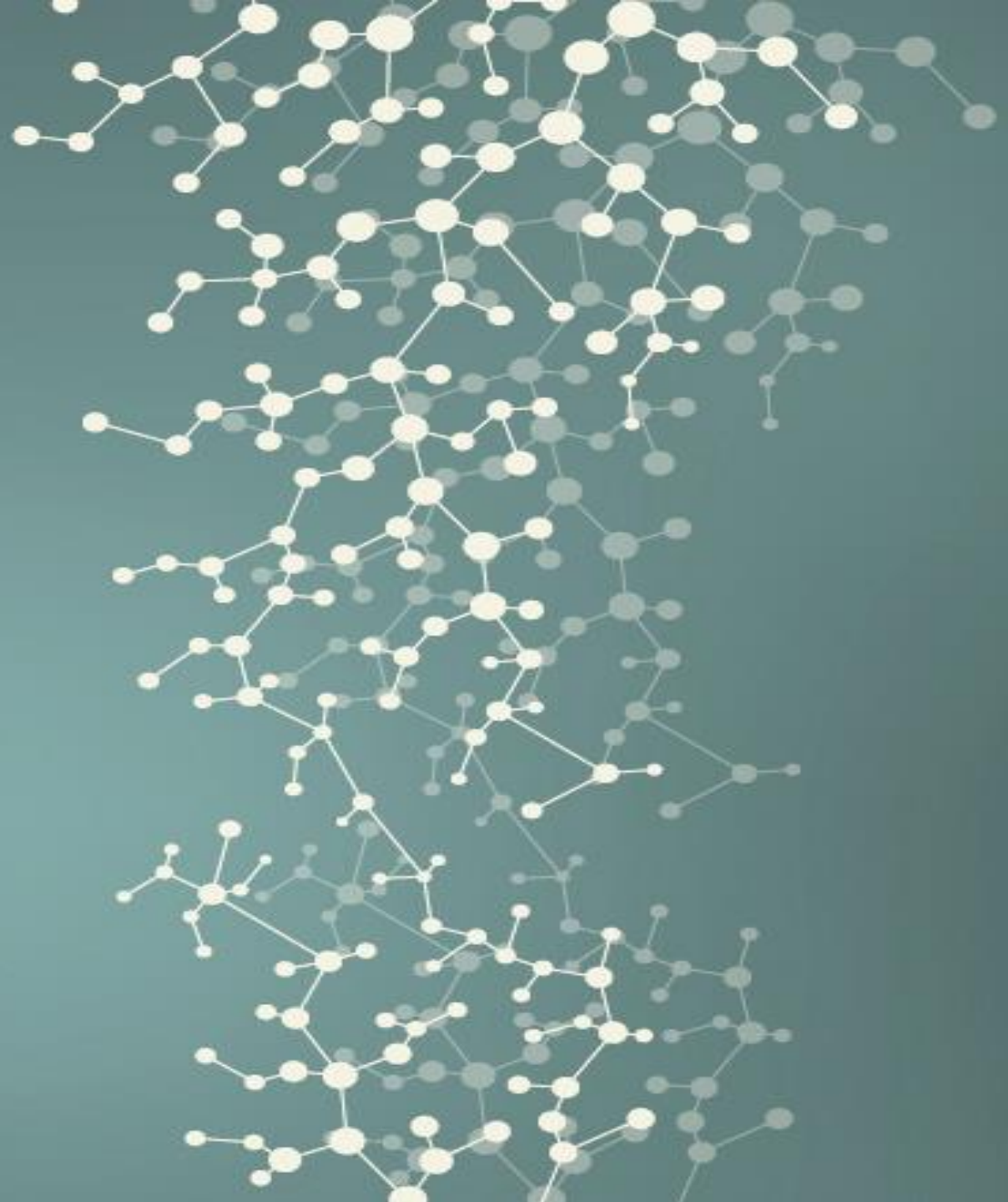
Michael Linke, PhD
Program Director, Education, SMART IRB

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

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 2 Overview

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

Onward!

Smart IRB Bootcamp
Single IRB: Communication!!! Communication!!! Communication!!!

Presenters

Stacey C. Goretzka, CIP
Independent Consultant
Smart IRB Ambassador

Ada Sue Selwitz, MA
Executive Integrity/Compliance Advisor, University of Kentucky
Smart IRB Ambassador

Acknowledgements

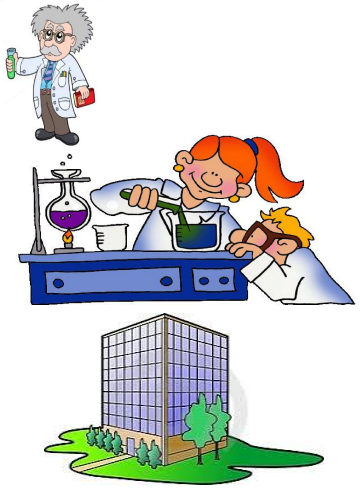
- Nichelle Cobb, Association for the Accreditation of Human Research Protection Programs
- John Heldens, University of Colorado-Denver
- Jennifer Hill, University of Kentucky
- Carissa Minder, Washington University-St. Louis

What we will discuss this session

- Who are the key players in a Single IRB 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/Study Team
- Relying Institution

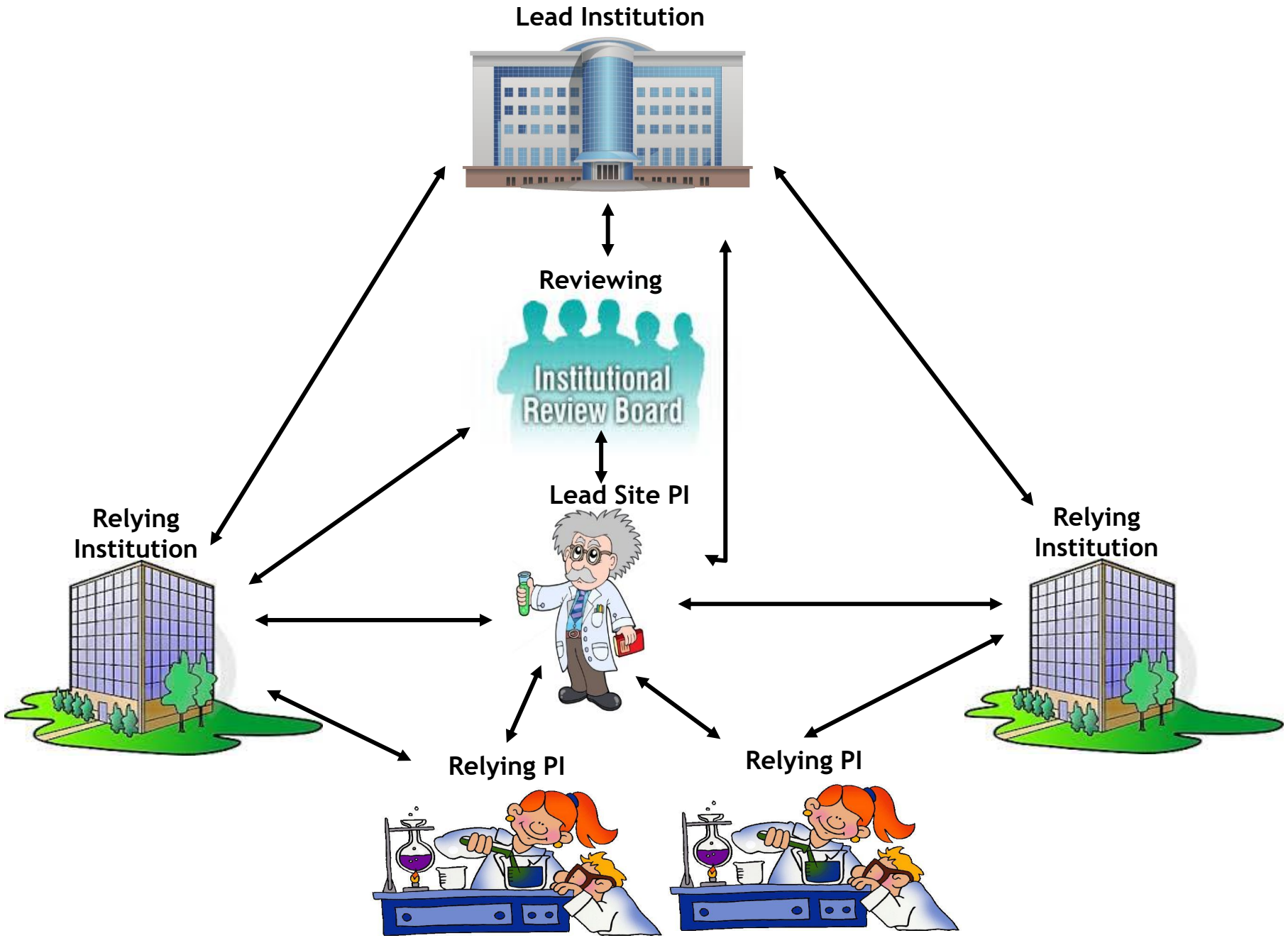


*Other players: Funding/Regulatory Agency or Coordinating Center, etc.

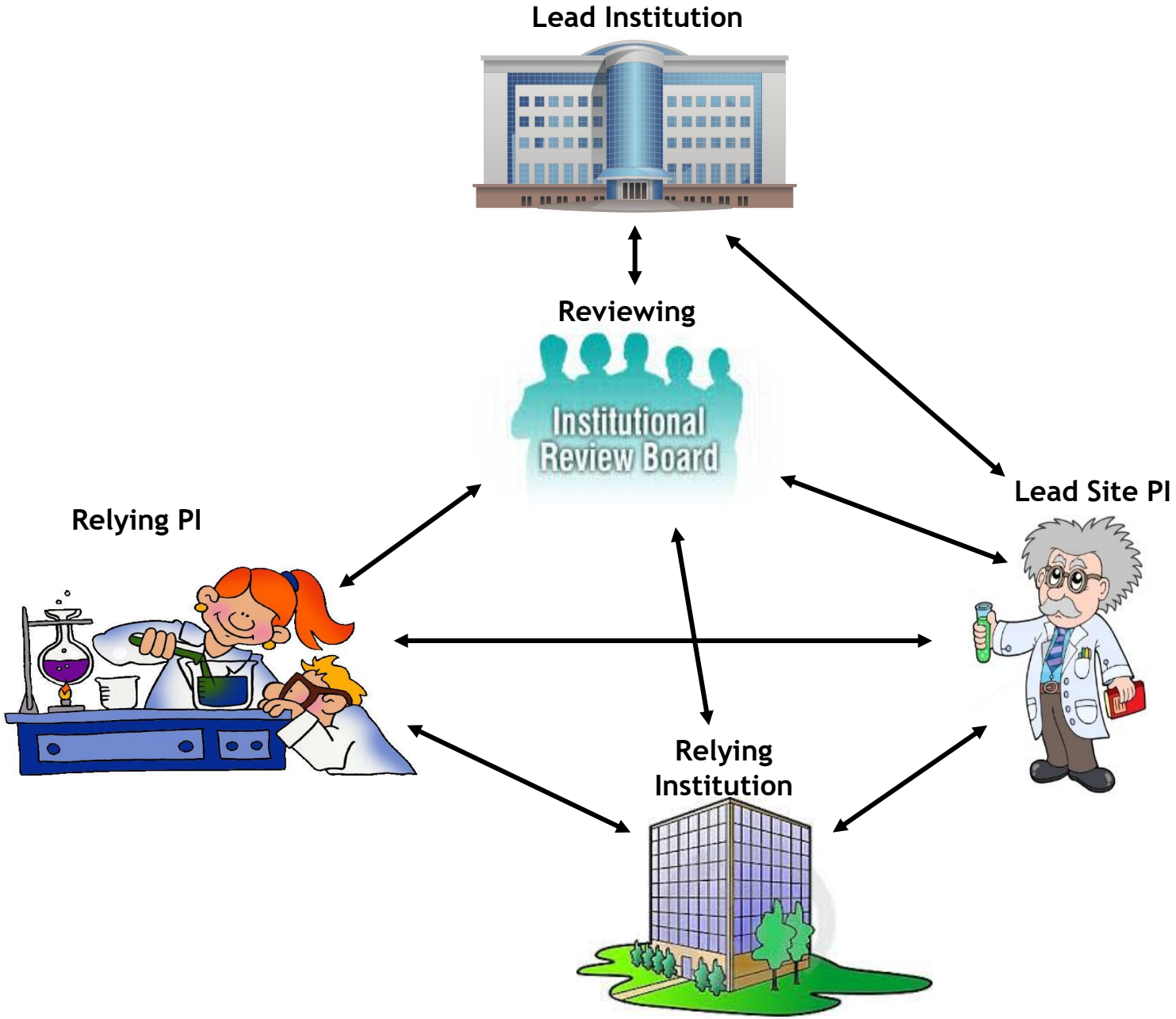
Two Popular Communication Models

- Lead PI Communication Model: 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, or a variety of other models, but the Smart IRB Resource documents are usually based on the Lead PI Communication Model

Lead PI Model



Relying PI Model



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, Protocol-specific Document)

Hint: Who communicates what? (Responsibilities)

- 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 requirements, the specific protocol procedures, institution policies/procedures, and institutional resources.

REVIEWING IRB Communication Responsibilities: Provide to Lead PI, Relying Institution and Relying PI

- Reviewing IRB policies and Procedures
- Communication Plan (identifying flow of communication)
- Implementation Plan (confirming who does what and use of default implementation in the agreement vs flexible implementation)
- Request for Local Considerations Information (e.g., applicable state or local laws, 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 Considerations Information such as state and local laws and regulations, institutional policies, local factors
  - Consent Form with customized site-specific information addressed
  - 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

LEAD/OVERALL PI & STUDY TEAM

Communication Responsibilities for the Lead PI Communication Model

- 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.)

LEAD/OVERALL PI & STUDY TEAM

Communication Responsibilities for the Lead PI Communication Model (Cont.)

- 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 considerations, 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

RELYING PI & STUDY TEAM Communication Responsibilities for the Lead PI Communication Model

- 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

RELYING PI & STUDY TEAM Communication Responsibilities for the Lead PI Communication Model (Cont.)

- 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.)

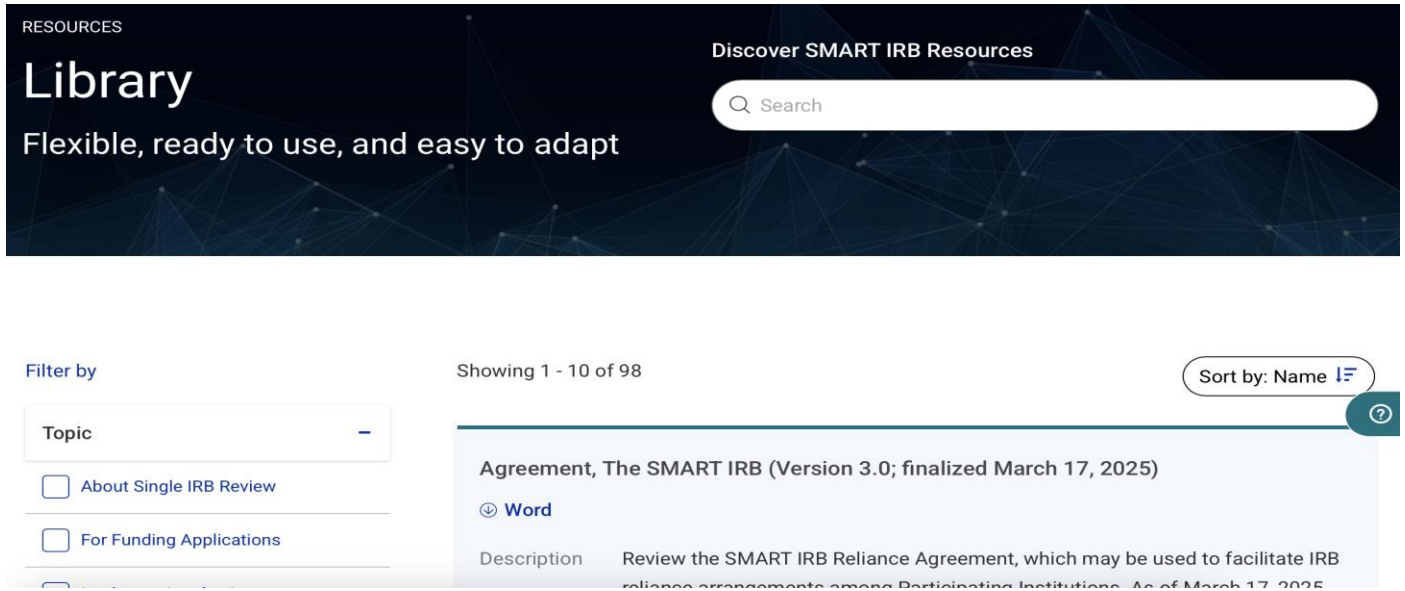
If the institution does not have any assigned HRPP/IRB Reliance staff, then the Relying PI will have increased responsibilities for communication.

Smart IRB Resources for Lead/Overall PI & Relying PI and Study Team

- Relying Site Investigator Guidance and Checklist https://smartirb.org/wp-content/uploads/Relying-Investigator-Guidance-and-Checklist.pdf
- Potential Relying Site Study Team Survey document https://smartirb.org/wp-content/uploads/Relying-Site-Team-Survey.pdf

Smart IRB Resources for all Key Players

- https://smartirb.org/resources/#l



- Implementation Checklist
- Template Communication Plan

Purpose of Form: This form documents the terms by which participating institutions will follow for the identified research. This form is intended to be validated by Reviewing IRB POC and Relying Institution POCs.

Implementation Checklist and Documentation Tool

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

Reviewing IRB	
1. Notification of Acceptance or Declination of Ceded Review	☐ **(DEFAULT) OPTION 1 – Reviewing IRB Will Provide Notification** The Reviewing IRB will notify the Overall PI (or designee), the Site Investigator(s), and involved Participating Institution(s) whether the identified research is accepted for Ceded Review and, if accepted, the designation of the Reviewing IRB and

Purpose of the form: This form should be used to document key communication roles/responsibilities for specific studies. Reviewing IRB/HRPPs may use this form to document general expectations of study teams and relying site IRB/HRPPs, or less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team. The SMART IRB recommends this form be kept up to date with all key information throughout the life of a study.

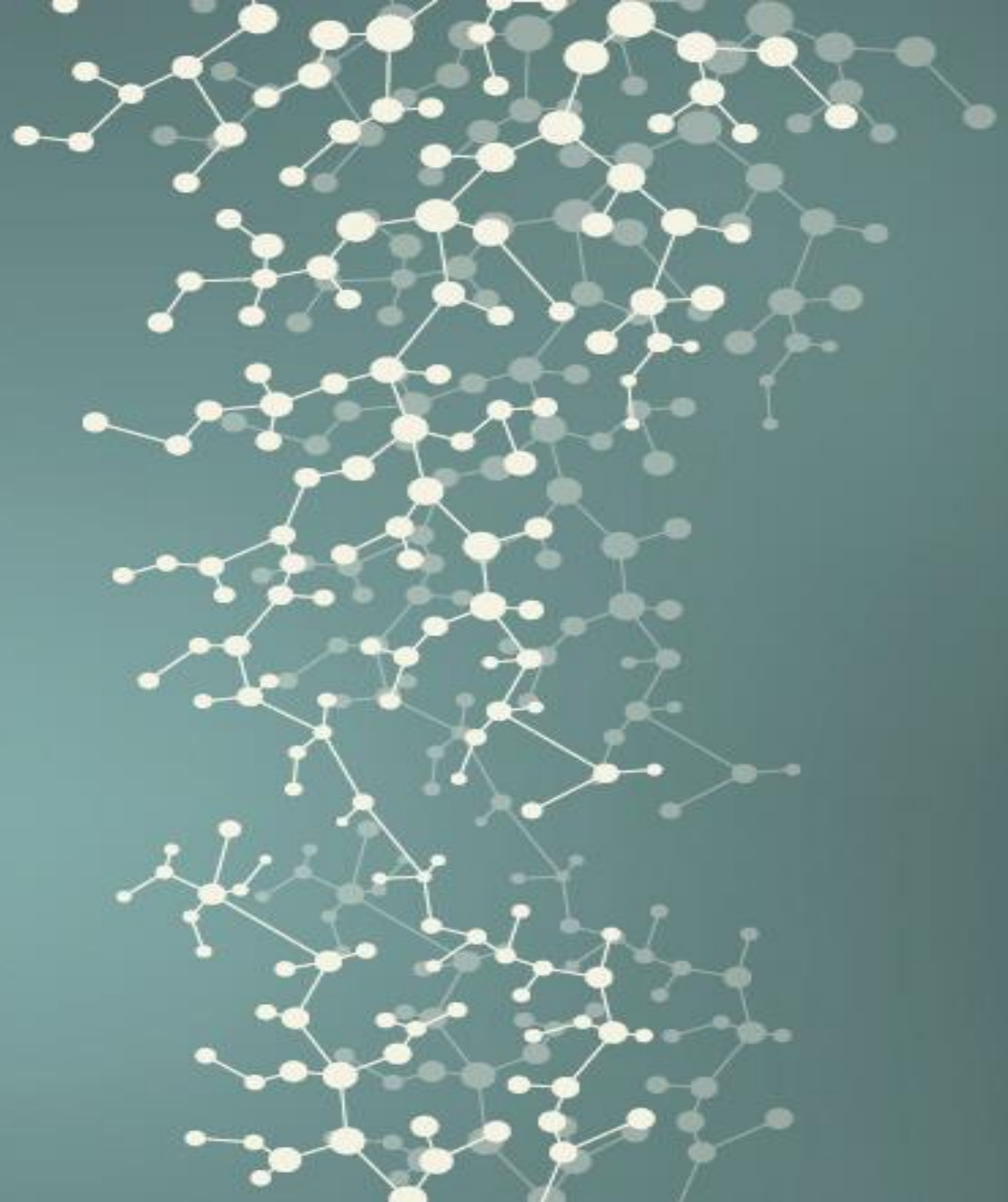
Communication Plan Template

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 – Representative:** 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 – Representative:** Main person responsible for communication with the Lead Study Team regarding the ceded study

AREA OF COMMUNICATION RESPONSIBILITY	RESPONSIBLE PARTY (*TYPICAL PARTY IDENTIFIED)	NOTES
Conflict of Interest: Providing applicable Relying Site Conflict of Interest management plans to the Reviewing IRB	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Study Team Training & Qualifications: Providing confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Local Considerations: Collecting local information related to Relying Institution's local and state laws; federalwide assurance applicability (e.g. "checking the box"); institutional requirements; unique cultural, language, geography, or socioeconomic factors; or standard of care	☐ Relying Site Study Team* ☐ Relying Site POC* ☐ Lead Study Team ☐ Other, specify:	
Local Considerations: Providing completed local context information to the	☐ Relying Site Study Team ☐ Relying Site POC	

Example Communicating Conflict of Interest



Determine who will perform the conflict of interest analysis

Relying Institution?

Reviewing IRB?

Implementation Checklist

5. Conflict of Interest
Sections 5.8 and 6.6

☐ **(DEFAULT) OPTION 1 – Relying Institution Will Perform Conflict of Interest Analyses of their Research Personnel Under Their Policies**
The Relying Institution 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 research. The Relying Institution'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.

☐ **OPTION 2 – Reviewing IRB will Perform Conflict of Interest Analyses of the Relying Institution's(s') Research Personnel Under Its Policies**
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 research. 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.

☐ **OPTION 3 – Relying Institution and Reviewing IRB have Agreed on an Alternate Plan for Conflict of Interest Analyses**

[DESCRIBE ALTERNATE PLAN]

Communication Plan

AREA OF COMMUNICATION RESPONSIBILITY	RESPONSIBLE PARTY (*TYPICAL PARTY IDENTIFIED)	NOTES
Conflict of Interest: Providing applicable Relying Site Conflict of Interest management plans to the Reviewing IRB	☐ Relying Site Study Team ☐ Lead Study Team* ☐ Relying Site POC ☐ Other, specify:	

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/Considerations Forms
  - SMART IRB Protocol-Specific Document

PROTOCOL-SPECIFIC DOCUMENT

To Collect Institutional Requirements from Relying Institutions

Resource

https://smartirb.org/wp-content/uploads/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.

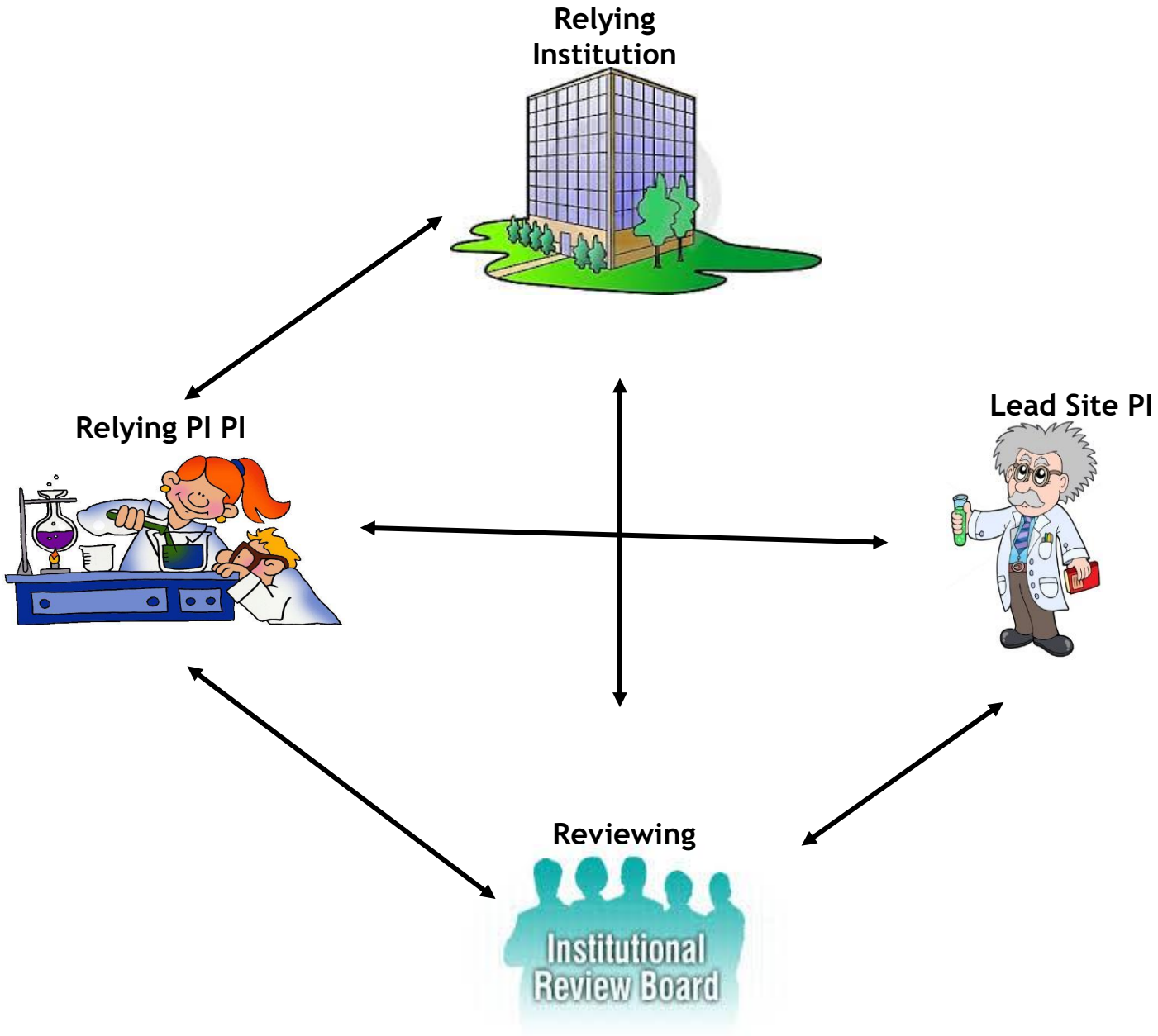
Lead PI Responsibilities for Conflict of Interest

- 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.

Reviewing IRB Responsibilities for Conflict of Interest

- 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.*

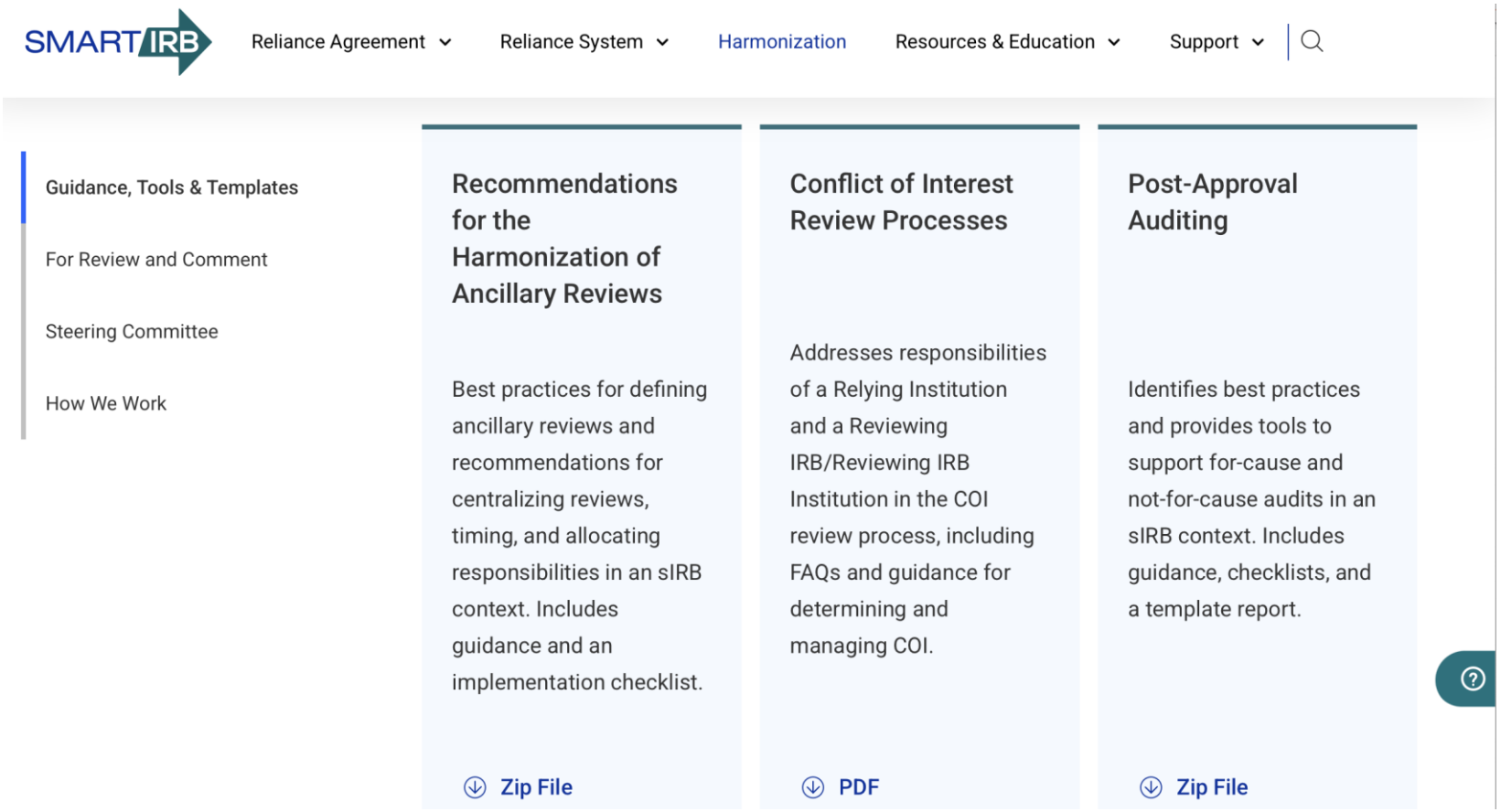
Conflict of Interest - Lead PI Model



Smart IRB Resources

- SMART IRB Harmonization Document
  - Conflict of Interest Review Process for sIRB Review

https://smartirb.org/harmonization/



Communicate Early and Often!

Things should be very clear from the beginning and through the life of the study

Use and understand the agreement

Use the implementation checklist

Use the template communication plan

Use the protocol-specific document

What do you do when there are disagreements or miscommunications?

Communication Tips

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

He said / She Said - A Case Example

- 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?

He said / She said - A Case Example
What should Reviewing IRB do?

- Assume the PI is right?
  - Be confused?
  - Get mad?
  - Waste time wondering?
  - Read their minds?
- Send an email or call the Relying Institution/IRB and ask?
  - Be Calm
  - Be Flexible
  - Solve it!

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

Relying Institution Position

- Ask questions/clarification or 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

Pro Tips on Communication

Be Willing to Talk and Listen

To other IRBs, to PIs, to anyone.

Don’t be Shy

Ask, Be responsive, Keep it short

Pro Tips on Communication (continued)

Assume Good Intentions

- It's for you, not for the other person
- Assume a friendly tone in emails, calls, etc.

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 Single IRB 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)

Reminder: Communicate Early and Often!

Things should be very clear from the beginning and through the life of the study

Use and understand the agreement

Use the implementation checklist

Use the template communication plan

Use the protocol-specific document

Training Study Teams

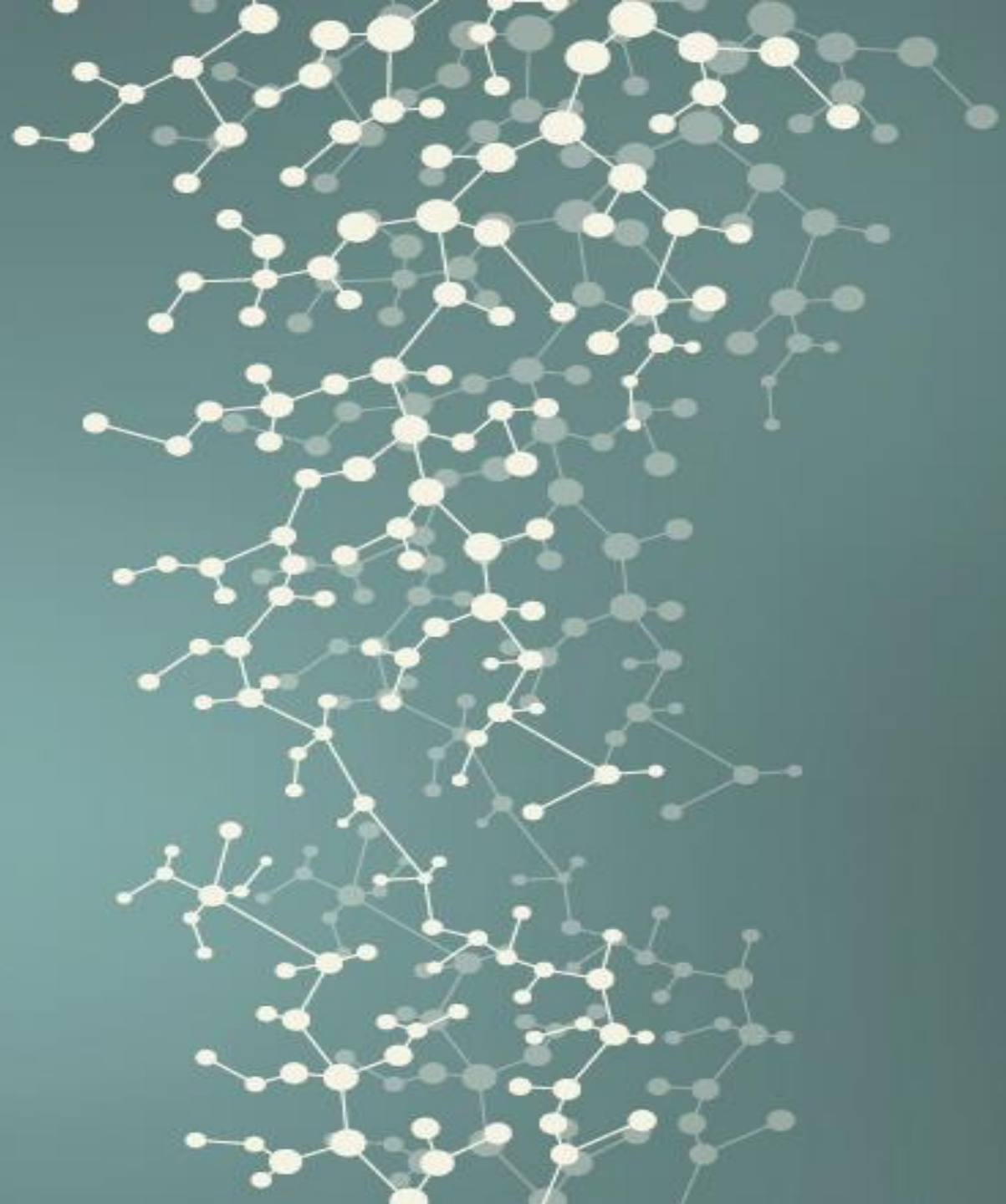
Nichelle Cobb, Senior Advisor for SMART IRB; Senior Advisor for Strategic Initiatives, Association for the Accreditation of Human Research Protection Programs (AAHRPP)

Mike Linke, SMART IRB Program Director for Education and Training; Chair, University of Cincinnati IRB and StrokeNet Central IRB; Adjunct Professor of Internal Medicine, University of Cincinnati

What We Will Cover

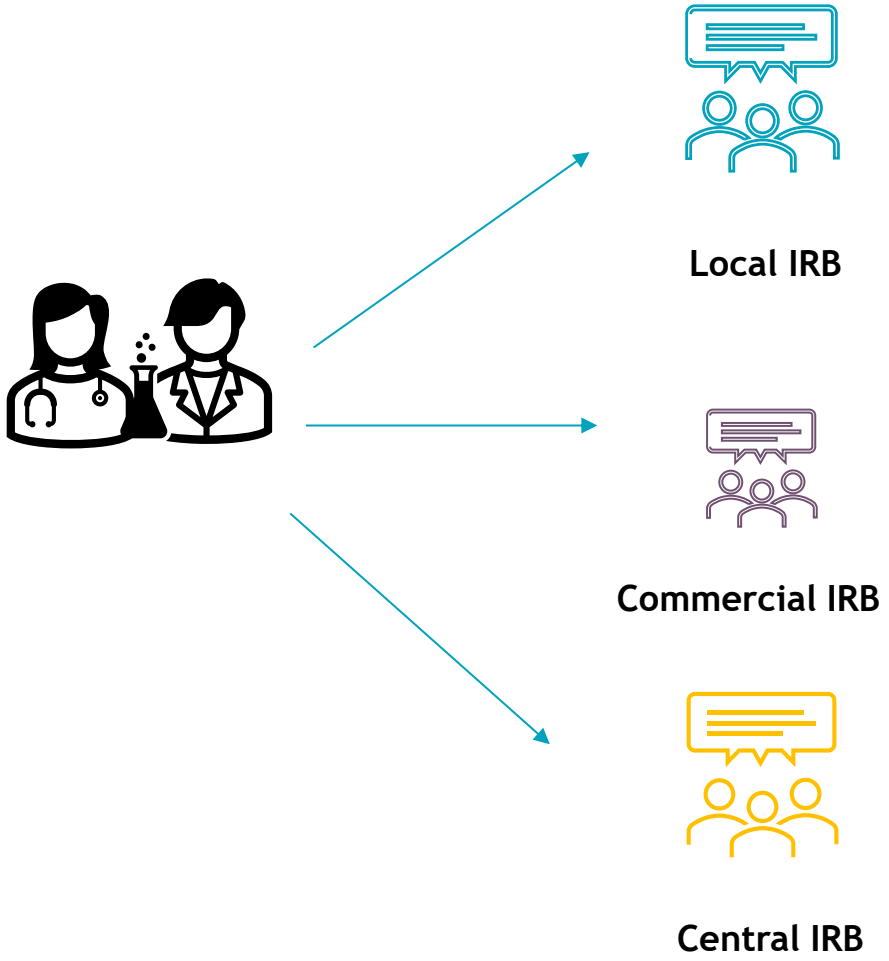
- Overview the effect of single IRB on study teams and impact on training needs
- SMART IRB resources that can be leveraged to train study teams
- Strategies for study team training and education

Study teams need to know what is different about single IRB compared to when they use their internal IRBs



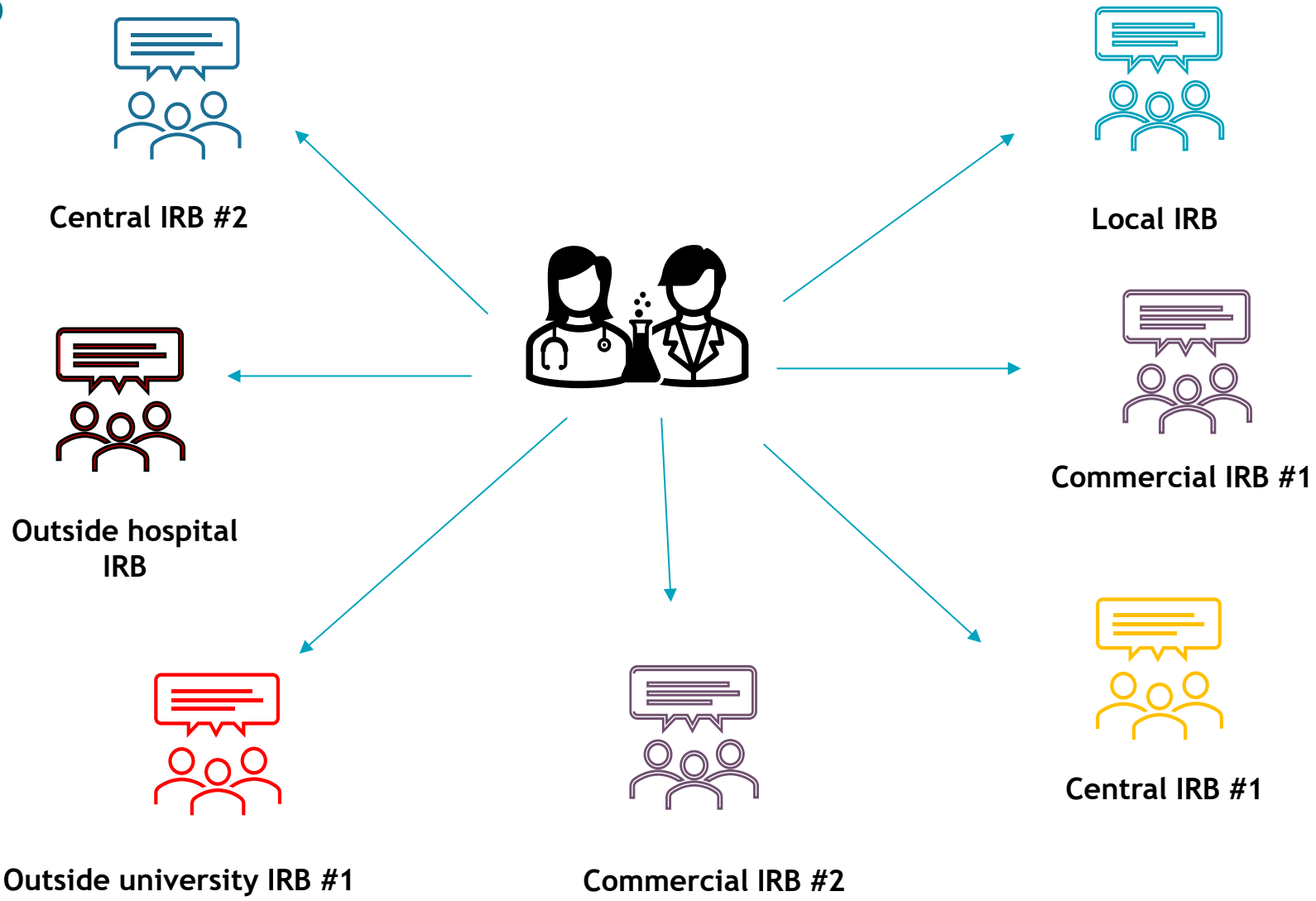
Before Single IRB

Researchers usually worked with their home institution IRBs and sometimes an independent IRB (aka commercial IRB) for industry-sponsored research and perhaps a disease-focused central IRB (e.g., the NCI Central IRB or StrokeNet IRB)



After Single IRB

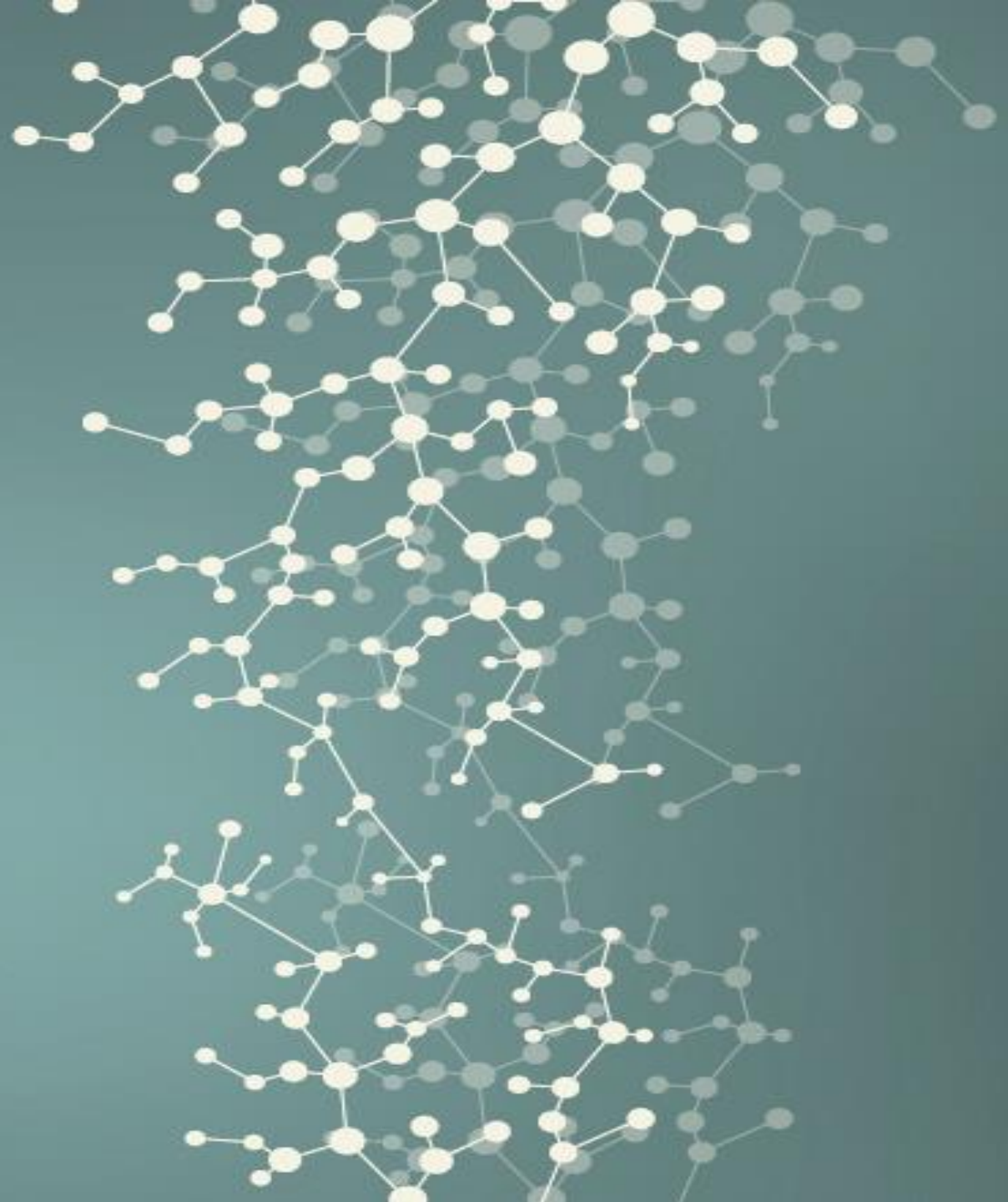
Researchers are working with so many more IRBs



Key Differences for Research Teams

- Budgeting for single IRB
- When they need to talk to their local IRB/HRPP office
- Additional steps for obtaining IRB approval
- Variations in forms, processes, and policies across IRBs both for setting up reliance agreements and IRB review
- Providing local context information
- Additional responsibilities, especially if they are the Lead Study Team
- What they need to report to their institution when they use an external IRB

Grants and Budgets



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

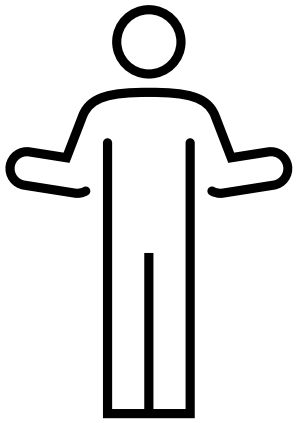
May need new platforms to disseminate documents to study teams

Federal Grants that include Multisite Human Participants Research

What IRBs said to research teams:

Before Single IRB Review

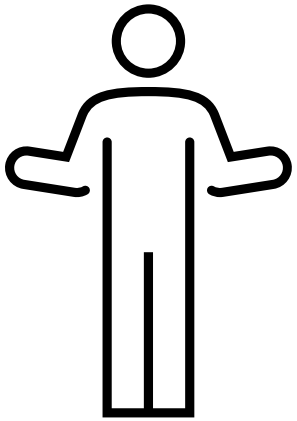
Come back to us when you get your funding!



The IRB

After Single IRB Review

Please talk to us ASAP when you are preparing your grant!



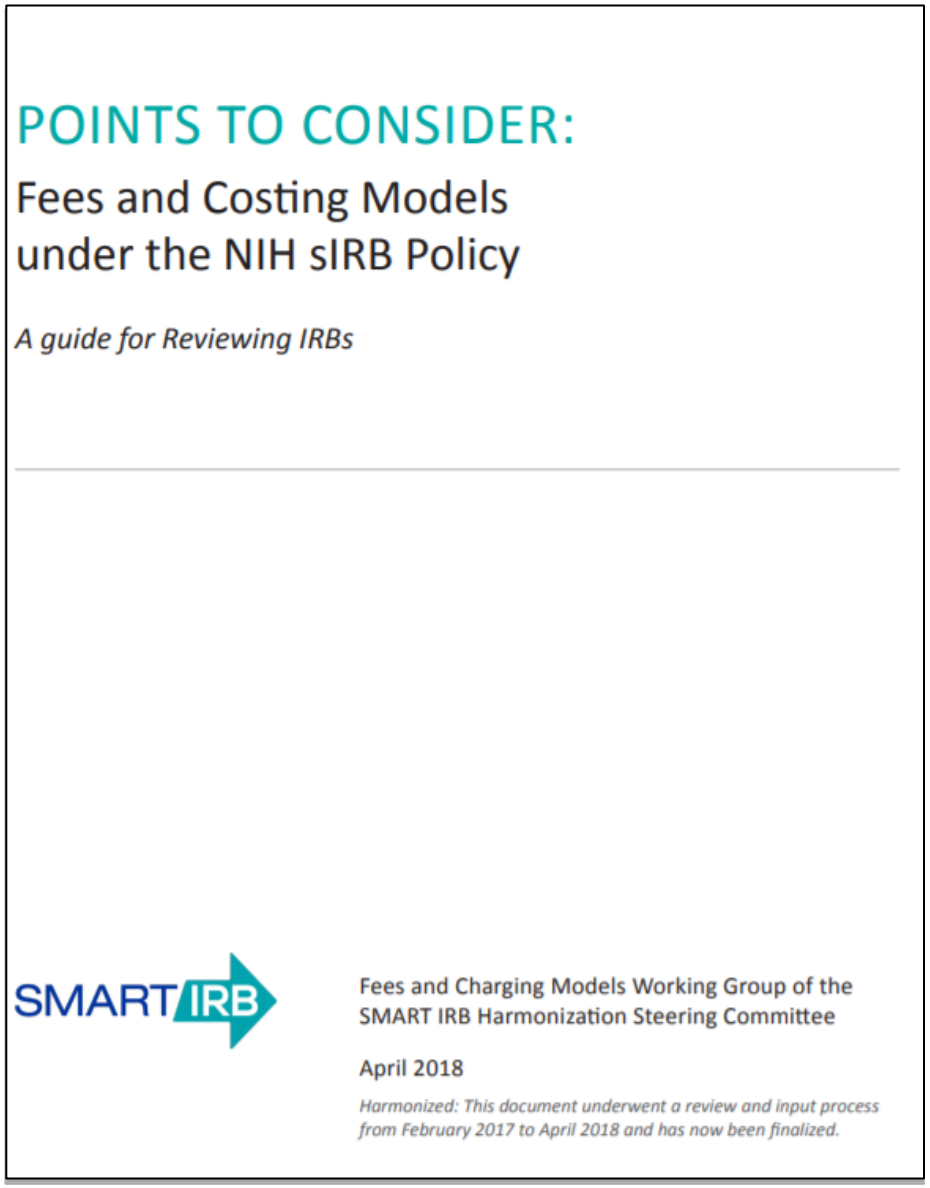
The IRB

You want to train your study teams to talk to you as soon as they are aware single IRB might be required.

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.

https://smartirb.org/assets/files/Fees-and-Costing-Models.pdf



POINTS TO CONSIDER:

Fees and Costing Models under the NIH sIRB Policy

A guide for Reviewing IRBs

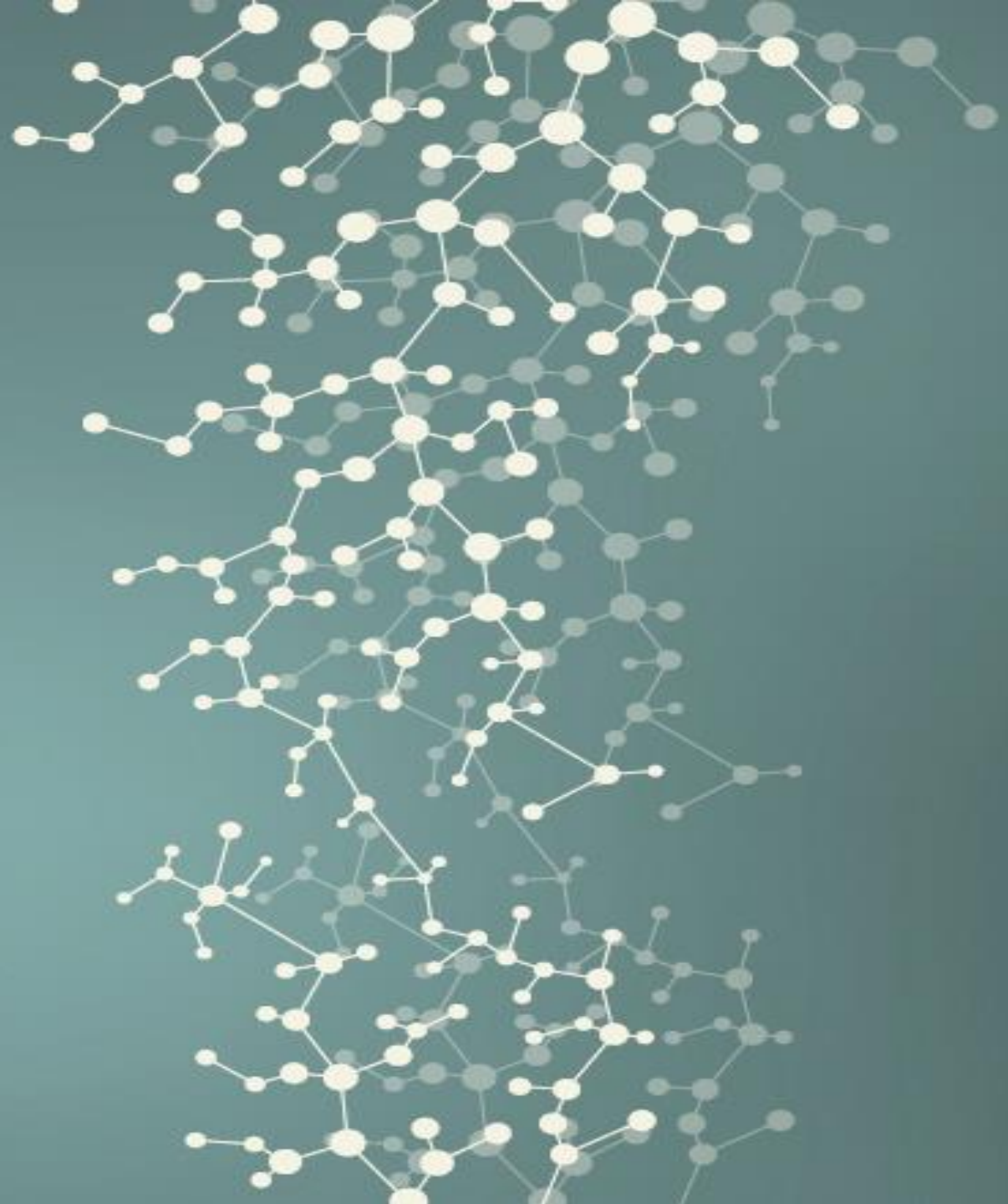
SMART IRB

Fees and Charging Models Working Group of the SMART IRB Harmonization Steering Committee

April 2018

Harmonized: This document underwent a review and input process from February 2017 to April 2018 and has now been finalized.

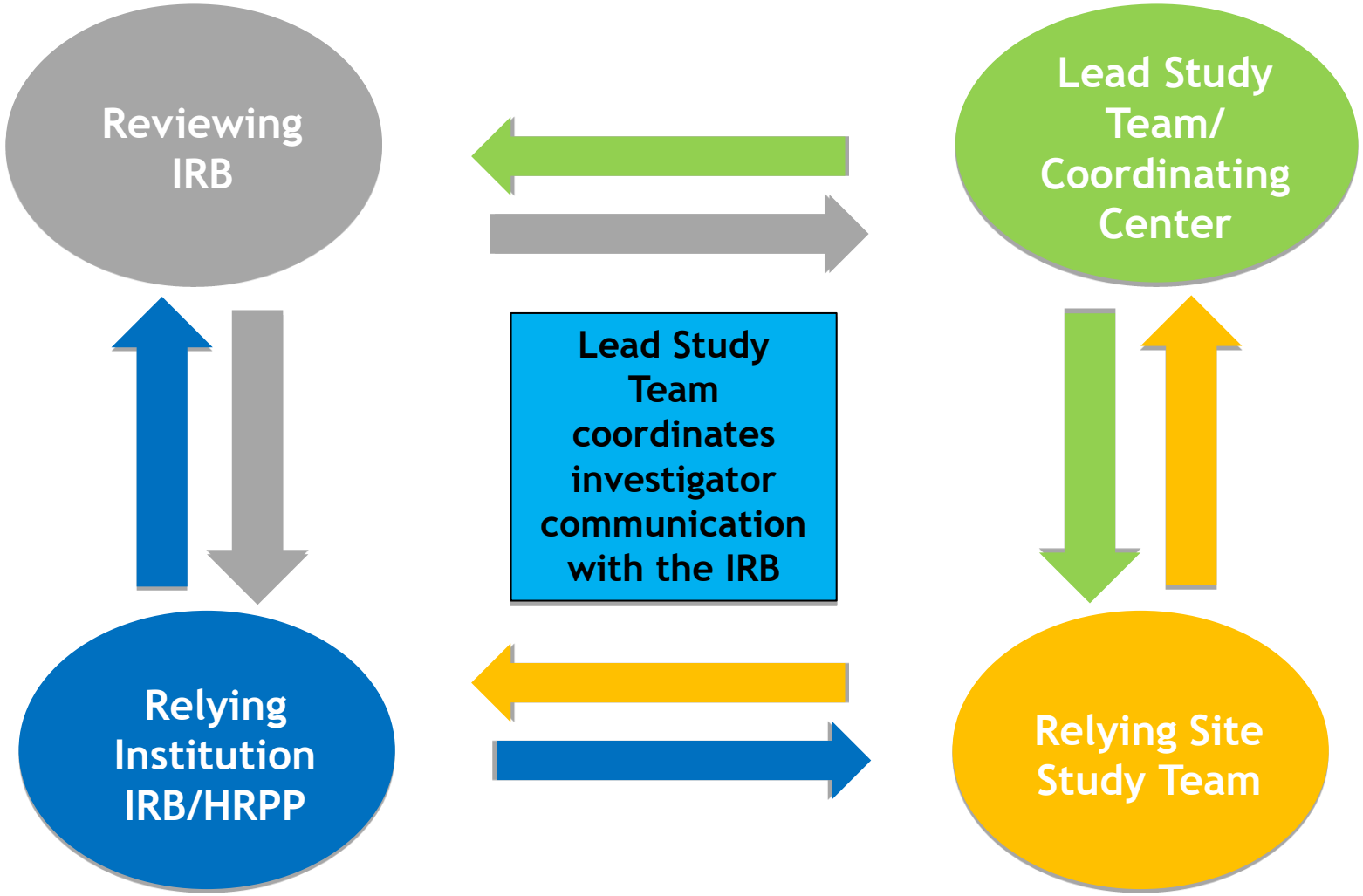
Responsibilities



The Reliance Process: What Study Teams Need to Know

- The process for requesting the use of an external IRB or for their internal IRB to serve as the Reviewing IRB for a multi-site study
- When and how they need to obtain sign off for their single IRB plan
  - Local forms they need to complete
  - Will they use the SMART IRB Reliance System to request a reliance arrangement?
- Their role in the reliance process
  - Who contacts the Reviewing IRB
  - Who coordinates the agreement process

Common Single IRB Communication Model



Key Study Team Roles

Overall Principal Investigator

Generally, the initiating or funding principal investigator

Site Investigator(s) (Site PIs)

Responsible for conduct of the research at their institution

Lead Study Team

Designated by the Overall PI

Ensure study coordination, communication, and routing of IRB submissions (in collaboration with Reviewing IRB)

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 Lead Study Team Key Responsibilities

Submit materials to the Reviewing IRB for all sites, including, initial protocol, 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, required checklists, other forms (e.g., local context)

Ensure study teams are **aware of Reviewing IRB policies and procedures**

Provide IRB-approved materials/determinations to all site study teams

Single IRB Readiness Checklist for Lead Study Teams & Coordinating Centers: Reliance Arrangements

This checklist will assist Lead Study Teams to identify the processes and resources they may need to facilitate a single IRB reliance arrangement for their multi-site research study.

SMART IRB

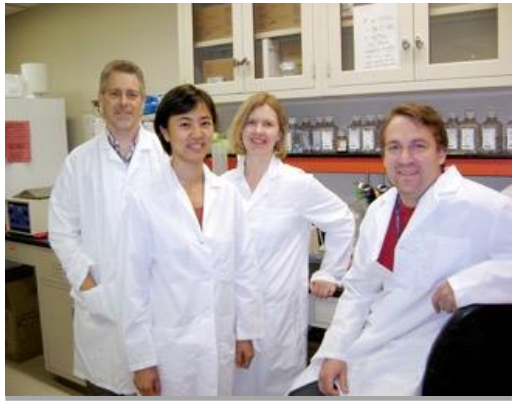
Single IRB Readiness Checklist for Lead Study Teams & Coordinating Centers: Reliance Arrangements

This checklist will help you identify the processes and resources you may need to facilitate a single IRB reliance arrangement for your multisite research study.

Any item on the checklist that prompts a "No" response means that you may need to address that gap.

AREA	YES	NO	NOTES
1. Have you contacted your local IRB or human research protection office regarding this study? You should contact them prior to completing this checklist.	☐	☐	*Enter Additional Notes*
2. Have you identified a Reviewing IRB that is willing to serve as the Single Reviewing IRB? Often, but not always, the Reviewing IRB is at the Overall Principal Investigator's institution. Link to helpful Resource for Selecting a Single IRB	☐	☐	*Enter Additional Notes*
3. Have you identified the reliance agreement the Reviewing IRB will use for this study?	☐	☐	*Enter Additional Notes*
4. Will the Reviewing IRB use the SMART IRB Agreement?	☐	☐	*Enter Additional Notes*

Common Responsibilities for Site PIs & Relying Site Study Teams



*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.

Follow	Provide	Use	Obtain
Follow the policies and procedures of the Reviewing IRB (e.g., for reportable events, personnel changes)	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	Use the Reviewing IRB's consent form template (excepting limited local language that can be added/ changed)	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

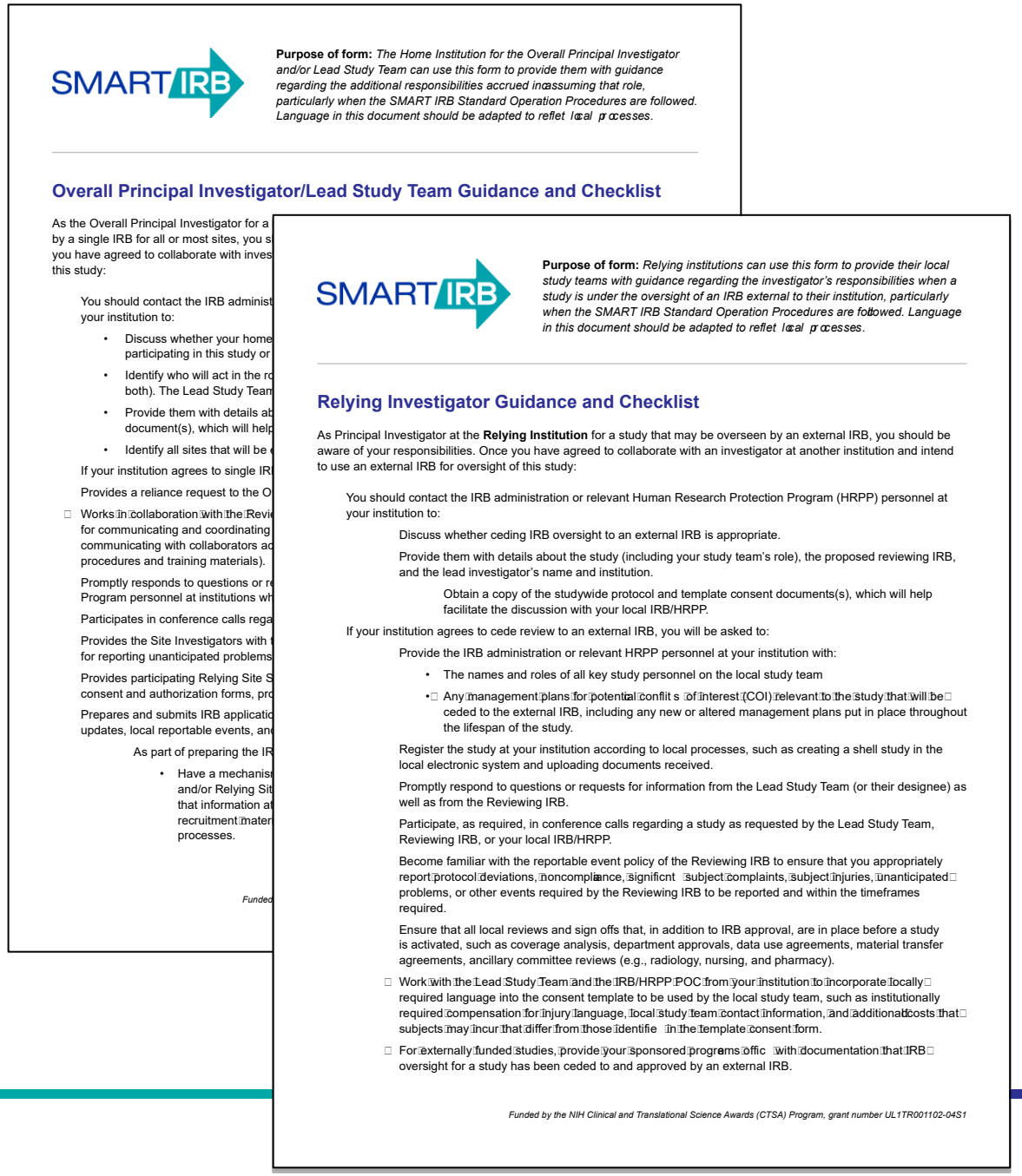
SMART IRB Resource: Investigator Checklists

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

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

Overall Principal Investigator/Lead Study Team Guidance and Checklist

As the Overall Principal Investigator for a
by a single IRB for all or most sites, you s
you have agreed to collaborate with inves
this study:

You should contact the IRB administ
your institution to:

- Discuss whether your home
participating in this study or
- Identify who will act in the r
both). The Lead Study Tean
- Provide them with details ab
document(s), which will help
- Identify all sites that will be

If your institution agrees to single IR

Provides a reliance request to the O

☐ Works in collaboration with the Revi
for communicating and coordinating
communicating with collaborators ac
procedures and training materials).

Promptly responds to questions or r
Program personnel at institutions wh

Participates in conference calls rega

Provides the Site Investigators with
for reporting unanticipated problems

Provides participating Relying Site S
consent and authorization forms, pro

Prepares and submits IRB applicatio
updates, local reportable events, an

As part of preparing the IR

- Have a mechanis
and/or Relying Sit
that information a
recruitment mater
processes.

Funded

SMART IRB

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

Relying Investigator Guidance and Checklist

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

You should contact the IRB administration or relevant Human Research Protection Program (HRPP) personnel at your institution to:

Discuss whether ceding IRB oversight to an external IRB is appropriate.

Provide them with details about the study (including your study team's role), the proposed reviewing IRB, and the lead investigator's name and institution.

Obtain a copy of the studywide protocol and template consent documents(s), which will help facilitate the discussion with your local IRB/HRPP.

If your institution agrees to cede review to an external IRB, you will be asked to:

Provide the IRB administration or relevant HRPP personnel at your institution with:

- The names and roles of all key study personnel on the local study team
- ☐ Any management plans for potential conflit s of interest (COI) relevant to the study that will be ceded to the external IRB, including any new or altered management plans put in place throughout the lifespan of the study.

Register the study at your institution according to local processes, such as creating a shell study in the local electronic system and uploading documents received.

Promptly respond to questions or requests for information from the Lead Study Team (or their designee) as well as from the Reviewing IRB.

Participate, as required, in conference calls regarding a study as requested by the Lead Study Team, Reviewing IRB, or your local IRB/HRPP.

Become familiar with the reportable event policy of the Reviewing IRB to ensure that you appropriately report protocol deviations, noncompliance, significnt subject complaints, subject injuries, unanticipated problems, or other events required by the Reviewing IRB to be reported and within the timeframes required.

Ensure that all local reviews and sign offs that, in addition to IRB approval, are in place before a study is activated, such as coverage analysis, department approvals, data use agreements, material transfer agreements, ancillary committee reviews (e.g., radiology, nursing, and pharmacy).

☐ Work with the Lead Study Team and the IRB/HRPP POC from your institution to incorporate locally required language into the consent template to be used by the local study team, such as institutionally required compensation for injury language, local study team contact information, and additional costs that subjects may incur that differ from those identifie in the template consent form.

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

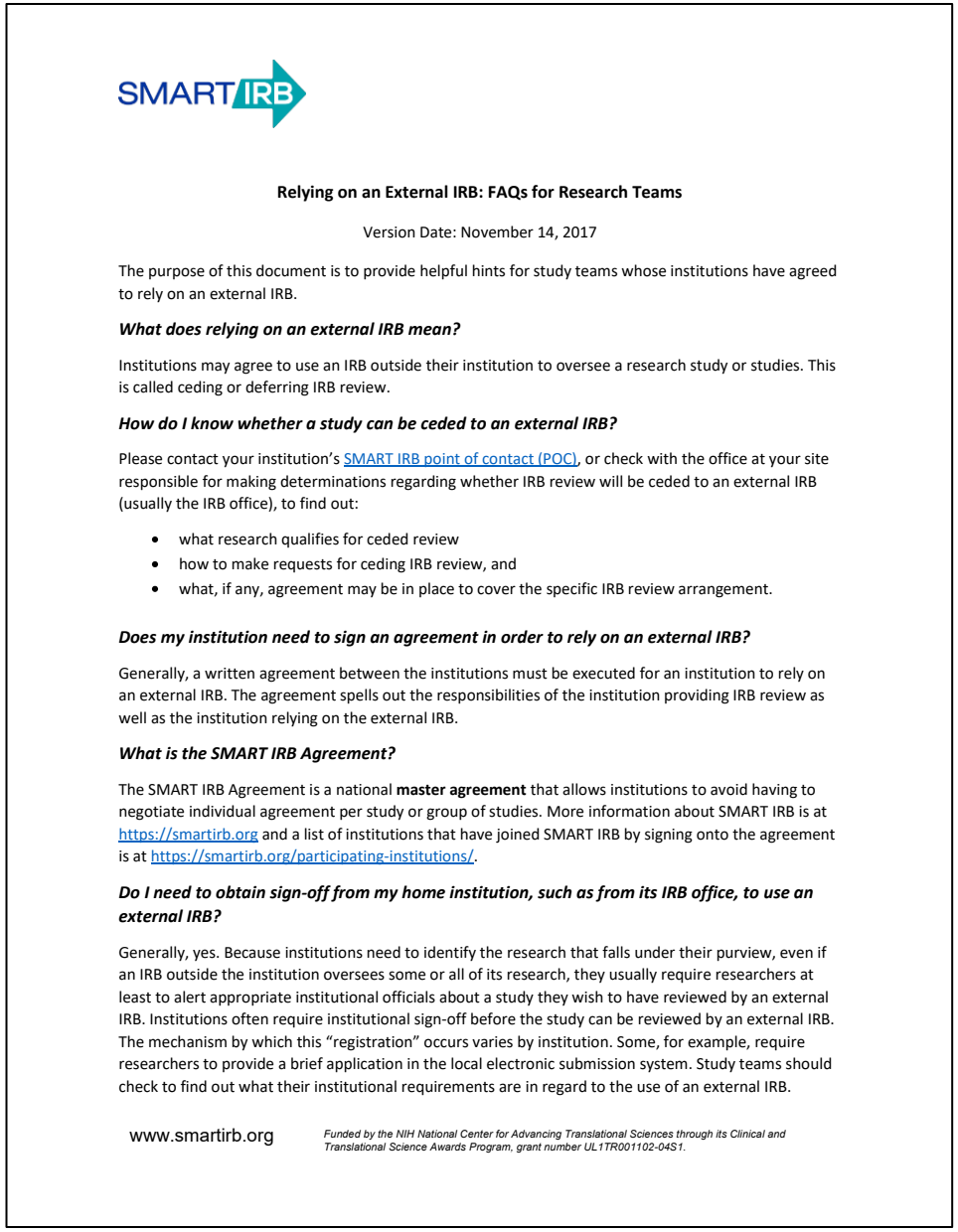
Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR001102-04S1

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.



SMART IRB

Relying on an External IRB: FAQs for Research Teams

Version Date: November 14, 2017

The purpose of this document is to provide helpful hints for study teams whose institutions have agreed to rely on an external IRB.

What does relying on an external IRB mean?

Institutions may agree to use an IRB outside their institution to oversee a research study or studies. This is called ceding or deferring IRB review.

How do I know whether a study can be ceded to an external IRB?

Please contact your institution's SMART IRB point of contact (POC), or check with the office at your site responsible for making determinations regarding whether IRB review will be ceded to an external IRB (usually the IRB office), to find out:

- what research qualifies for ceded review
- how to make requests for ceding IRB review, and
- what, if any, agreement may be in place to cover the specific IRB review arrangement.

Does my institution need to sign an agreement in order to rely on an external IRB?

Generally, a written agreement between the institutions must be executed for an institution to rely on an external IRB. The agreement spells out the responsibilities of the institution providing IRB review as well as the institution relying on the external IRB.

What is the SMART IRB Agreement?

The SMART IRB Agreement is a national **master agreement** that allows institutions to avoid having to negotiate individual agreement per study or group of studies. More information about SMART IRB is at https://smartirb.org and a list of institutions that have joined SMART IRB by signing onto the agreement is at https://smartirb.org/participating-institutions/.

Do I need to obtain sign-off from my home institution, such as from its IRB office, to use an external IRB?

Generally, yes. Because institutions need to identify the research that falls under their purview, even if an IRB outside the institution oversees some or all of its research, they usually require researchers at least to alert appropriate institutional officials about a study they wish to have reviewed by an external IRB. Institutions often require institutional sign-off before the study can be reviewed by an external IRB. The mechanism by which this "registration" occurs varies by institution. Some, for example, require researchers to provide a brief application in the local electronic submission system. Study teams should check to find out what their institutional requirements are in regard to the use of an external IRB.

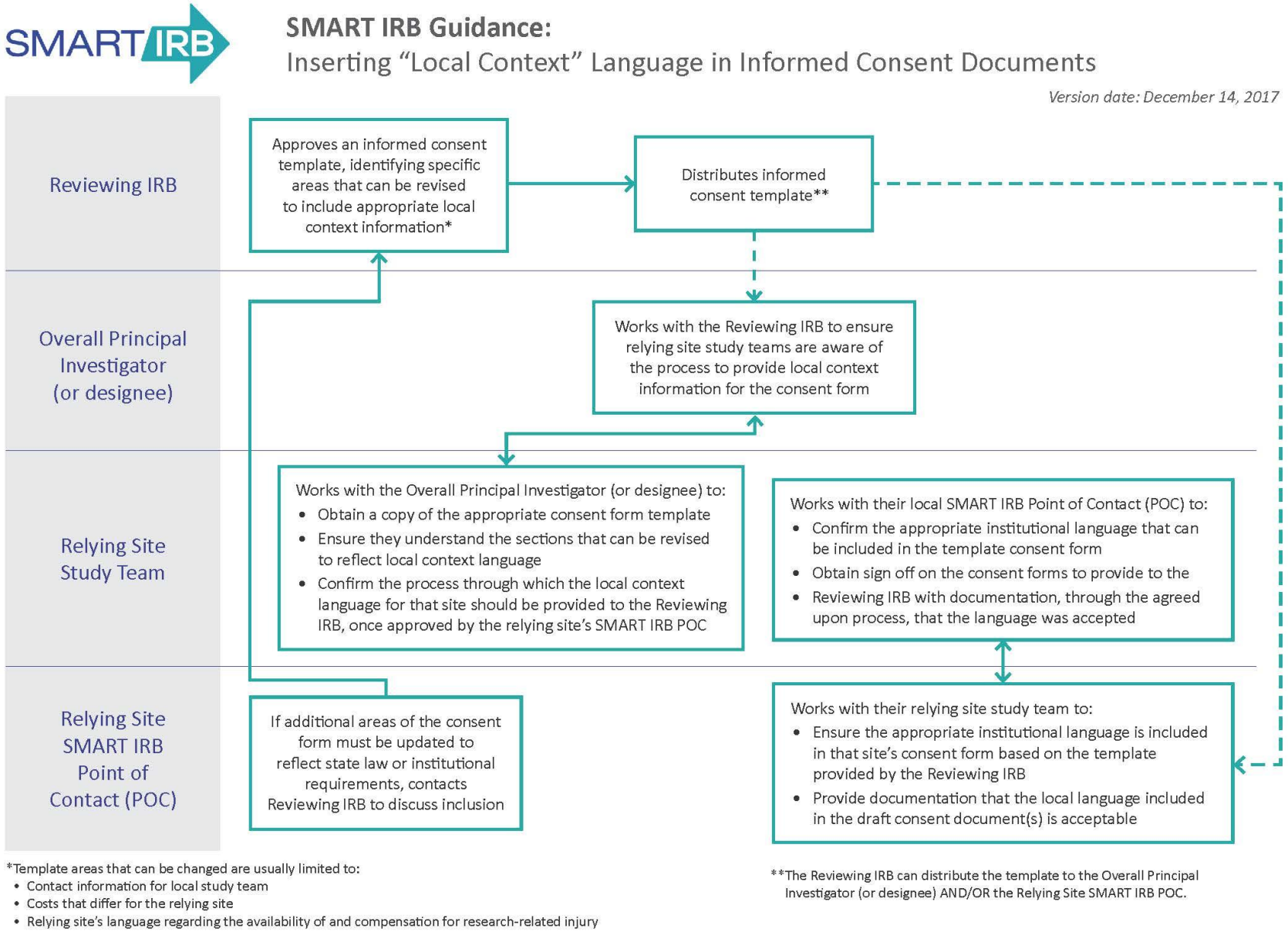
Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

Local Context: What Study Teams Need to Know

- What local context information they are responsible for providing and to whom
  - Any procedures that will differ locally from what is described in study protocol
  - If the standard of care at their organization is different
- How to create a consent form that includes required institutional language

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.

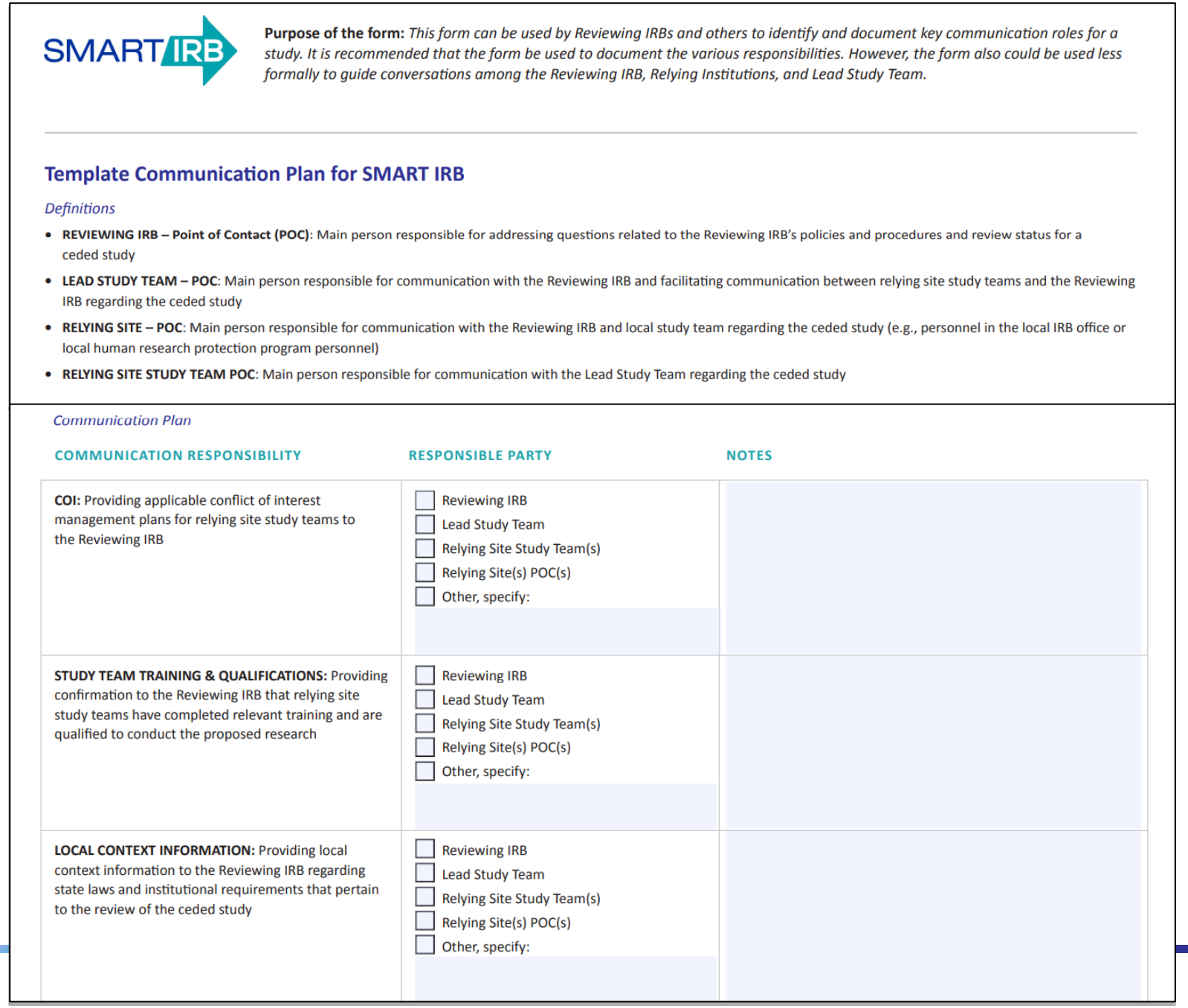


SMART IRB Resource: Communication plan for single IRB review

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



SMART IRB

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

Template Communication Plan for SMART IRB

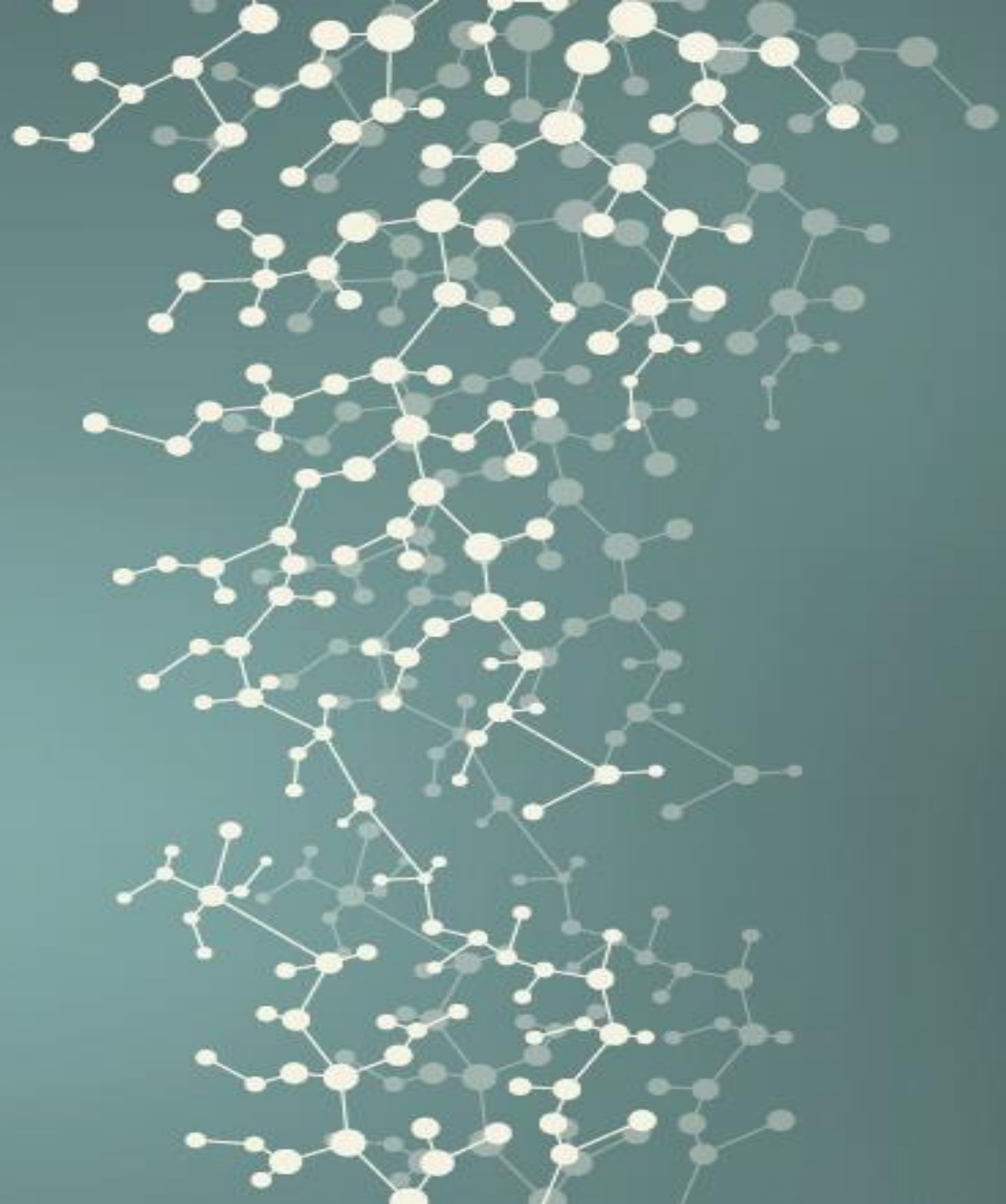
Definitions

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

Communication Plan

COMMUNICATION RESPONSIBILITY	RESPONSIBLE PARTY	NOTES
COI: Providing applicable conflict of interest management plans for relying site study teams to the Reviewing IRB	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
STUDY TEAM TRAINING & QUALIFICATIONS: Providing confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	
LOCAL CONTEXT INFORMATION: Providing local context information to the Reviewing IRB regarding state laws and institutional requirements that pertain to the review of the ceded study	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s) ☐ Other, specify:	

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:

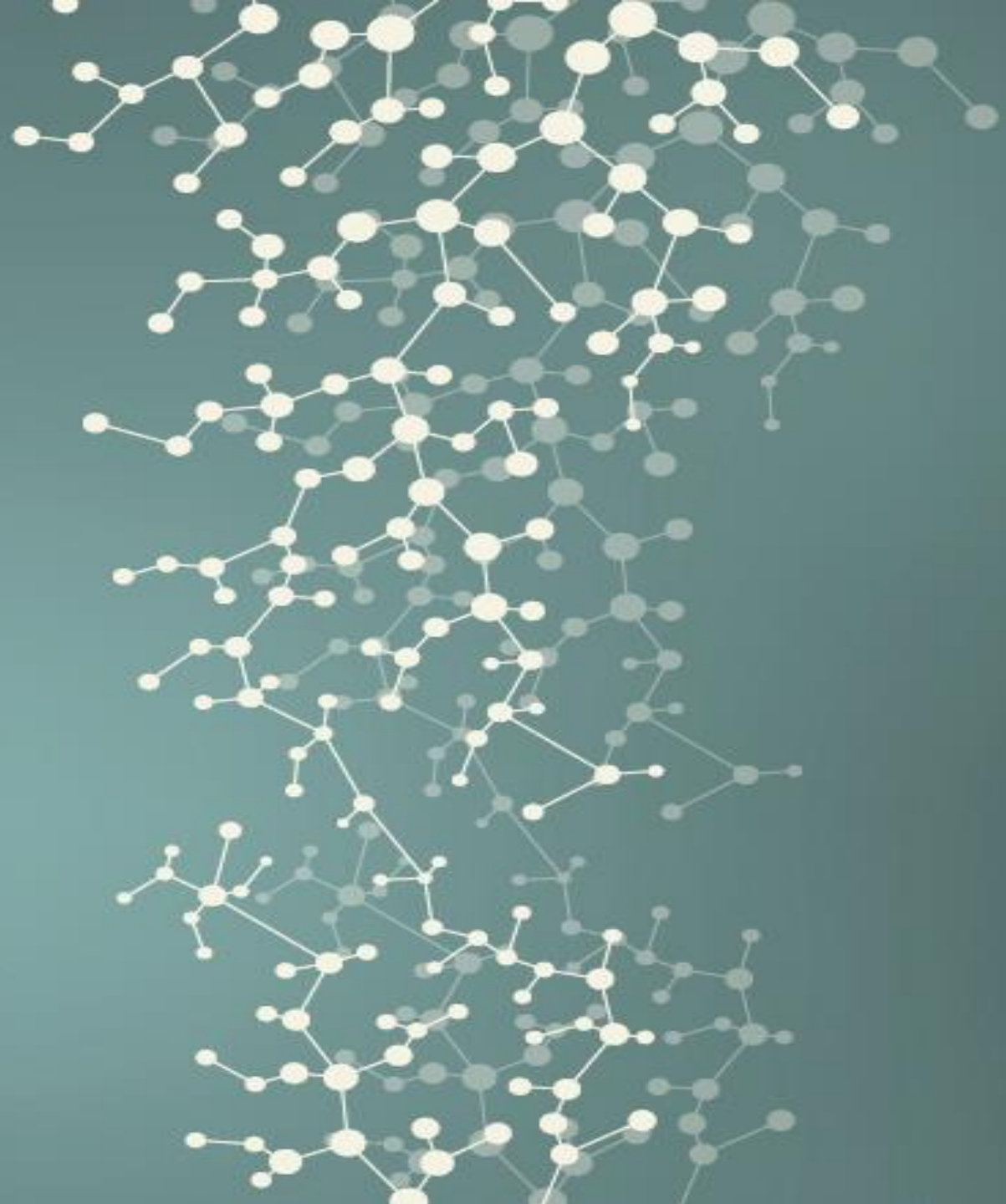
What to report to the Reviewing IRB and adhering to the Reviewing IRB's policies, such as for:

- Reportable events
- Personnel updates, including when they trigger the need to communicate a new or updated conflict of interest management plan

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

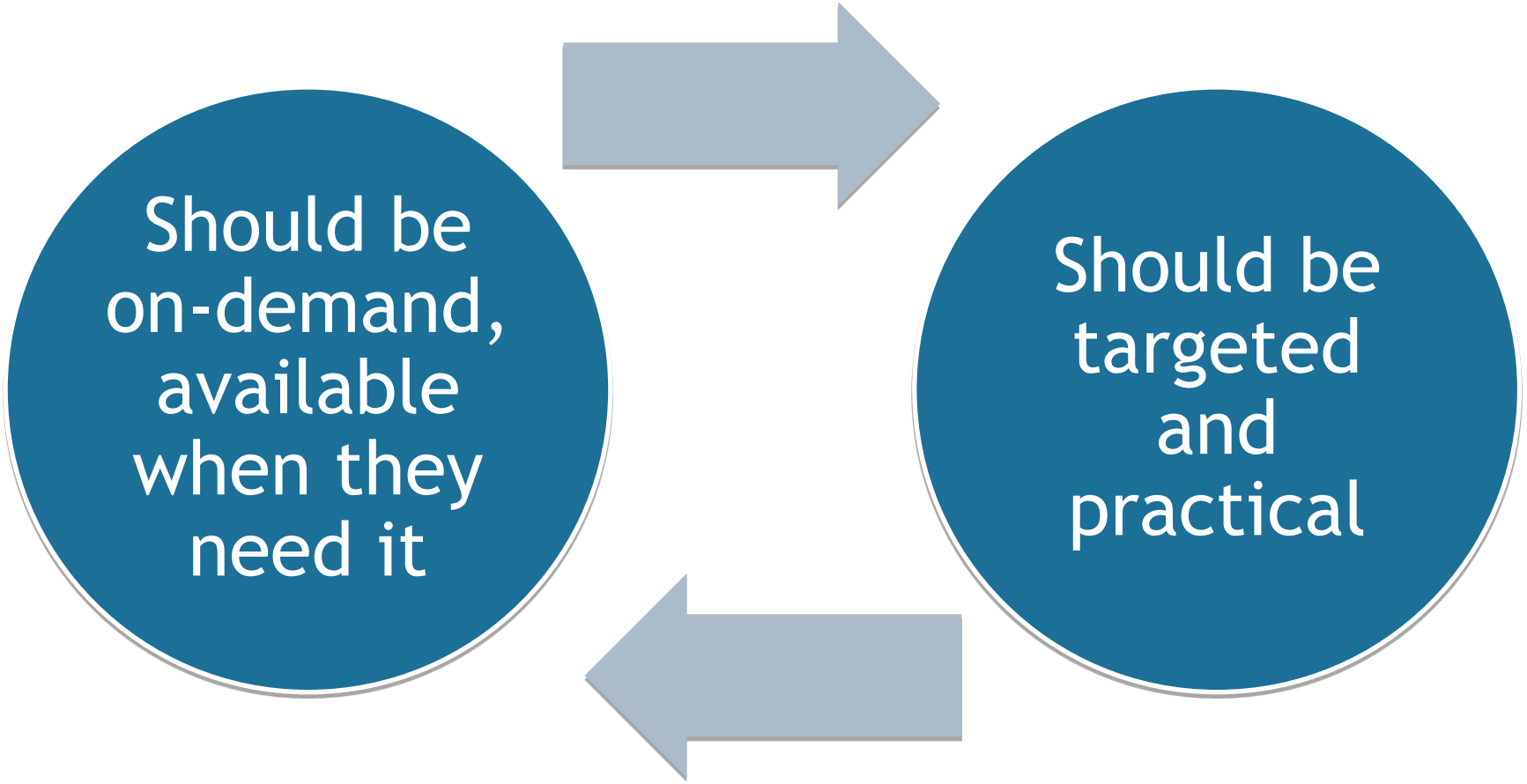
Training Approaches



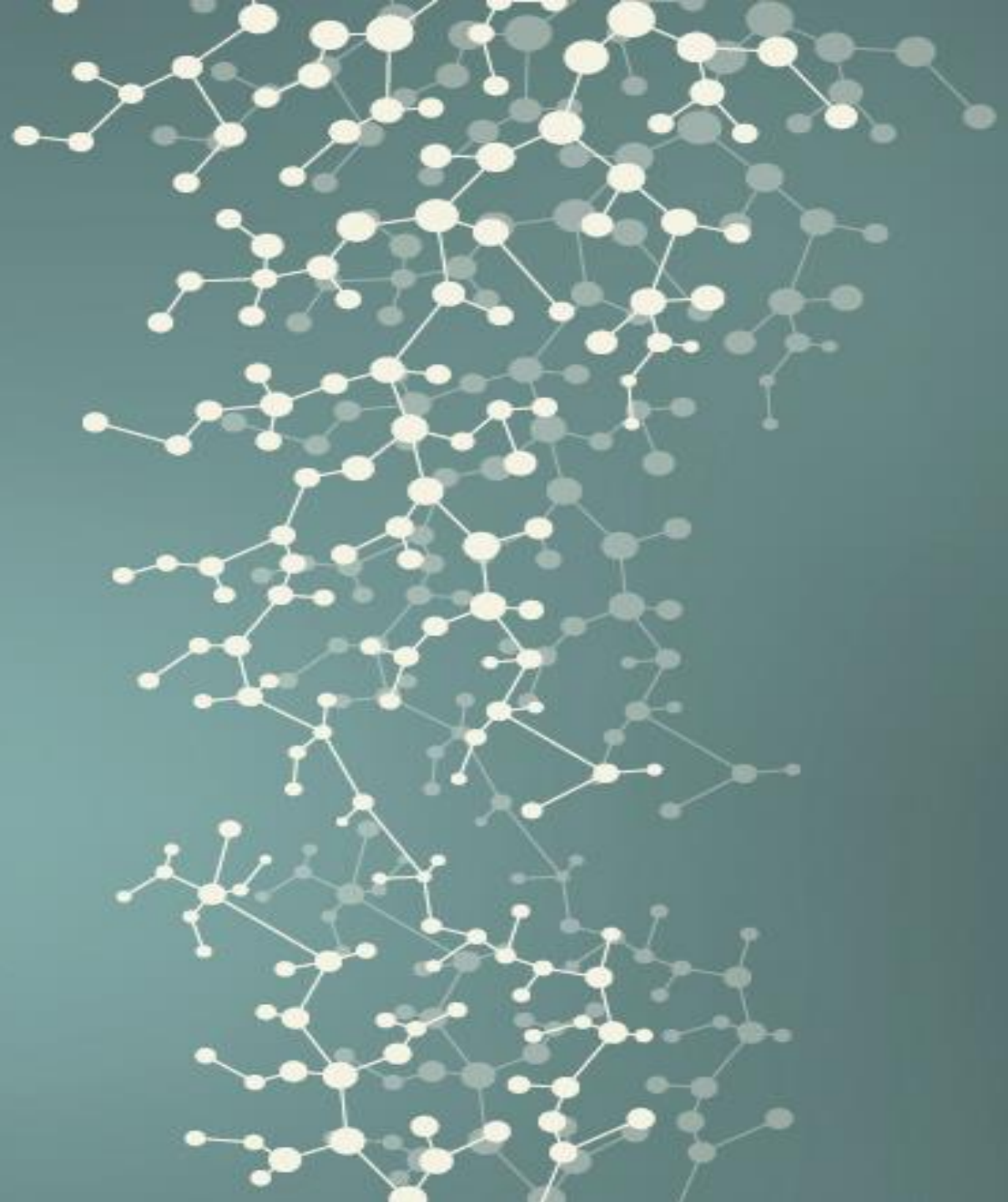
A model: one-on-one, study specific training

- Many organizations designate a staff person to meet with study teams to discuss:
  - What single IRB is and how it is different from local IRB review
  - Responsibilities the study team assumes, especially if they serve as a Lead Study Team
  - The steps in the reliance process
  - Local requirements and institutional policies that must be followed at initial IRB review and throughout the life of the study

Another Approach to Study Team Training



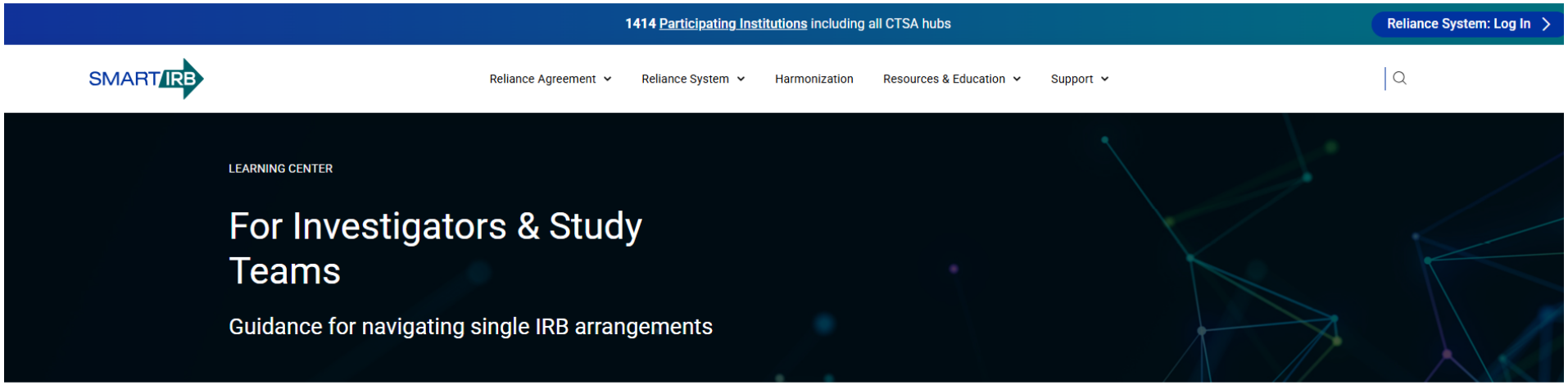
Resources to Support Training

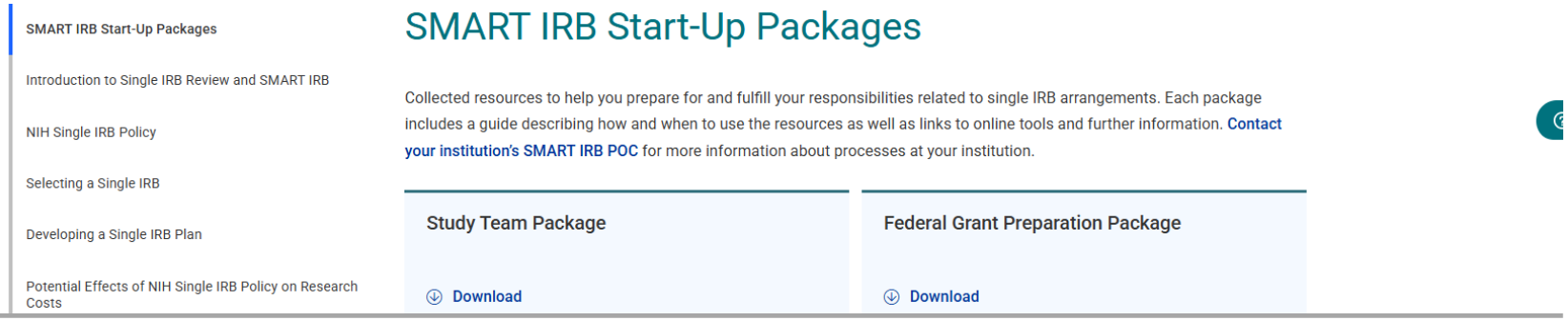


SMART IRB Resources for Study Teams

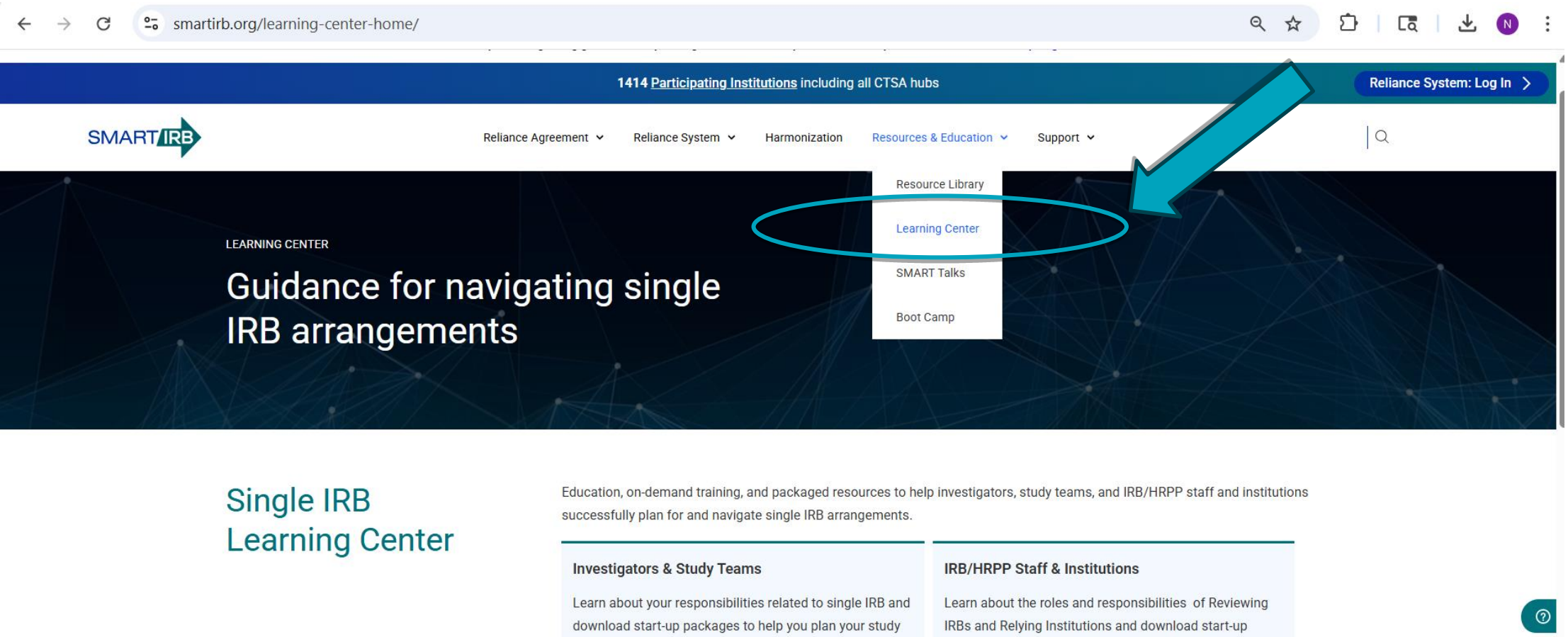
https://smartirb.org/study-teams/

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





Customizing the Training: Go to smartirb.org



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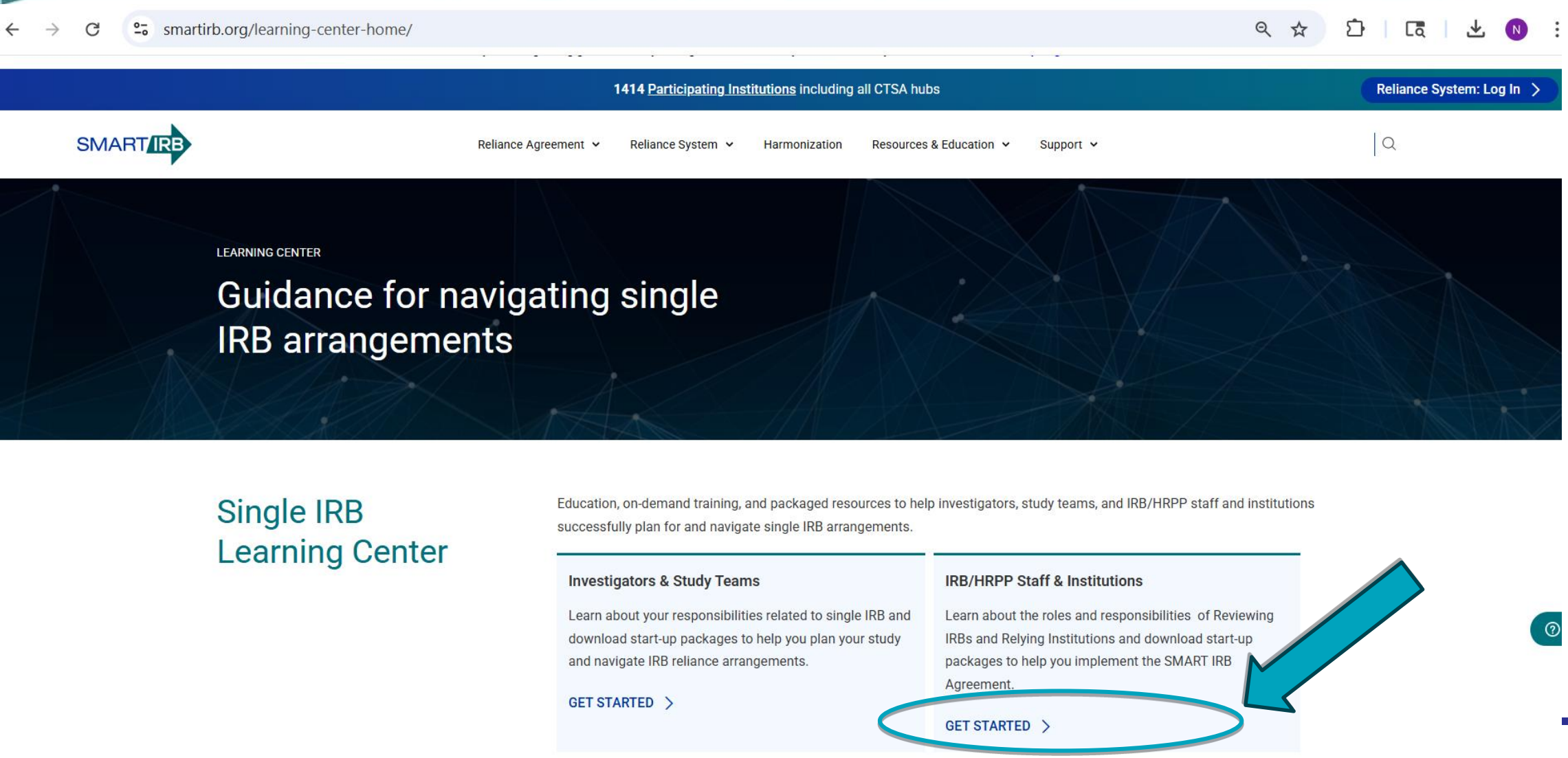

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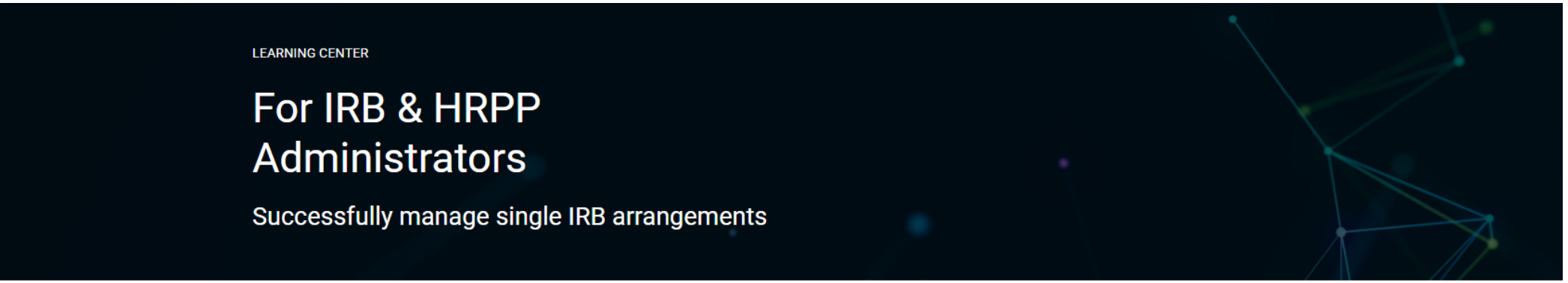
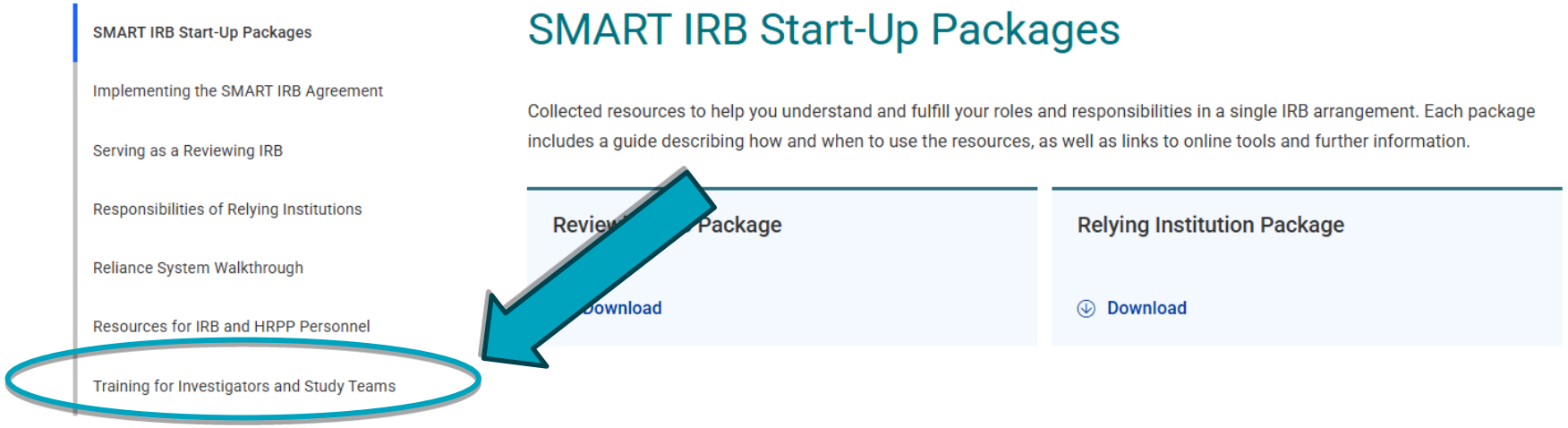




Download and Edit

SMART IRB

Reliance Agreement | Reliance System | Harmonization | Resources & Education | Support

Training for Investigators and Study Teams

Training for Investigators and Study Teams

SMART IRB offers a suite of training videos and resources that may be used as is or customized to reflect local processes and policies.

- **Visit the Learning Center for Investigators and Study Teams** to view available materials; send investigators here for self-guided learning.
- **Download presentations (no audio)** to use for local trainings or customize to reflect local processes.
- Download presentations with embedded audio:
  - **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**

SMART IRB Study Team Advisory Meeting (STEAM)

The SMART IRB Study Team Advisory Meeting was established to obtain input from investigators and study teams on the best ways to navigate single IRB review arrangements for their studies.

Goals

1. Identify ways to better engage study teams in the sIRB process
2. Improve dissemination and utilization of current SMART IRB research team resources.
3. Learn what works well with the process for study teams and areas that present challenges.

Recent STEAM Guidance Documents

- Guidelines for Study Teams: Enhancing Standardization of the sIRB Process at Relying Sites
- Relying on an External Single IRB: FAQs for Relying Site Study Teams

STEAM meets quarterly by Zoom. The next meeting will be held later this fall.

Know study team members that might want to join STEAM or learn more? Have them reach out to Mike Linke at linkemj@uc.edu.

Questions

SMART IRB

Harmonization Guidance

Nichelle Cobb, PhD, CIP
AAHRPP Senior Advisor for Strategic Initiatives

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)

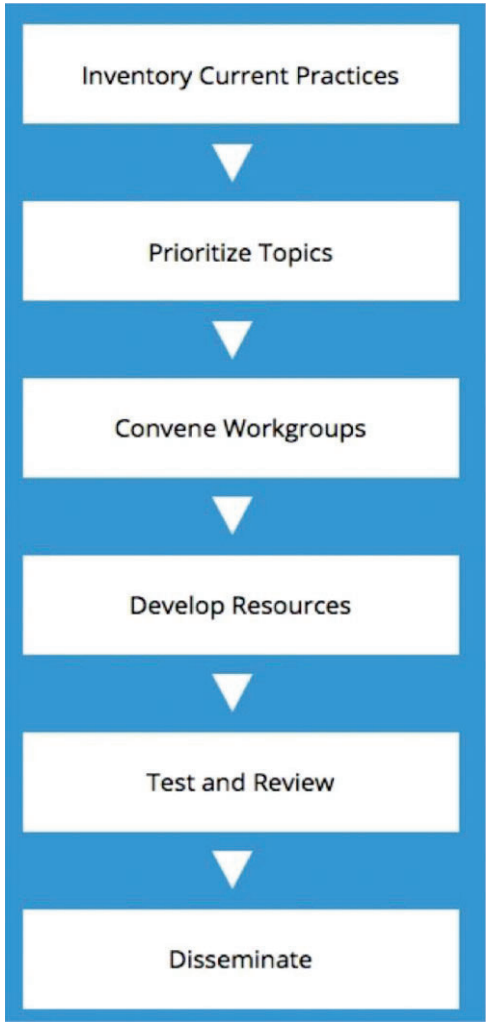
- To promote a more strategic, effective, efficient and cooperative approach to policies, processes and procedures related to single IRB review of multisite studies

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

Erica Rosemond, PhD
Deputy Director, 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:

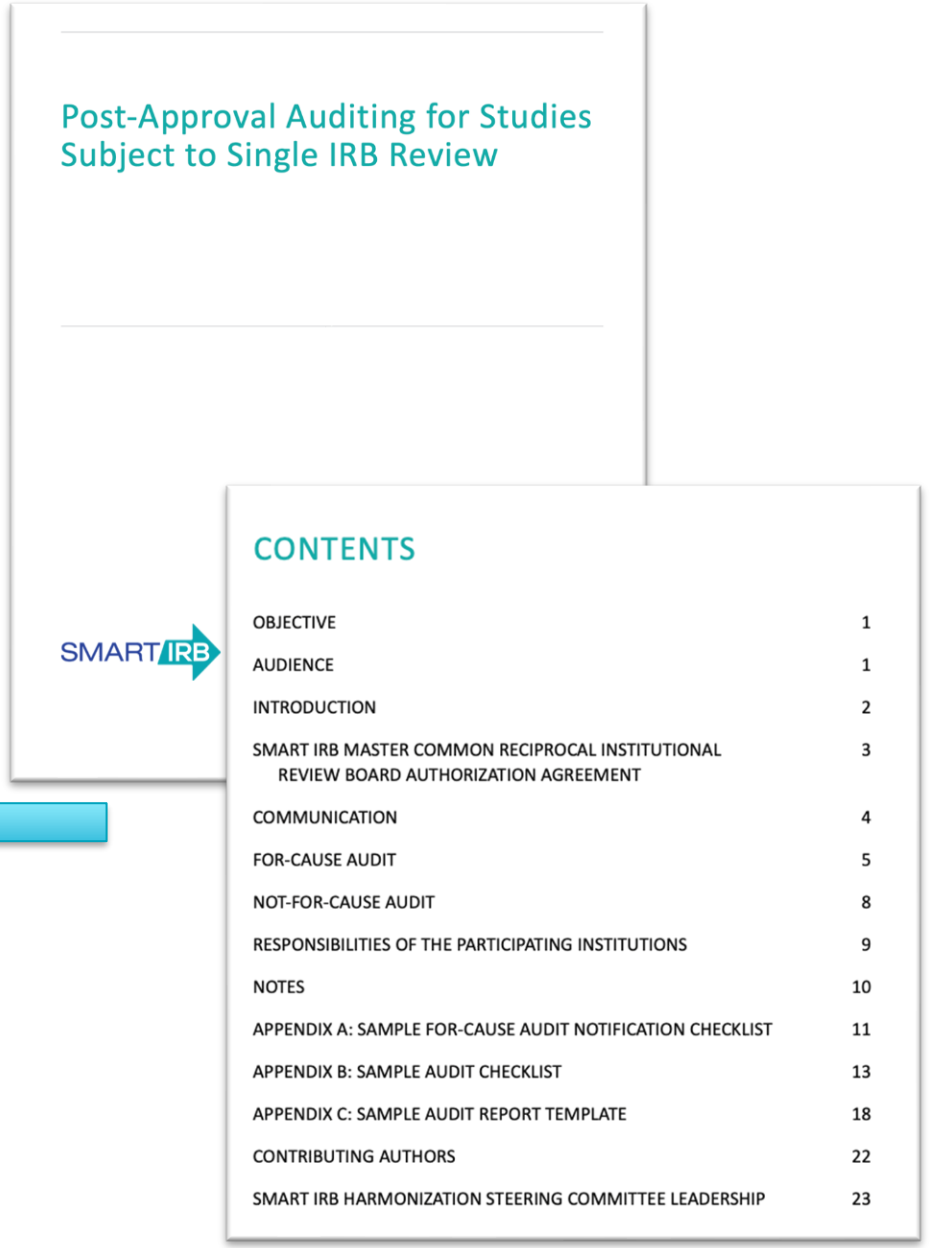
- Through "Emerging Issues Workshop" to HSC for selection

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



https://smartirb.org/harmonization/

Checklists and Templates

Harmonized: This document underwent a review and input process from December 2020 to April 2021 and has now been finalized.

SMART IRB

SAMPLE FOR-CAUSE AUDIT NOTIFICATION CHECKLI

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/NIH ☐

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 unanticipated problem involving r
others based on information received in a submission or upon report of an investigator or other member of the

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

☐ Reason to need verification that the Research is being conducted in accordance with the IRB-approved pr
[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 MA
REGARDING NON-COMPLIANCE?** (include relevant subject selection and/or percent of records to be reviewed wh

☐ Current Protocol in use by site

☐ Current Consent Documents in use by site

☐ Investigator/Study Team Training Documentation

☐ Source Documentation *(Specify)*: _____

☐ Other (e.g., Relying Institutions Policies, Study Manuals, Investigator Brochures, Notes to file, Adverse Eve
Deviation logs, etc.) *(Specify)*: _____

☐ Additional information *(Specify)*:

www.smartirb.org

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-0451.

Harmonized: This document underwent a review and input process from December 2020 to April 2

SMART IRB

SAMPLE AUDIT CHECKLIST

FOR USE BY INDIVIDUAL(S) CONDUCTING THE AUDI

A. REGULATORY DOCUMENTATION

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

1.1 Is the IRB Approval Letter(s) on file?

1.2 Is this an FDA regulated study? (If no, go to 1.3)
- 1.2.1 Is there a signed FDA 1572 on file?
- 1.2.2 Are all versions of the Investigator Brochure or package insert on file?
- 1.2.3 Are all versions of the package insert or device manual on file?
- 1.2.4 Is all correspondence to and from the FDA on file?

1.3 CVs of PI/Co-PI and all study staff on file?
- 1.3.1 For all CVs on file, are they current in alignment with applicable requirements?
- 1.3.2 For all CVs on file, are they signed and dated, if required?
- 1.3.3 Is there a staff training log?
- 1.3.4 Is the staff training log complete and up-to-date?

1.4 Is there a subject enrollment log?
- 1.4.1 Is the subject enrollment log complete?

1.5 Is/will the site (be) monitored?
- 1.5.1 Who is the monitoring body? _____
- 1.5.2 How often? _____
- 1.5.3 Is there a monitoring log?
- 1.5.4 If yes, is the monitoring log complete?

1.6 Is there a staff signature and delegation of responsibilities log?
- 1.6.1 Is the staff signature and delegation log complete and up-to-date?

1.7 Is all correspondence to and from the sponsor on file?

1.8 Are lab tests required?
- 1.8.1 If yes, is a copy of normal lab values on file?
- 1.8.2 Is a copy of the lab certification on file?

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Harmonized: This document underwent a review and input process from December 2020 to April 2021 and has now been finalized.

SMART IRB

SAMPLE AUDIT REPORT TEMPLATE[1]

PROTOCOL TITLE: _____

PRINCIPAL INVESTIGATOR: _____
Name

_____
Department, School

FUNDING SOURCE: _____

DATE OF REVIEW: _____

AUDITORS: _____

_____

_____

DATE OF REPORT: _____

DISTRIBUTION: _____
PI Name

CONFIDENTIAL

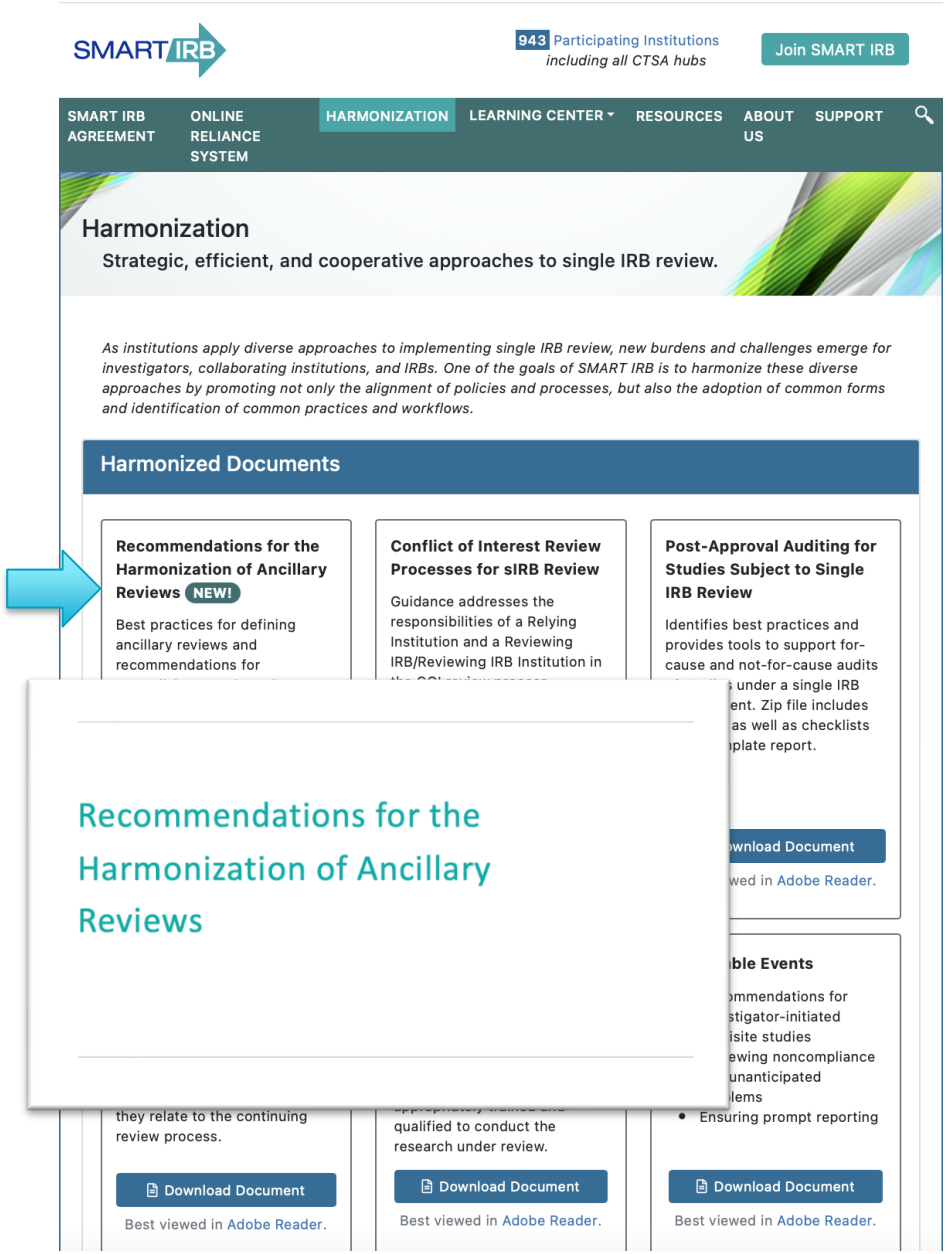
1. Howes, L. M., White, S. A., & Bierer, B. E. (2019). Quality Assurance and Quality Improvement Handbook for Human Research (1st ed.). Johns Hopkins University Press.

www.smartirb.org

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-0451.

https://smartirb.org/harmonization/

Recommendations for the Harmonization of Ancillary Reviews



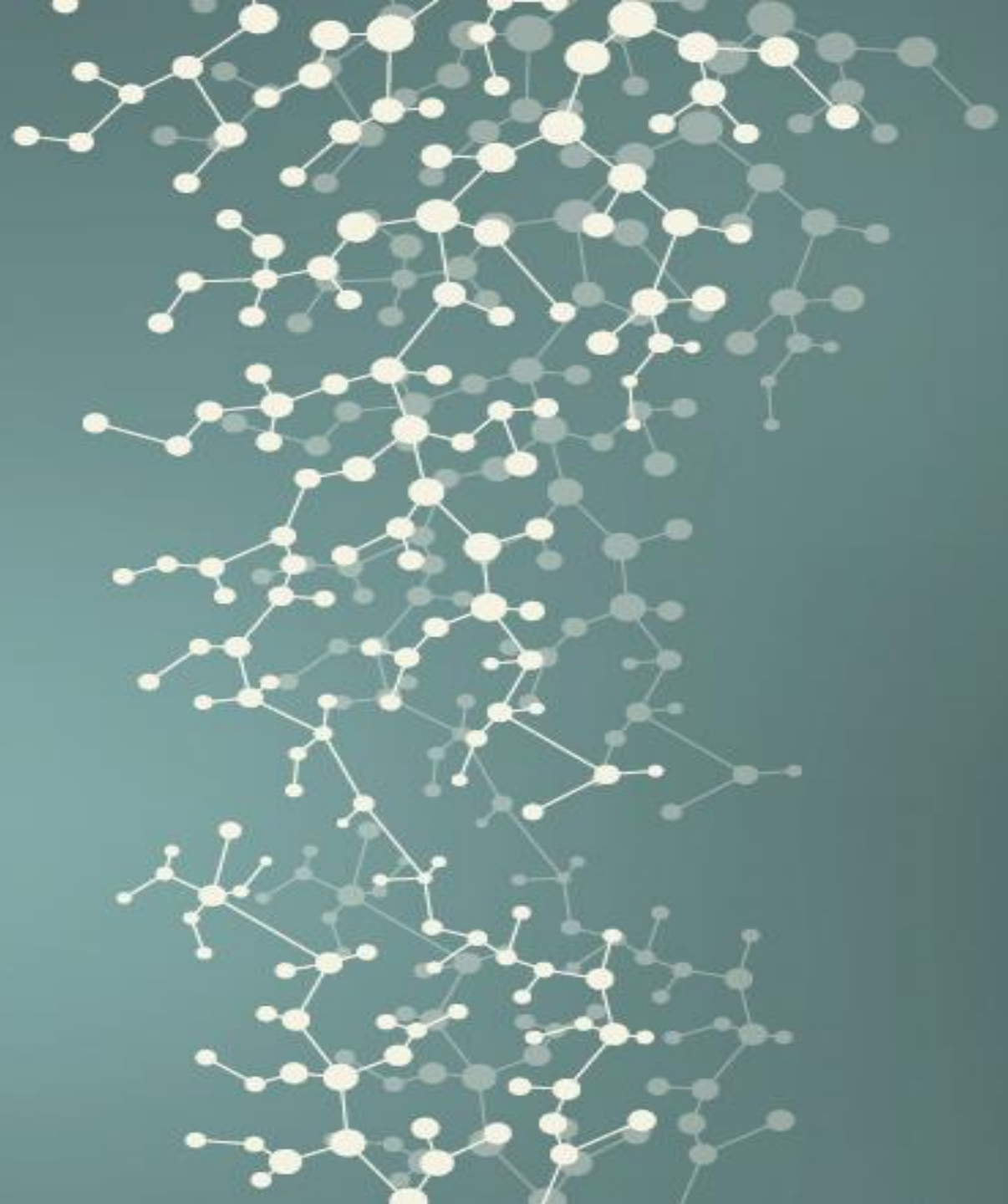
- Challenges
- Recommendations
  - Ancillary Review Definitions
  - Centralizing Ancillary Reviews for sIRB
  - Timing of Ancillary Reviews
  - Allocating Ancillary Review Responsibilities
- Implementation Checklist
- Ancillary Reviews that may be centralized after sIRB approval

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…

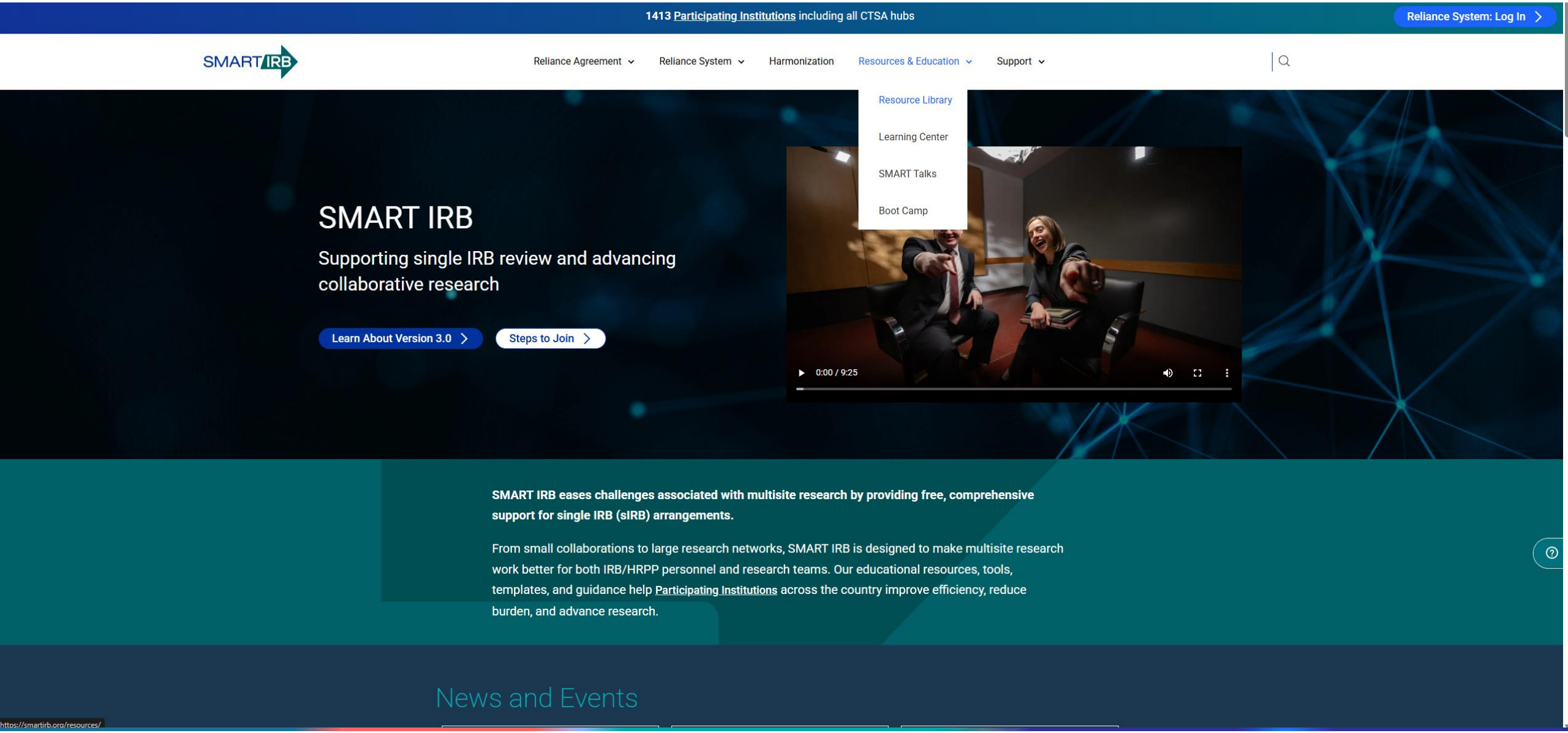
Discussion/Questions

Resources Recap and Frequently Asked Questions

Polly Goodman, CIP
Sr. Associate Director, SMART IRB

Jeremy Lavigne, MA, CIP
Sr. Officer, SMART IRB

SMART IRB Resources



SMART IRB Resources

Resources cover a wide range of topics across sIRB, including key documents like:

- SOP
- Templates
- Guidance
- Checklists
- And more!

SMART IRB Resource Implementation

Remember:

- SMART IRB Resources are often customizable to fit *your* institution's needs
- Work with your leadership to determine *what* SMART IRB resource(s) will be used and *how*
- Consider meeting with other stakeholders as well (study teams, institutional officials, compliance monitoring teams) to ensure consistent understanding of materials

Resource Evolution and Customization

Purpose of Form: *If not using the SMART IRB Online Reliance System to coordinate and document study-specific reliance arrangements, institutions may use this template to document the Reviewing IRB and Relying Institutions for a study.*

Template Letter: Acknowledgement of Site Agreement to Cede IRB Review and Reviewing IRB to Provide Oversight

This form documents that:

1) [NAME OF REVIEWING IRB INSTITUTION] will serve as the Reviewing IRB for [NAME OF RELYING INSTITUTION] for the study noted below;

   and

2) [NAME OF RELYING INSTITUTION] has agreed to cede IRB review to [NAME OF REVIEWING IRB INSTITUTION] for the study noted below.

Study Title:	
Overall PI:	
Relying Site Investigator:	

IRB review will be ceded under the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement.

Questions about the IRB review process or study status should be directed to [POINT OF CONTACT EMAIL AND TELEPHONE].

cc: *<Overall PI>*

<Relying Site Investigator>

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

Purpose of Fo
Reviewing IR
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cknowledgemer
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Institution	Loca
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titution PI/IRB#	Dr. F
ution Site RB#	Dr. J

Acknowledgment was

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perating Procedures:
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plies) HIPAA Determ
itution or a third party
connection with the r

plies) HIPAA Author
, the Relying Institution
nt document(s), or the
gation to ensure HIPAA

Interest: Relying Inst

.org SMART IRB encourage
"This information was
part with Federal fund
Department of Health

Purpose of Form: This form documents that the following Reviewing IRB Institution will serve as 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.

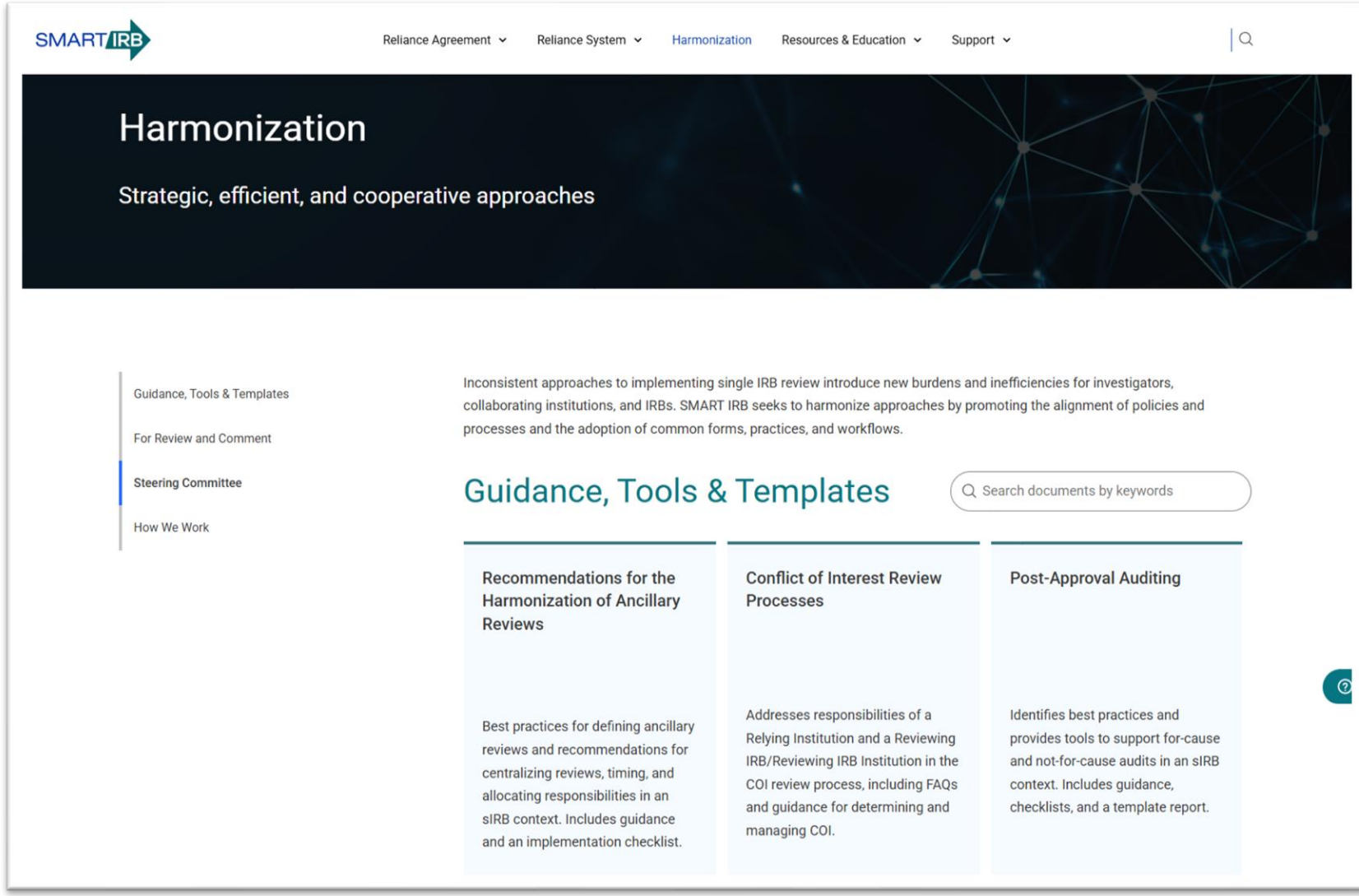
Reviewing IRB Institution	
Relying Institution	
Research Study Title(s):	
Reviewing Institution PI	
Relying Institution Site Investigator	
SMART IRB Terms	☐ Default Implementation Applies (per Implementation Checklist) ☐ Flexible Implementation Applies (per Implementation Checklist)
This Letter of Acknowledgment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

Harmonization

Best practices on pressing sIRB topics from experts around the country

- Ancillary Reviews
- Conflict of Interest
- Continuing Review
- Reportable Events
- And More!

Soon: Local Considerations and Exemptions



Learning Center and Start-Up Packages

- SMART IRB Start-Up Packages
- **Implementing the SMART IRB Agreement**
- Serving as a Reviewing IRB
- Responsibilities of Relying Institutions
- Reliance System Walkthrough
- Resources for IRB and HRPP Personnel
- Training for Investigators and Study Teams

SMART IRB Start-Up Packages

Collected resources to help you understand and fulfill your roles and responsibilities in a single IRB arrangement. Each package includes a guide describing how and when to use the resources, as well as links to online tools and further information.

Reviewing IRB Package

Download

Relying Institution Package

Download

SMART Talks

- Established in 2019, monthly forum for discussing pressing Single IRB Issues.
  - 1.5 hours per month
  - ~300-500 attendees
  - Recorded slides and video disseminated after discussion
- All SMART Talks and slides are available online at www.smartirb.org

1413 Participating Institutions including all CTSA hubs

Reliance System: Log In

SMART IRB

Reliance Agreement

Reliance System

Harmo

SMART IRB

Supporting single IRB review and advancing collaborative research

Learn About Version 3.0

Steps to Join

SMART IRB eases challenges associated with multisite research by providing free, comprehensive

SMART IRB

Community Contact Us

SMART IRB Support Center > Contact Us

Search

Contact Us

Your email address *

herbertwest@localu.edu

Full Name *

Herbert West

Subject *

Login

Suggested articles

Login Issues: I'm receiving an 'unauthorized' error message upon login.

Login Instructions: Which login options should I choose when I create my account?

Logging in to the Reliance System

Login Instructions: Creating a SMART IRB Account

Login Issues: I have an existing account from the previous Online Reliance System or Joinder System. Do I need to create a new SMART IRB account?

I'm having a technical issue in the Reliance System. Who should I reach out to for assistance?

How can I change/correct information on the Participating Institutions page?

Create an account to submit a request for reliance

Description *

Please enter the details of your request. A member of our support staff will respond as soon as possible.

SMART IRB Support Center

For all your questions related to:

- SMART IRB Agreement
- Reliance System
- Implementing sIRB
- General Single IRB Questions
- Best Practices for sIRB

http://smartirb.org/support

The SMART IRB Agreement

SMART IRB Agreement v2.0: NIH Revisions to the SMART IRB Agreement

Background on SMART IRB Agreement v2.0

Background: Why are the revisions to the SMART IRB Agreement reflected in SMART IRB Agreement v2.0 necessary?

Background: How will SMART IRB Agreement v2.0 allow NIH to collaborate with extramural organizations?

Admninistrative Issues: If my institution has already joined SMART IRB Agreement v1.0, can my institution continue to use that Version 1.0?

Administrative Issues: My institution is not serving as a Reviewing IRB for the NIH nor is it ceding IRB review to the NIH Intramural Research Program IRB. Does my institution need to sign SMART IRB Agreement v2.0?

Administrative Issues: If my institution serves as a Reviewing IRB for the NIH engaged and for other institutions engaged in the Research, would all of the institutions engaged in that Research need to sign SMART IRB Agreement v2.0?

See all 22 articles

Using SMART IRB for a Study

Can the SMART IRB Agreement be used for a study even if the Overall PI's home institution is NOT a SMART IRB Participating Institution?

What laws and regulations must the Reviewing IRB consider?

What constitutes a significant subject complaint that must be reported to the Reviewing IRB?

Who is responsible for addressing a subject's complaint?

If one of the Relying Institutions does not submit the necessary information for continuing review in advance of the expiration date, will all Relying Institutions be affected?

If the Reviewing IRB requests an audit of a study conducted at a Relying Institution, will the Relying Institution receive documentation that the audit was conducted, regardless of the result?

See all 32 articles

SOPs

Is my institution required to use the SMART IRB SOPs?

What are the SMART IRB Standard Operating Procedures?

Termination of Participation in SMART IRB

If an institution terminates participation in SMART IRB, are there any ongoing rights and obligations?

Reach out to a SMART IRB Ambassador

Aaron Kirby
Harvard Catalyst

Polly Goodman
Harvard Catalyst

Jeremy Lavigne
Harvard Catalyst

Ada Sue Selwitz
University of Kentucky

Find your SMART IRB Ambassador Today: www.smartirb.org

Kathy Lawry
AAHRPP

Nichelle Cobb
AAHRPP

Stacey Goretzka
Independent Consultant

Carissa Minder
Washington University in St. Louis

SMART IRB Newsletter

6,000+ subscriber monthly email newsletter provides the sIRB community:

- SMART IRB Announcements,
- News,
- Resources, education
- And more!

Join today at www.smartirb.org

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 pumpkin lattes downloaded separately.

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.

Study hall.

Questions and Key Takeaways!

Common SMART IRB Questions – Version 3.0

- Can Version 3.0 be used for any type of human subjects' research?
- I’m starting a new reliance arrangement. Do I *need* to use Version 3.0, or can I use legacy versions (e.g. V2.0, V1.0)?
- Who is in the driver’s seat for relying site HIPAA-related items in V3.0?
- Does my institution need to sign the indemnification addendum to join V3.0?

Common SMART IRB Questions- Reliance System

- **Login-** I can't login to the system and receive an 'unauthorized' message. What is this and what should I do?
- **Login-** How do I know if my institution is in InCommon or not?
- Who can **edit** a reliance request?
- What does 'Admin withdrawn' or 'Admin reliance reached' mean?
- Do I still need to 'batch' my reliance requests like in the old system?

Common SMART IRB Questions - Resources

- **Letters of Acknowledgment:** Do they have to be signed, and if so, by who at my institution?
- Who completes the **Implementation Checklist** document?
- What is **'Default Implementation'** and what is **'Flexible Implementation'**?
- How do I know if the **SMART IRB SOPs** apply to a given study?
- Which version of the **Letter of Acknowledgment** should my institution use?

Common SMART IRB Questions

- **Documenting Reliance:** Can I document reliance for multiple studies on one LOA? If so, how?
- Who completes the **Implementation Checklist** document?
- What is **'Default Implementation'** and what is **'Flexible Implementation'**?
- How do I know if the **SMART IRB SOPs** apply to a given study?
- Which version of the **Letter of Acknowledgment** should my institution use?