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

Day 2 - October 8, 2026

This project has been funded in whole or in part with Federal funds from the National Center for Advancing Translational Sciences, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N950C00008.

Michael Linke, PhD
Program Director, Education, SMART IRB

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.

Meet Your SMART IRB Ambassadors!



Aaron Kirby
Harvard Catalyst



Polly Goodman
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Jeremy Lavigne
Harvard Catalyst



Nichelle Cobb
AAHRPP



Ada Sue Selwitz
University of Kentucky



Kathy Lawry
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Stacey Goretzka
Independent Consultant



Carissa Minder
WashU in St. Louis

SMART IRB

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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	Kathy Lawry Mike Linke
1:50 – 2:00 pm	Break	
2:00 – 2:25 pm	Local Considerations	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
University of Kentucky
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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

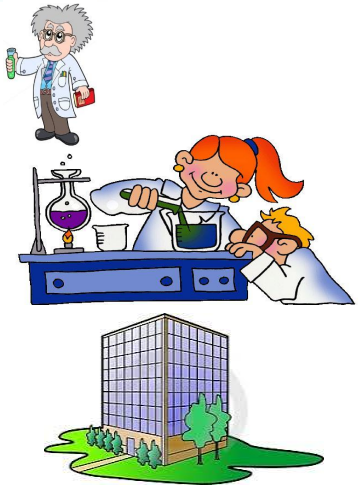
- Who are the key players in a Single IRB Communication Plan?
- What are examples of Communication Models? (Flow of communication)
- Who communicates what? (Responsibilities)
- What to do when there are disagreements or miscommunications? (Challenge)

Key Players*

- Lead Institution
- Reviewing IRB
- Lead/Overall PI
- Relying PI/Study Team
- Relying Institution





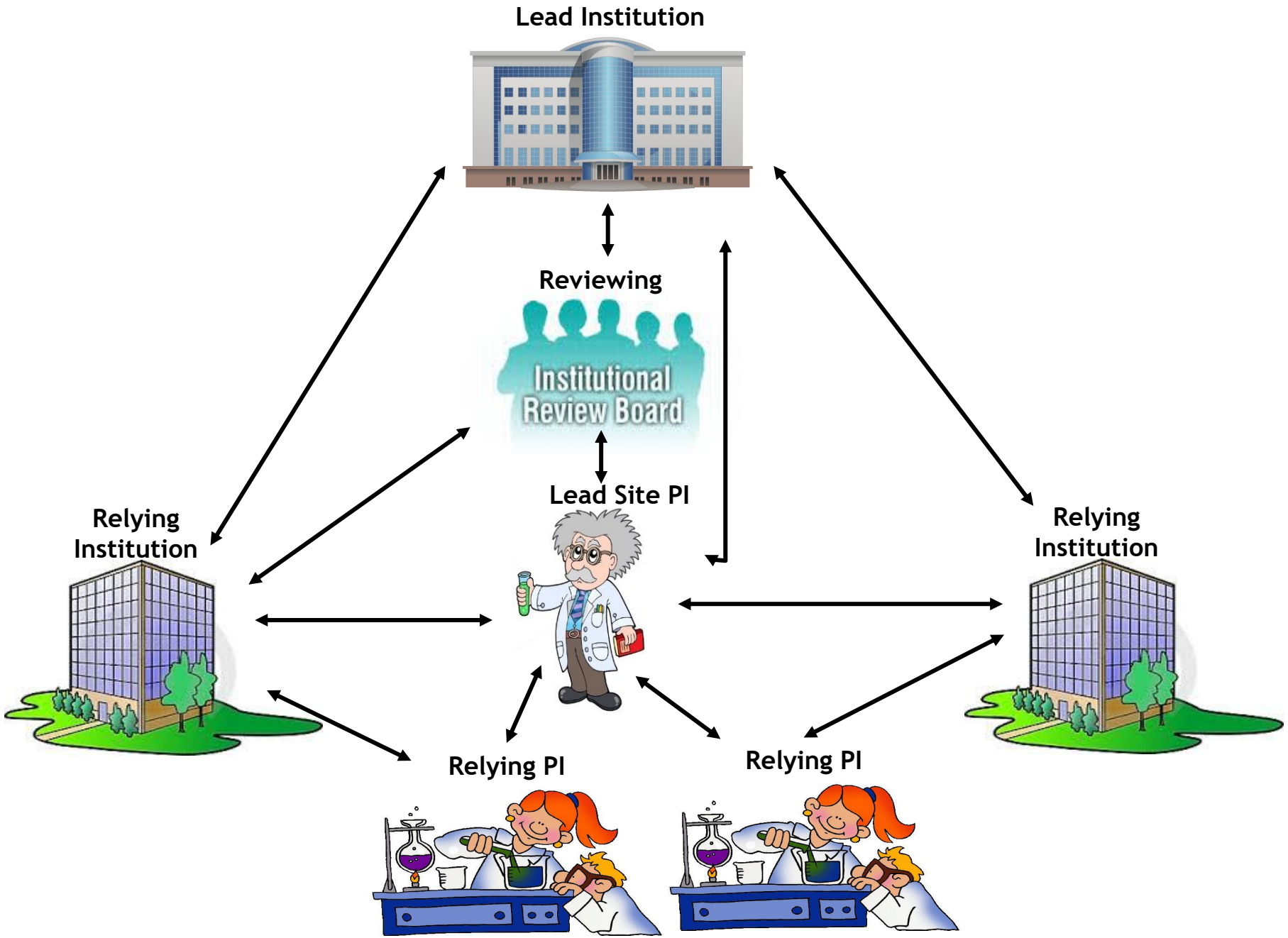


*Other players: Funding/Regulatory Agency or Coordinating Center, etc.

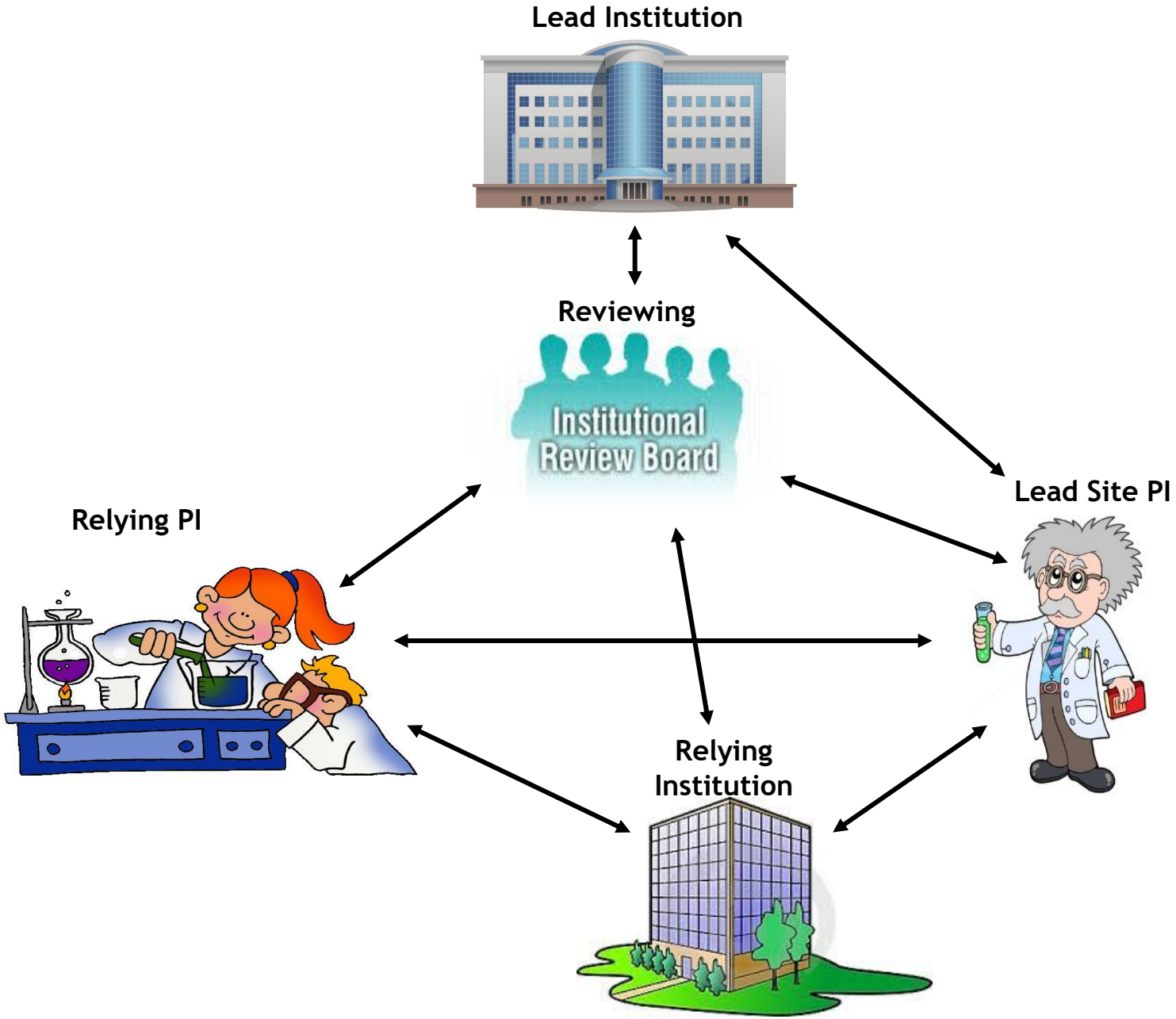
Two Popular Communication Models

- 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 Checklist and Documentation Tool, Communication Plan Template, Overall and Relying Site PI Checklists, Study-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.)

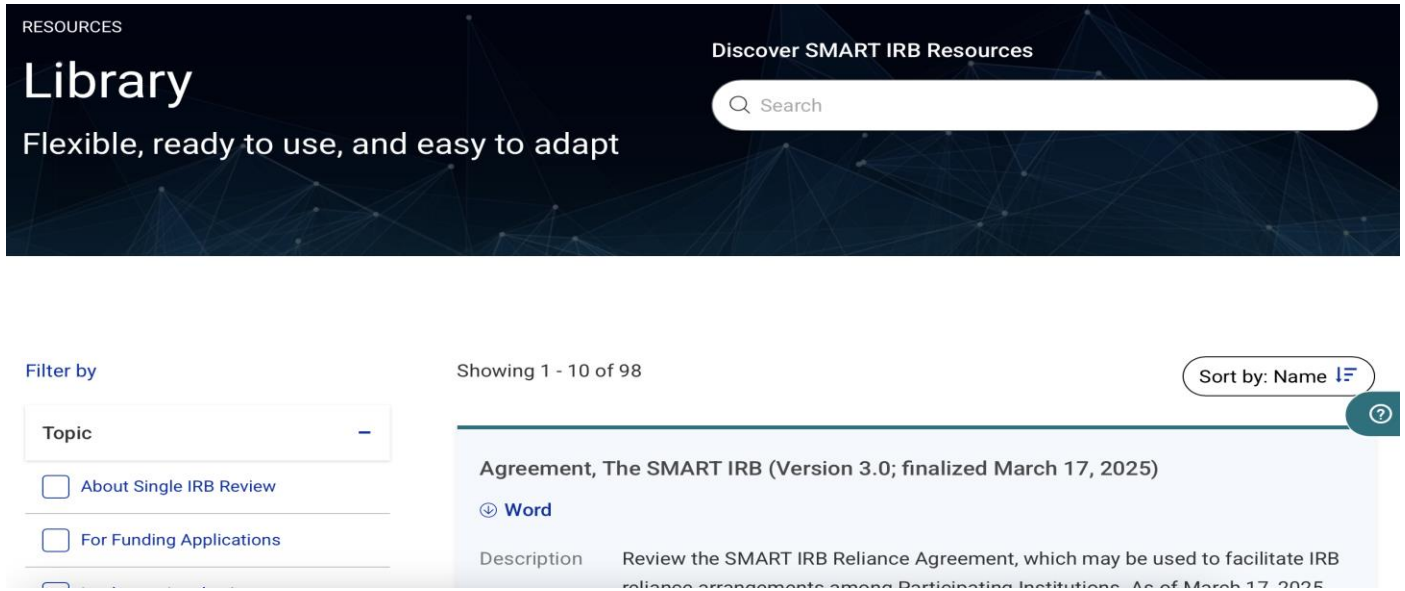
If the institution does not have any assigned HRPP/IRB Reliance staff, then the Relying PI will have increased responsibilities for communication.

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.

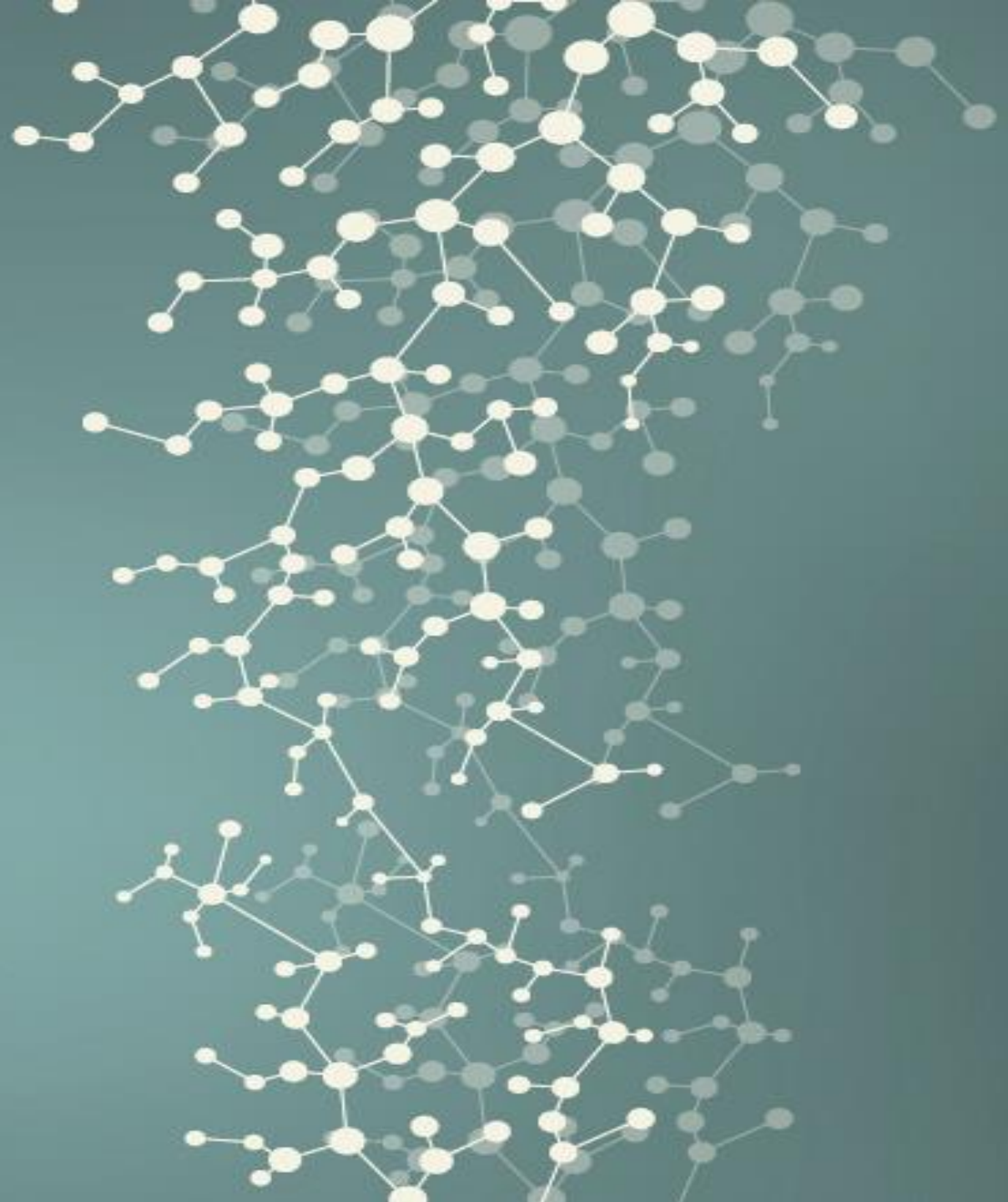
Communication Plan Template

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 Study-Specific Document



Resource

https://smartirb.org/wp-content/uploads/2024/09/SmartIRB_Study-Specific-Document_accessible-Remediated.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

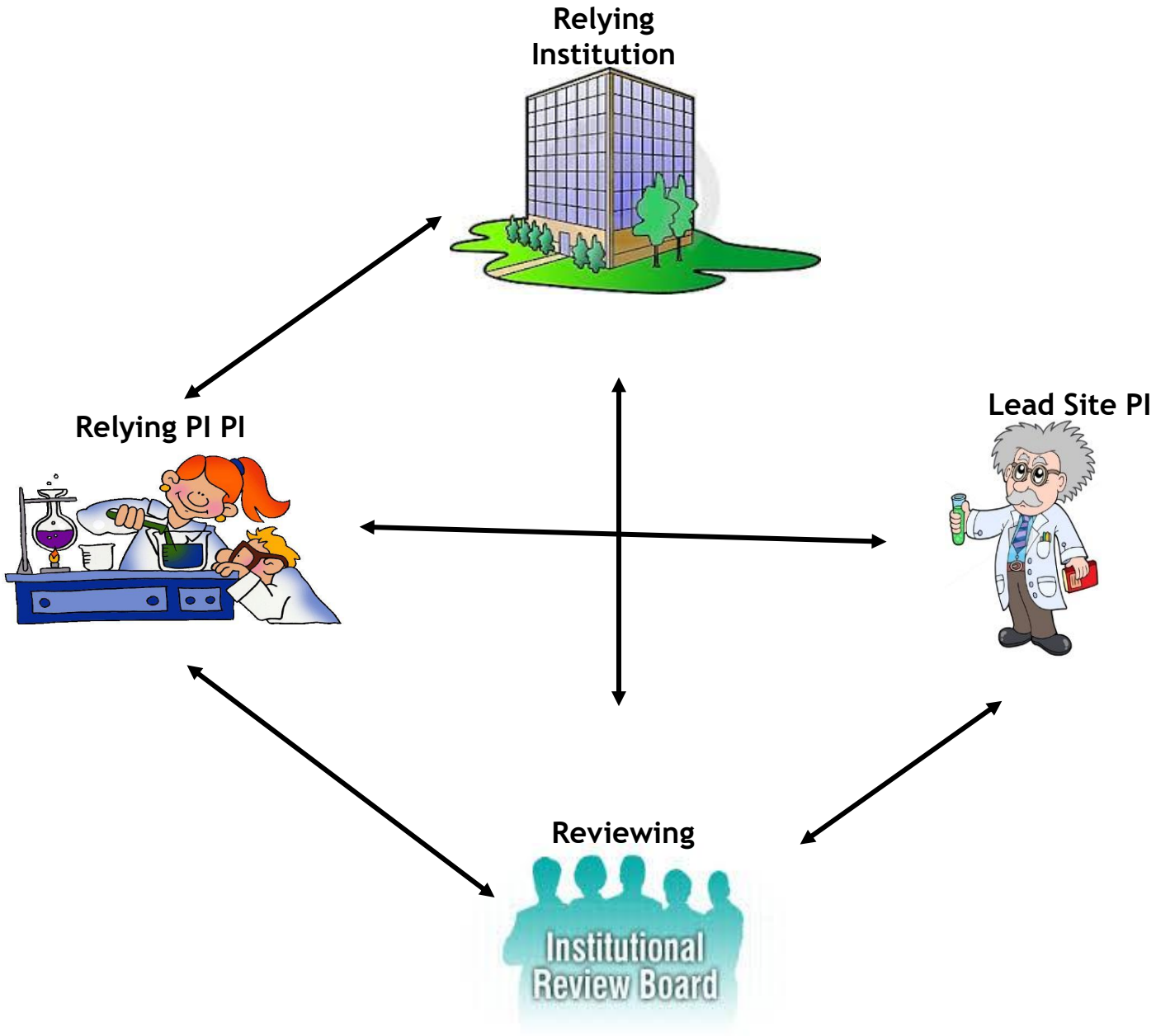


- Using the example of the Lead PI Communication Model, the Lead PI:
  - Communication to the relying sites how the reviewing IRB will receive information regarding COI.
  - Communicates COI information from relying sites to the reviewing IRB.

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 "Study-Specific Document" to collect COI information, there is a designated area to provide the contact information for POC at the relying institution.*

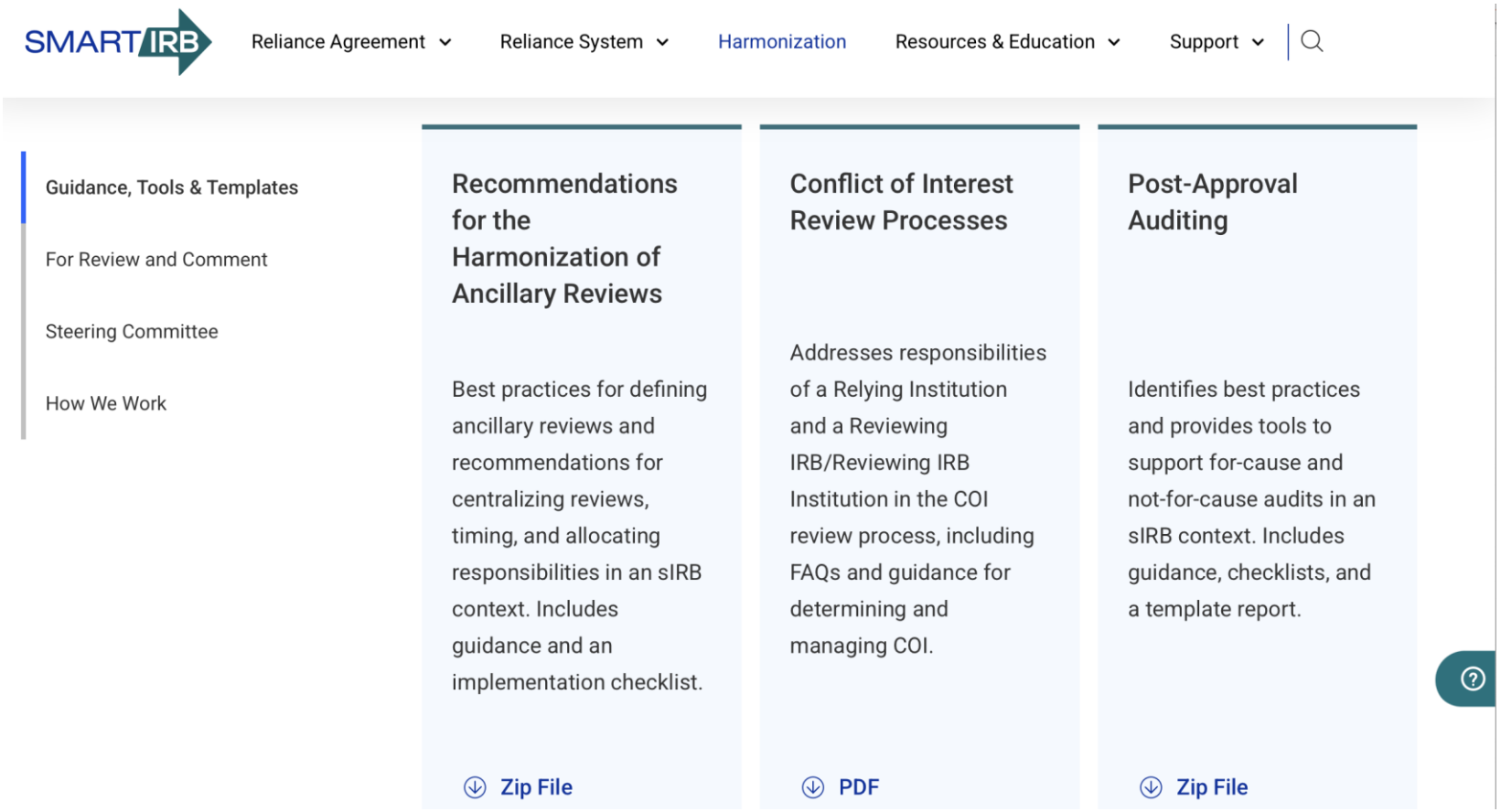
Conflict of Interest - Lead PI Model



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 study-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

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)

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 study-specific document

Training Study Teams

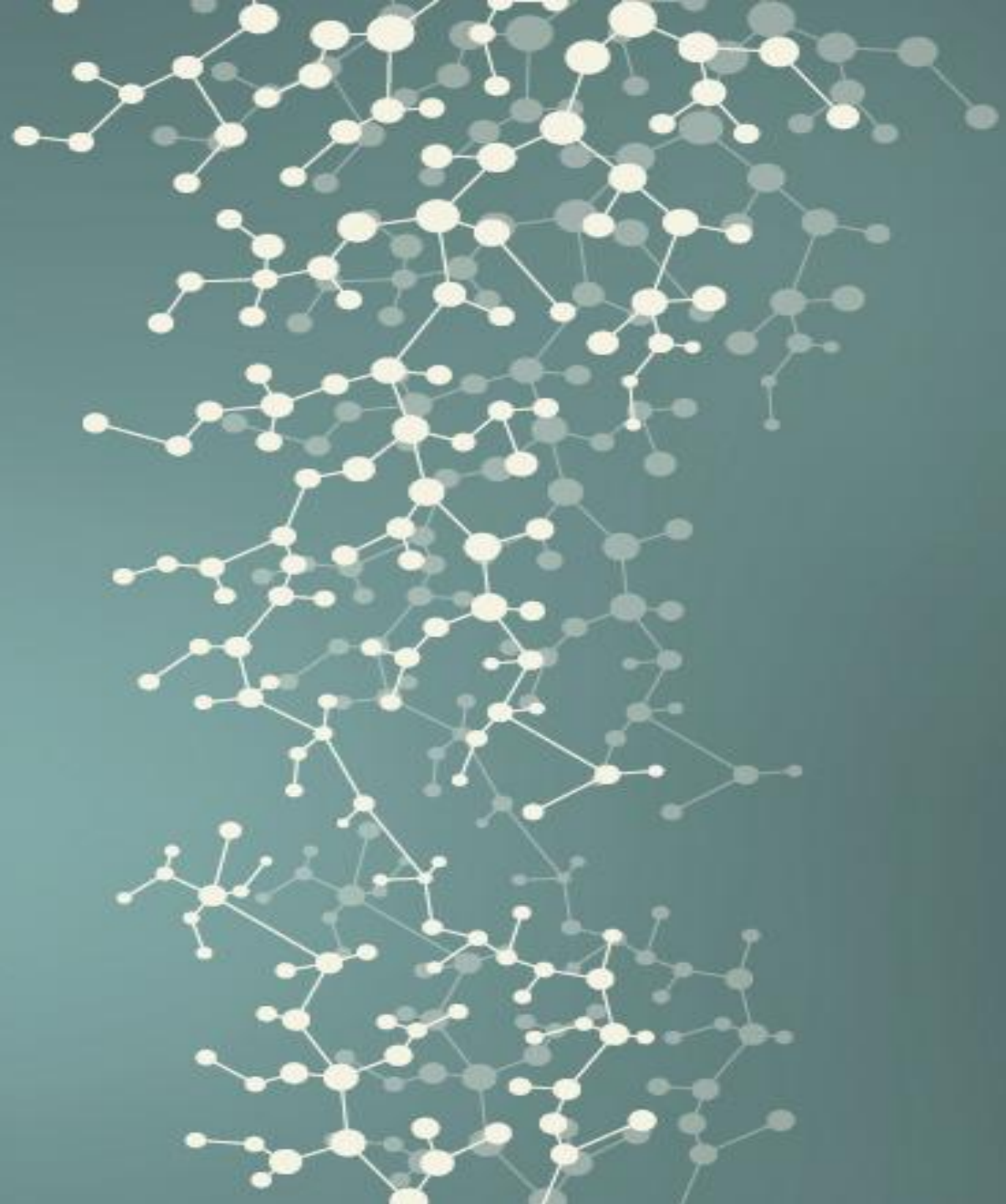
Nichelle Cobb, Senior Advisor for SMART IRB; Senior Advisor for Strategic Initiatives, Association for the Accreditation of Human Research Protection Programs (AAHRPP)

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

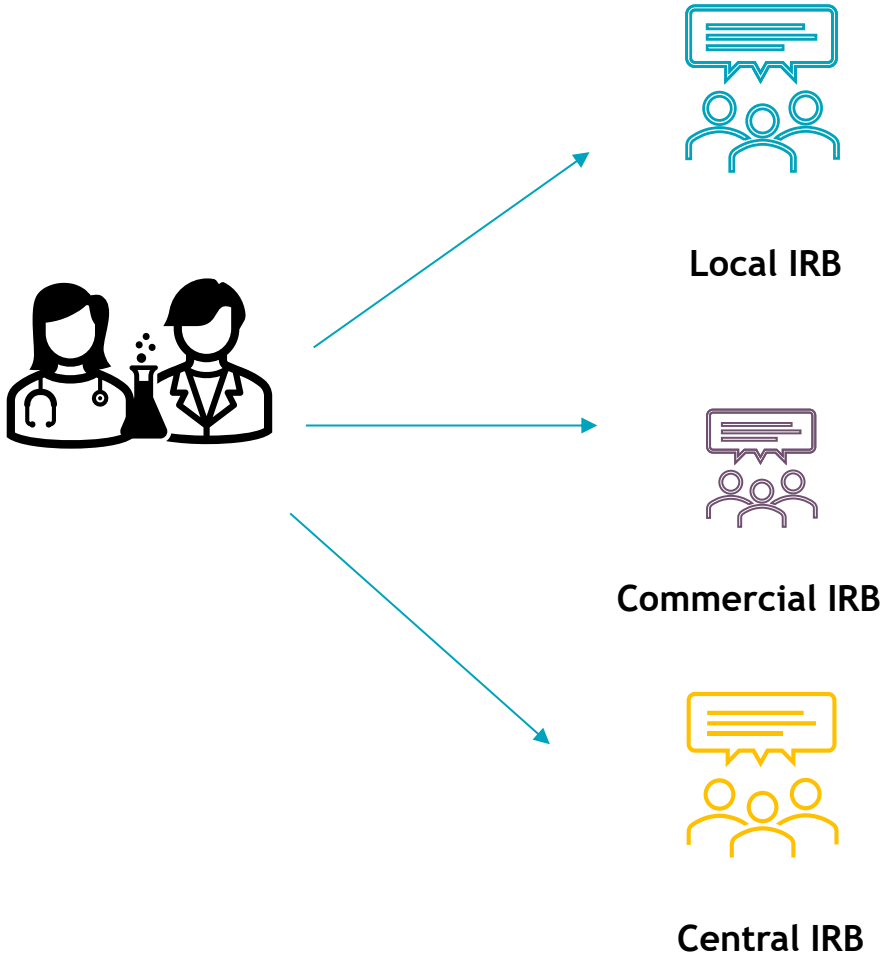
- Overview the effect of single IRB on study teams and impact on training needs
- SMART IRB resources that can be leveraged to train study teams
- Strategies for study team training and education

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



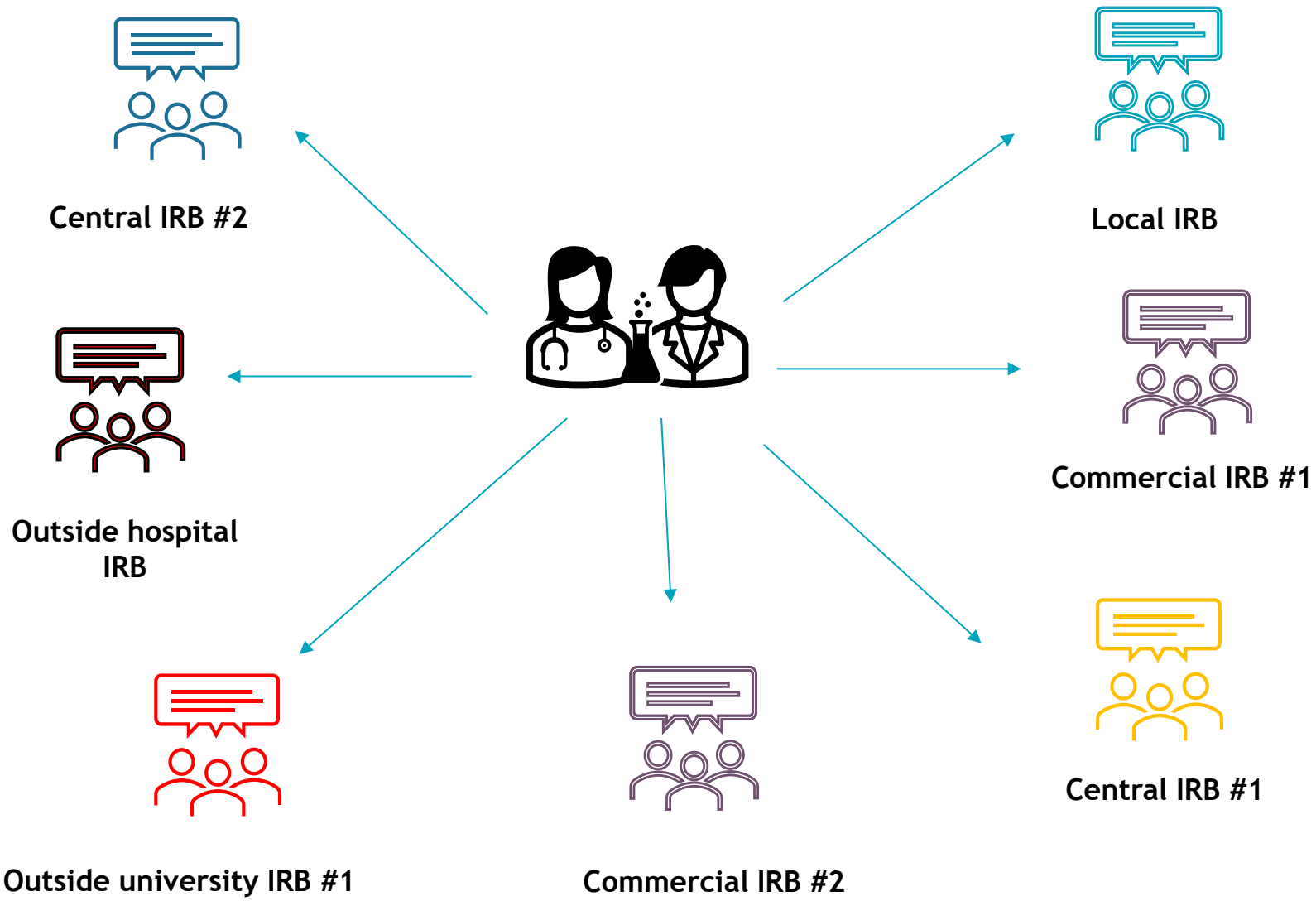
Before Single IRB

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

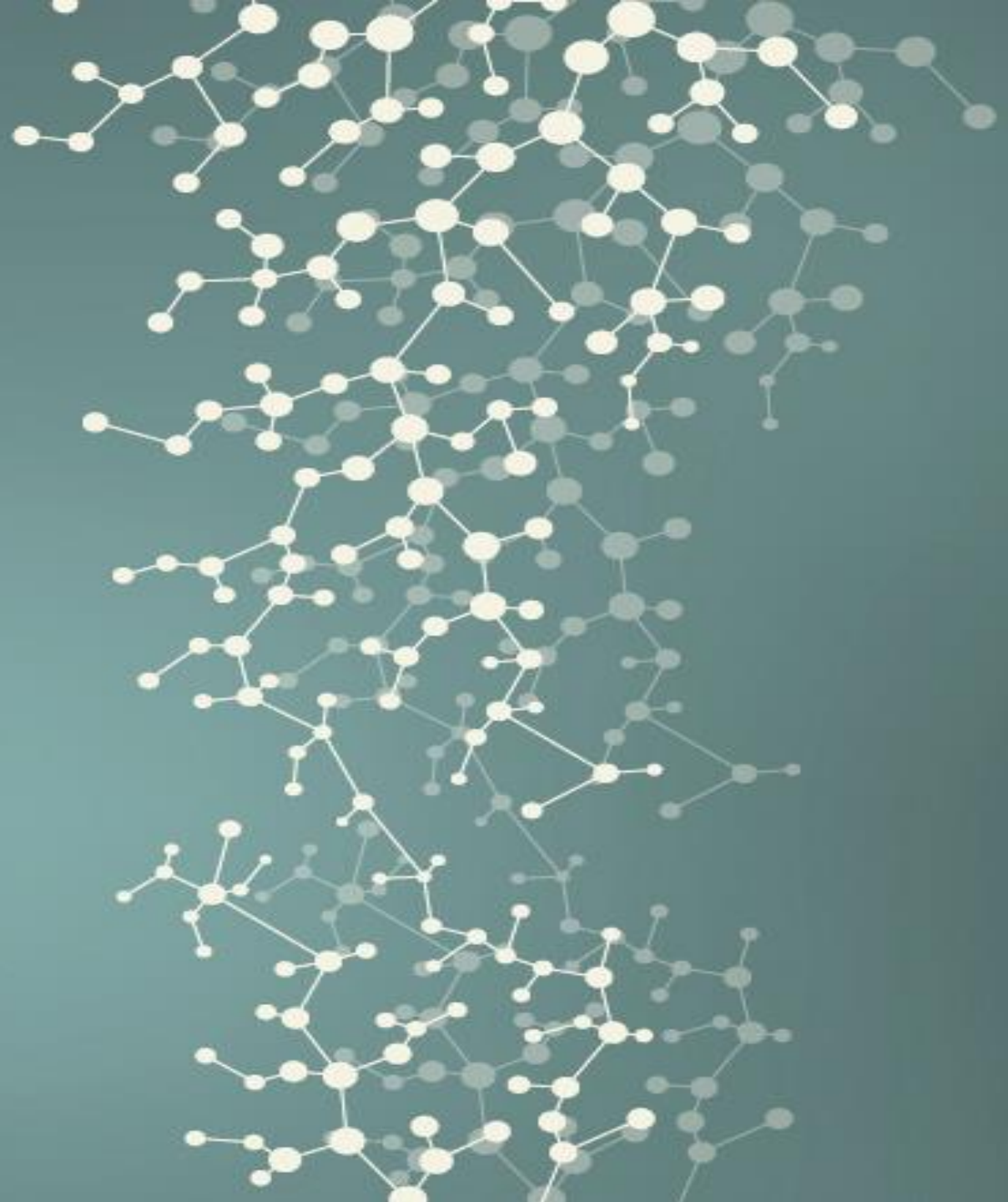
Researchers are working with so many more IRBs



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

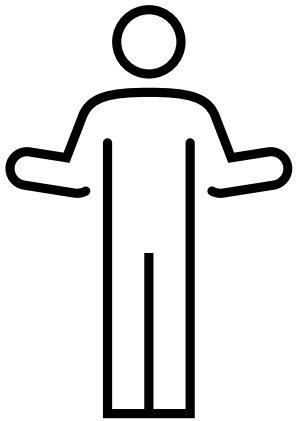
May need new platforms to disseminate documents to study teams

Federal Grants that include Multisite Human Participants Research

What IRBs said to research teams:

Before Single IRB Review

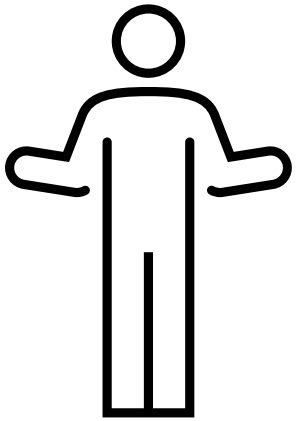
Come back to us when you get your funding!



The IRB

After Single IRB Review

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



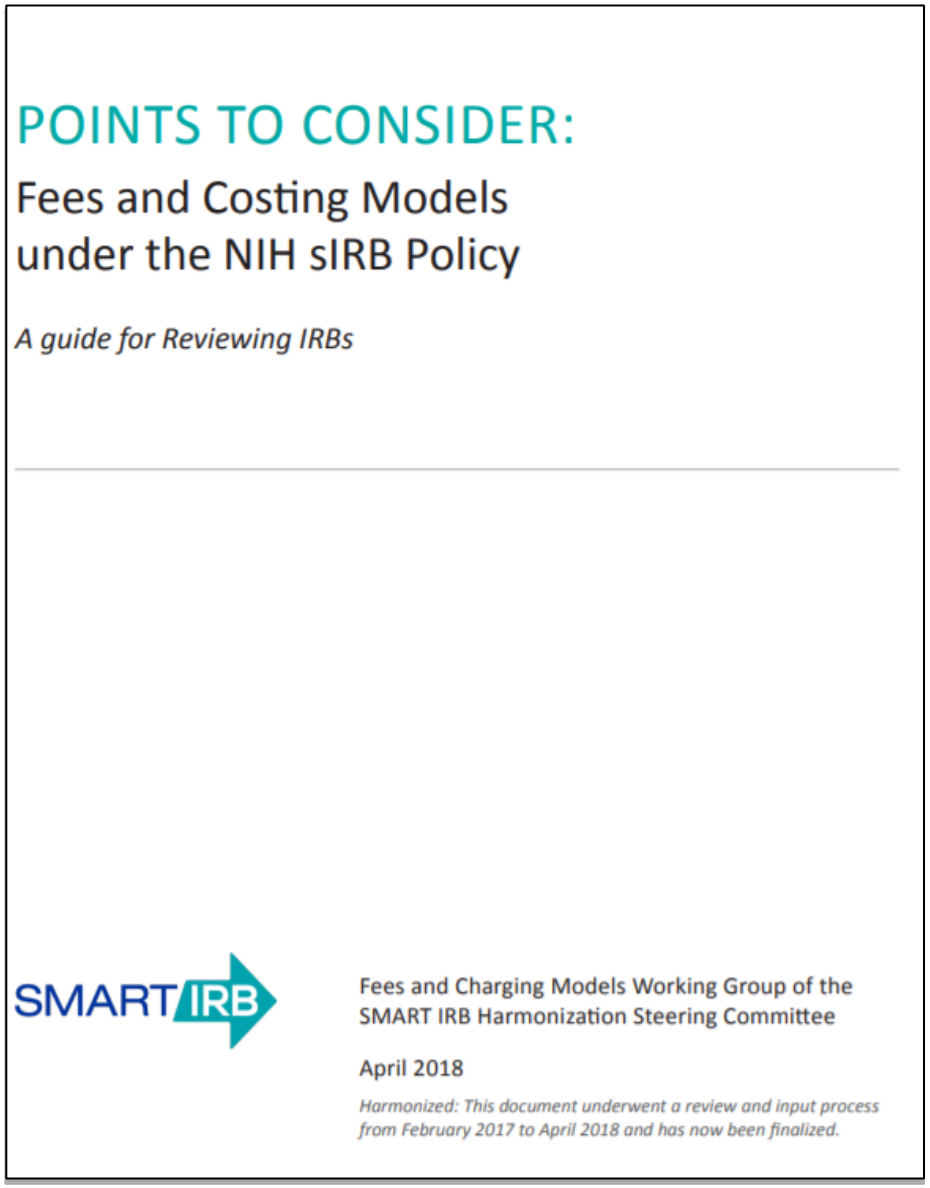
The IRB

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

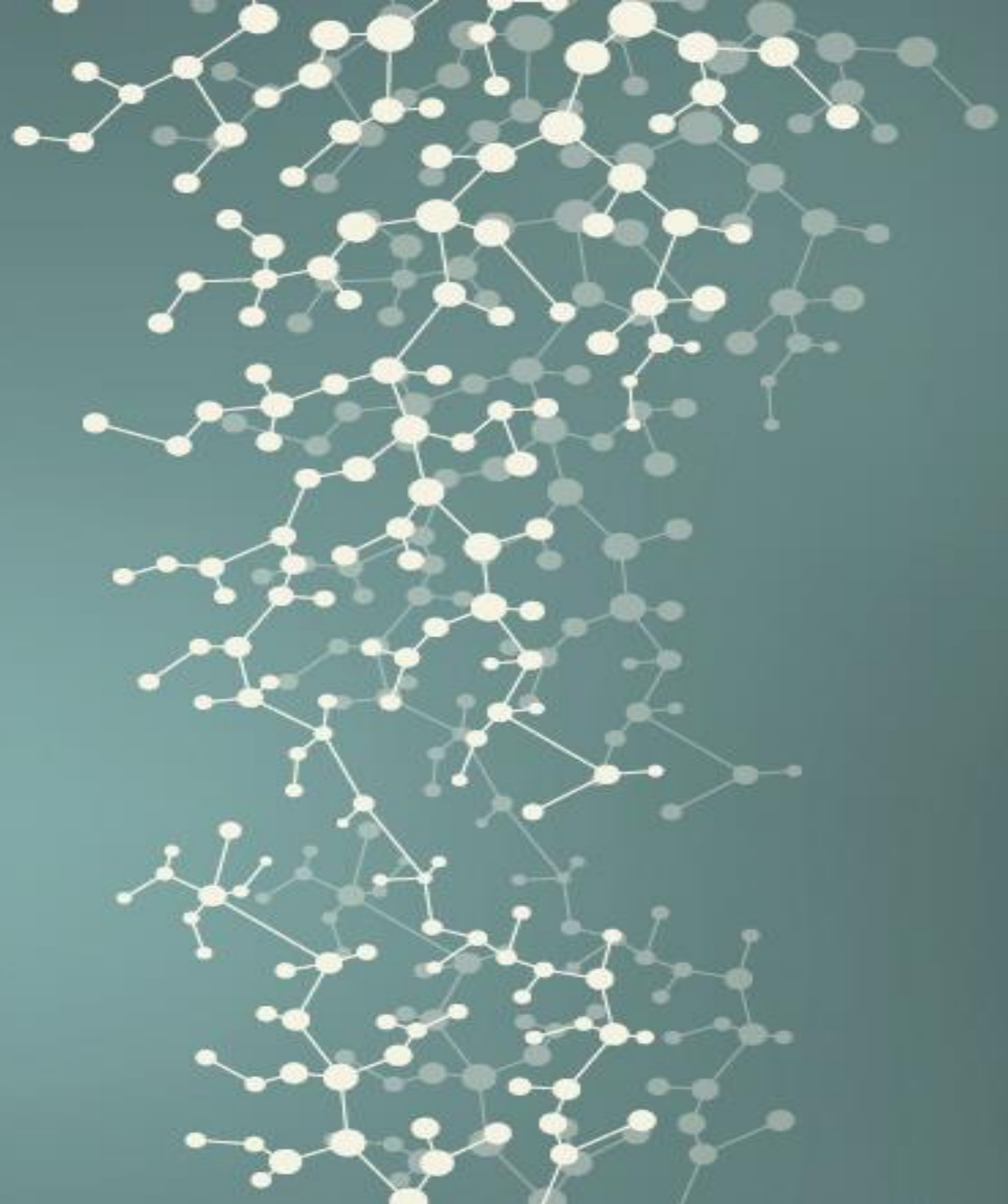
SMART IRB

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.

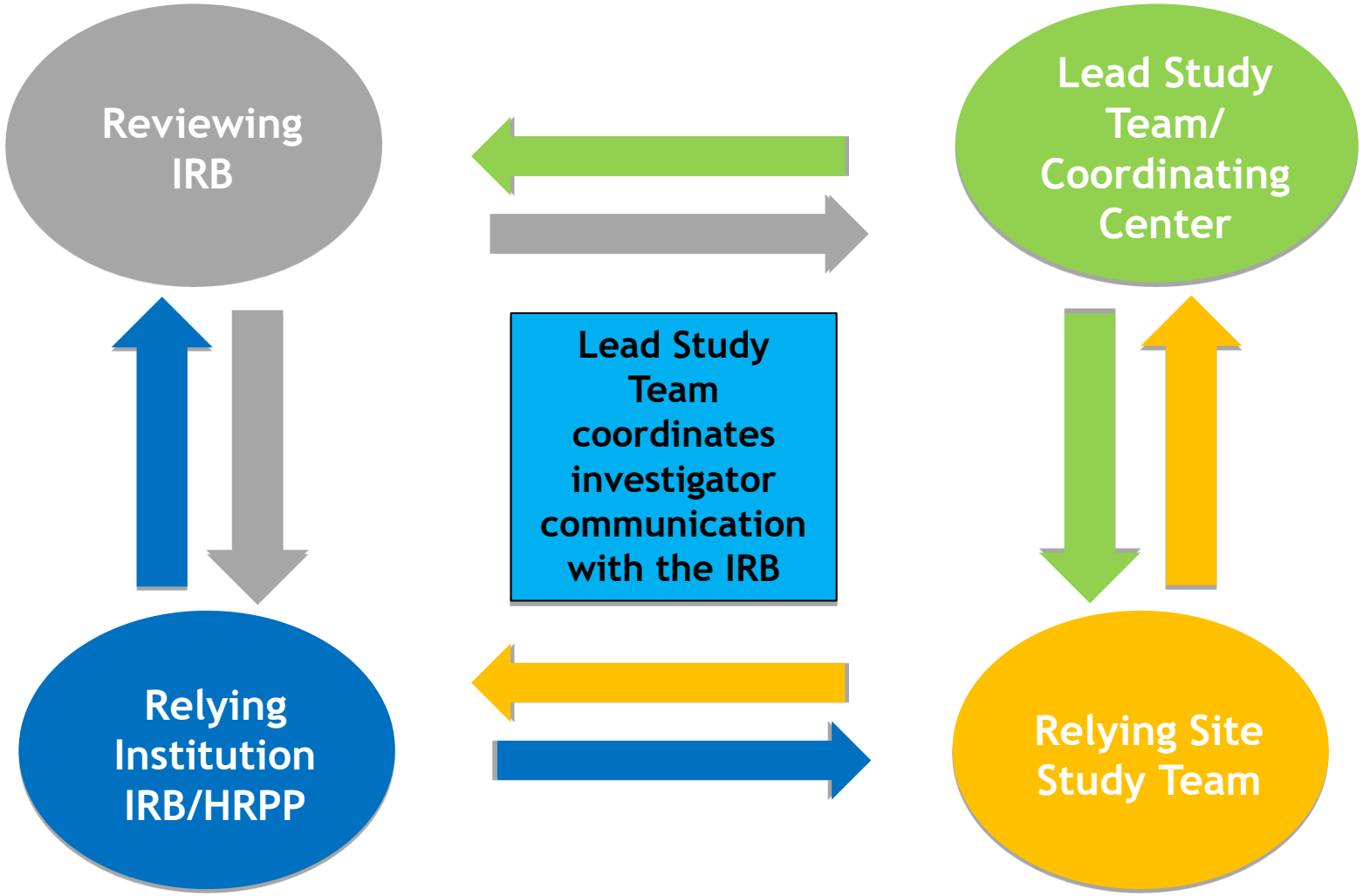
Responsibilities



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.



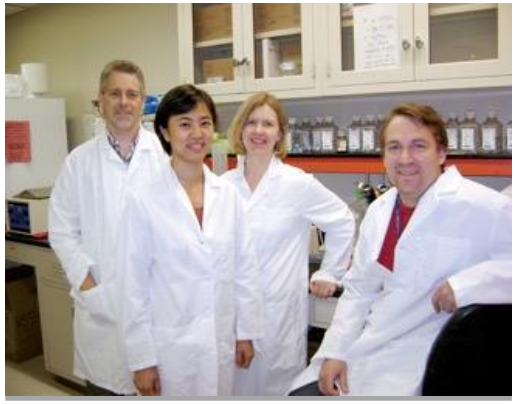
Single IRB Readiness Checklist for Lead Study Teams & Coordinating Centers: Reliance Arrangements

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

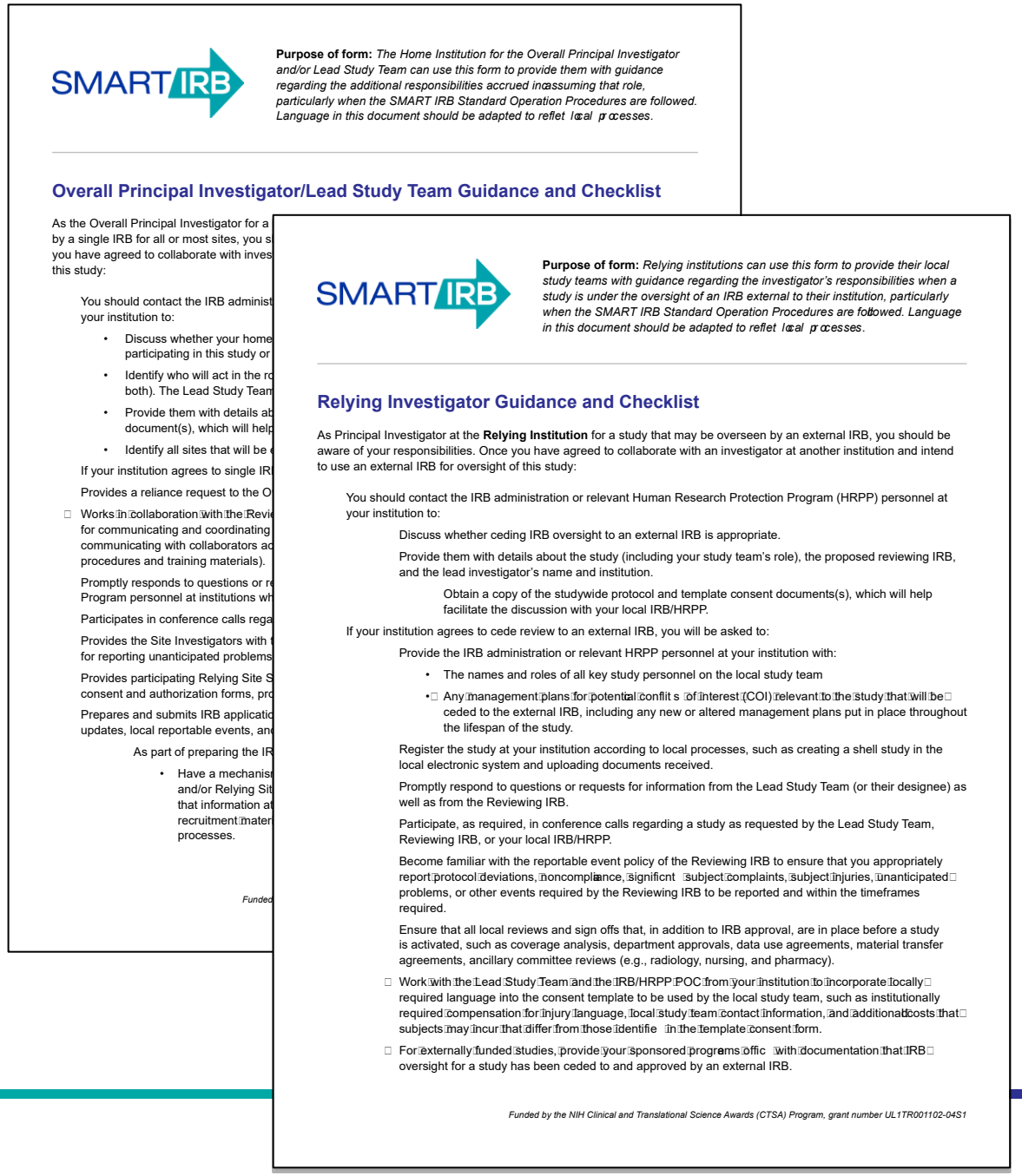
SMART IRB Resource: Investigator Checklists

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.

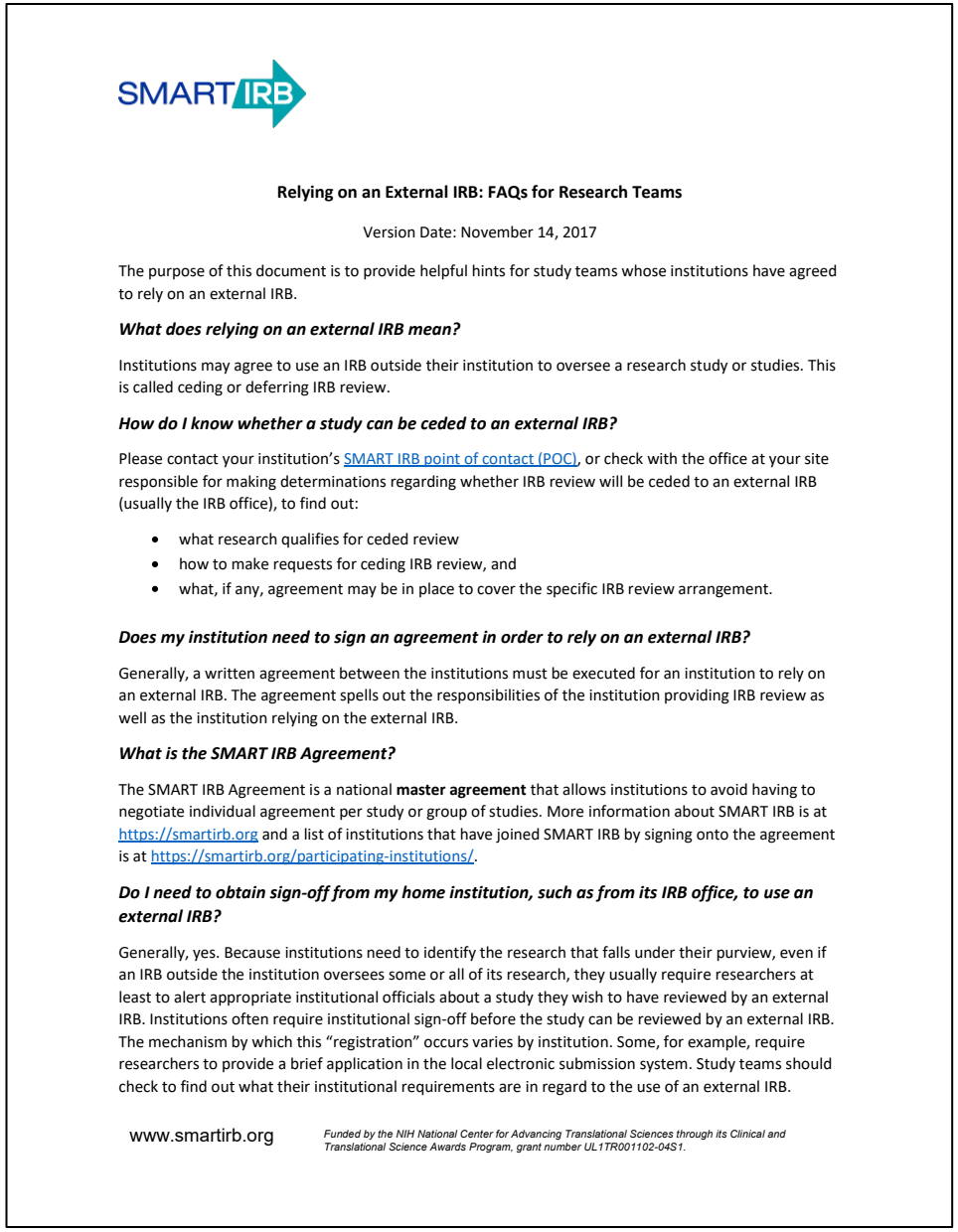
Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR001102-04S1

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.

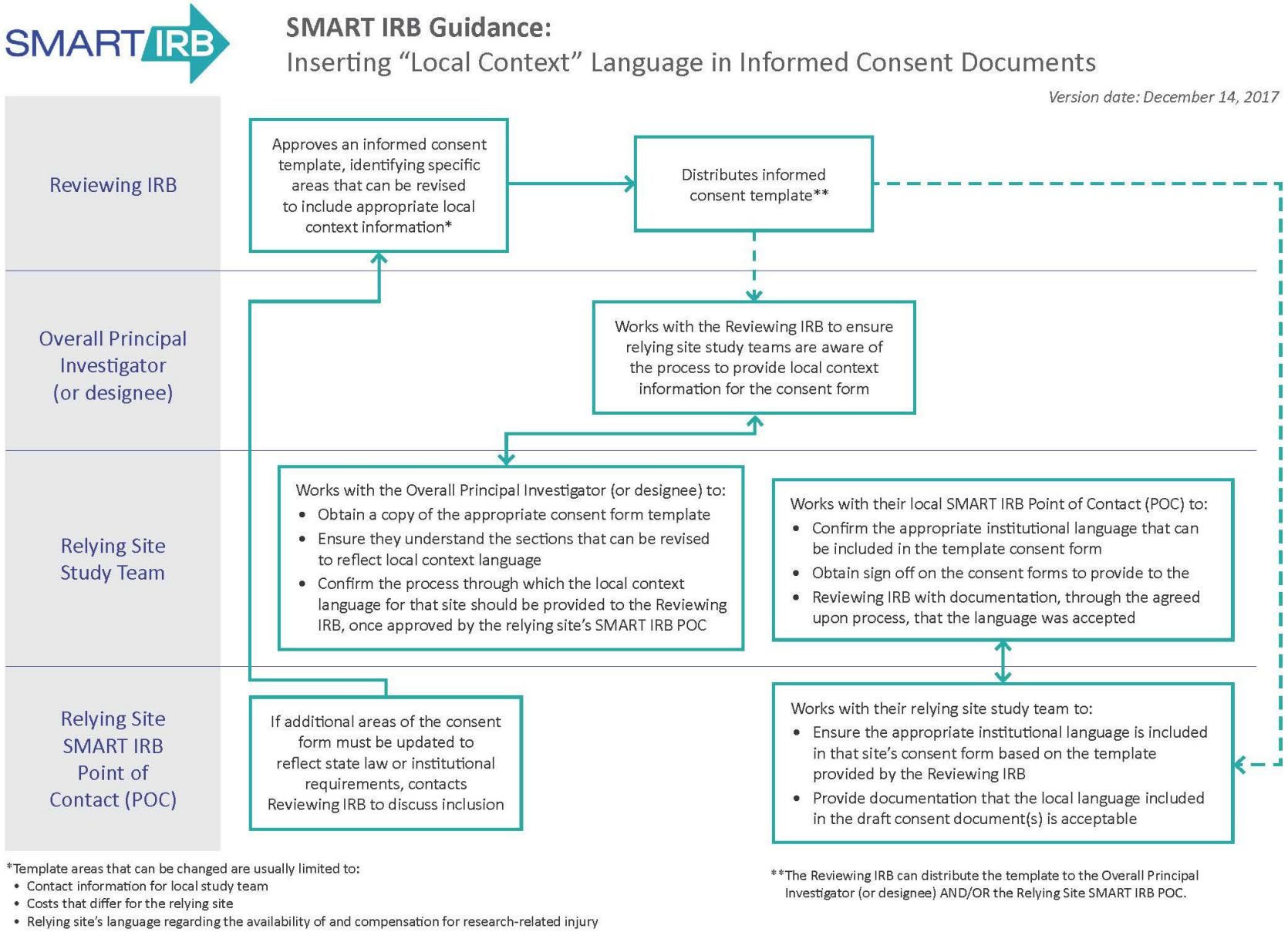
Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

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.

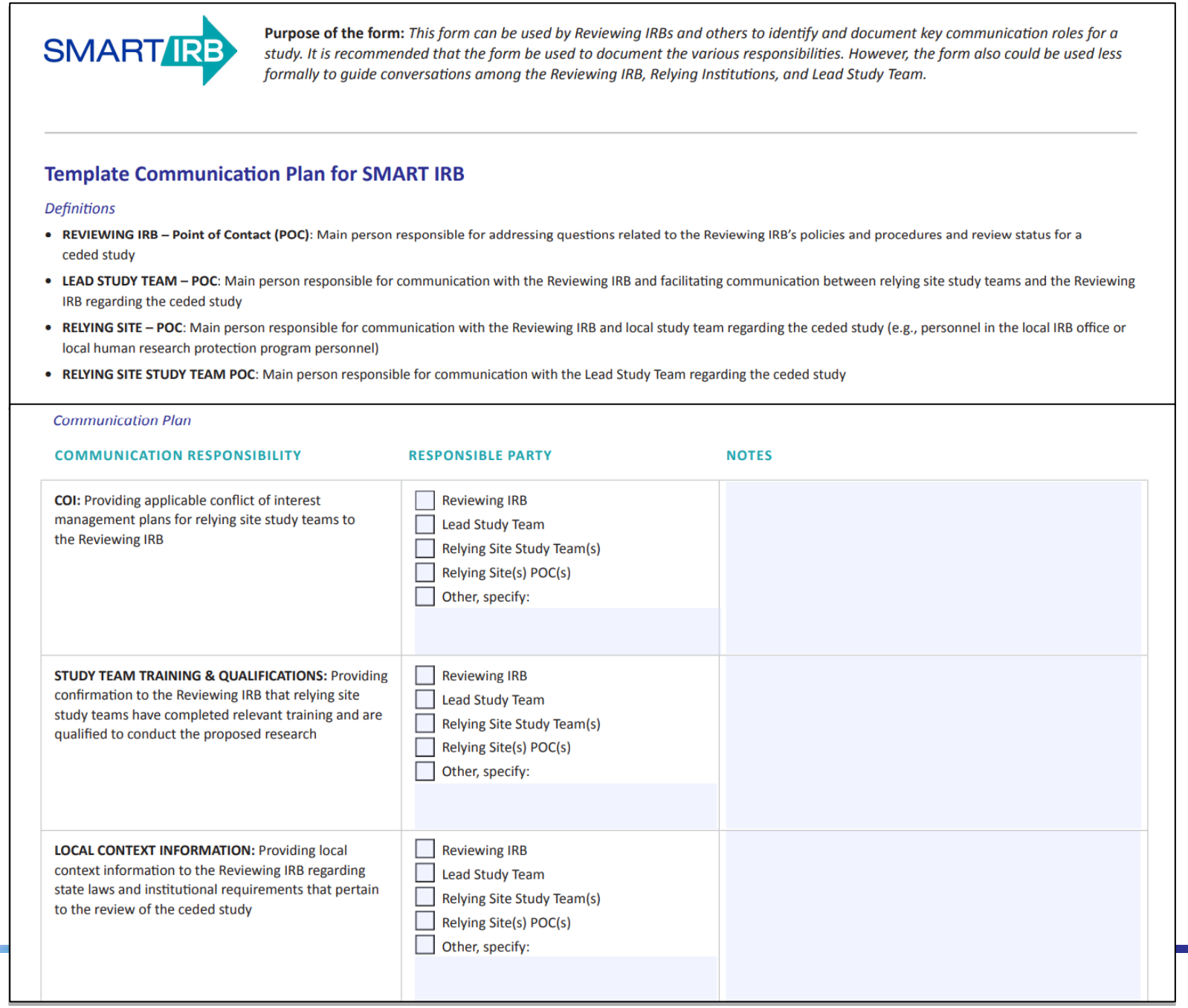


SMART IRB Resource: Communication plan for single IRB review

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

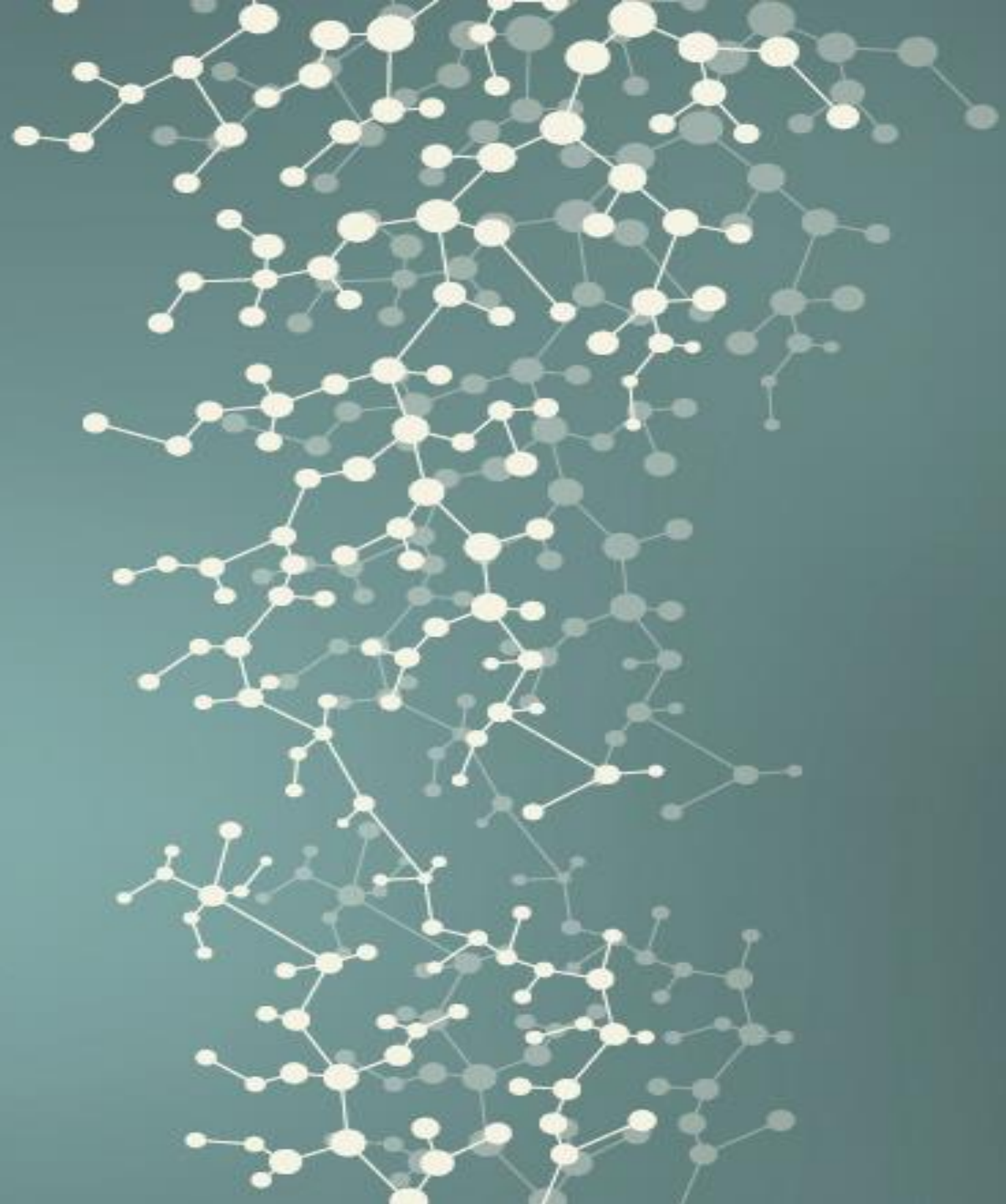
Definitions

- **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:

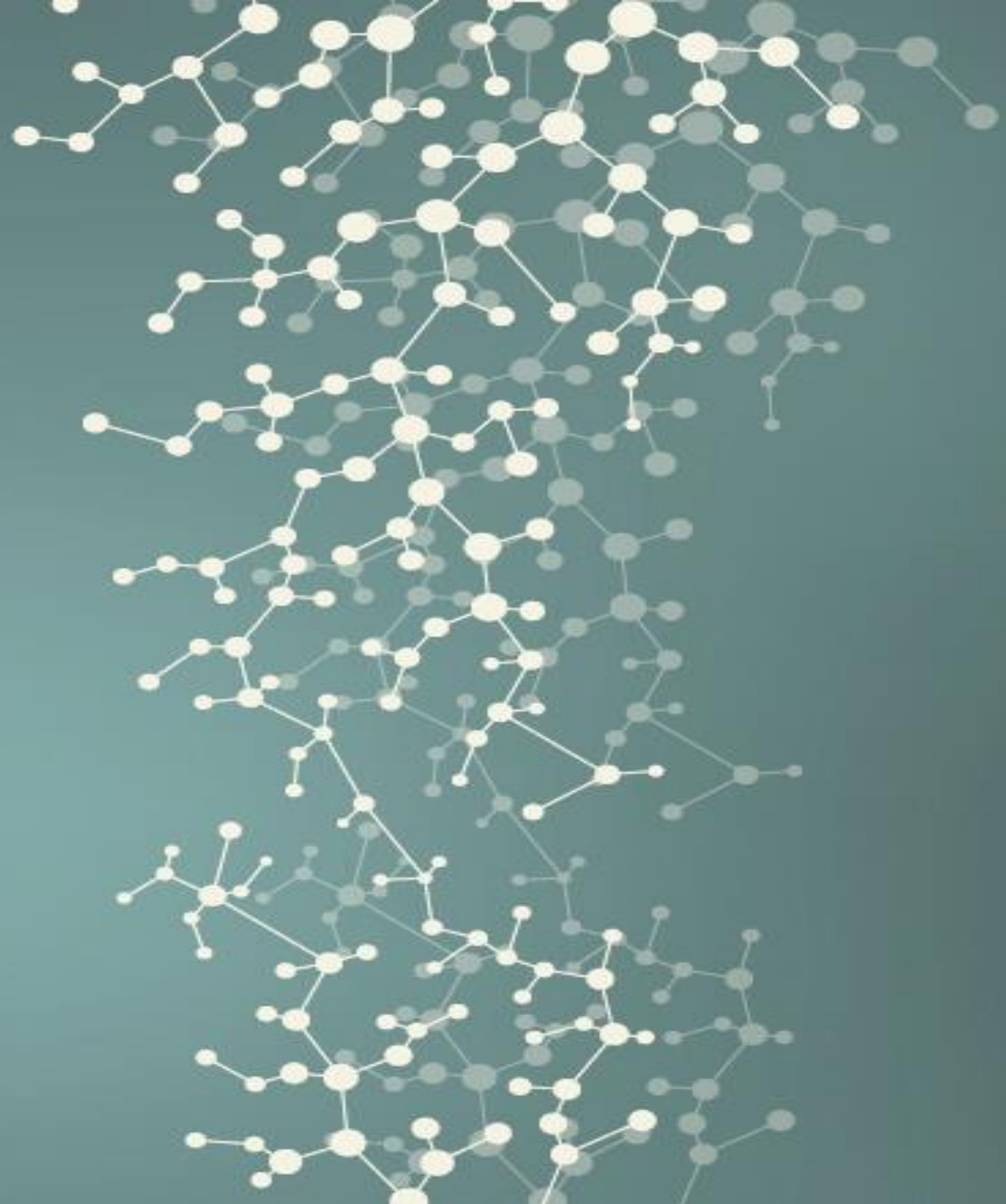
What to report to the Reviewing IRB and adhering to the Reviewing IRB's policies, such as for:

- 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

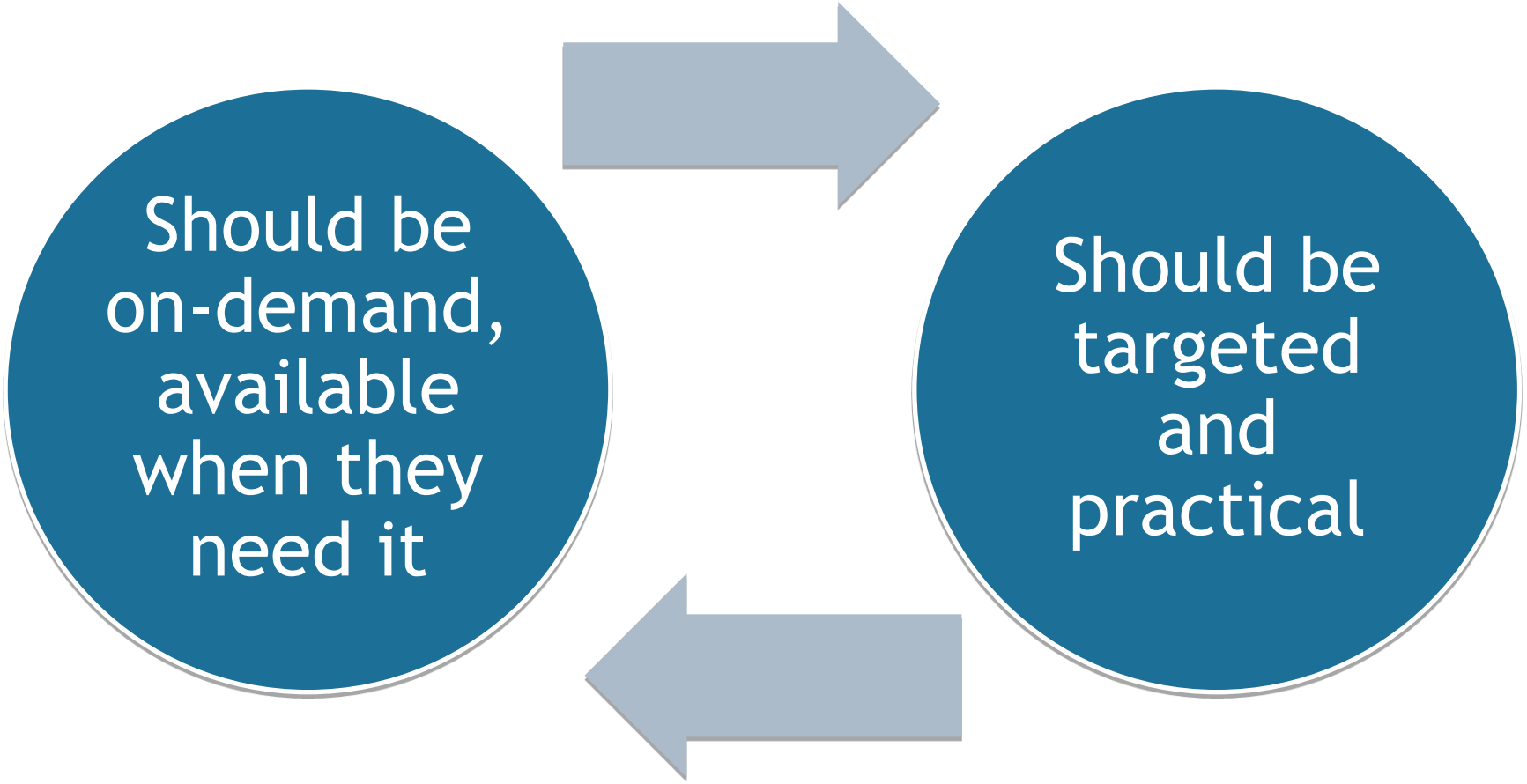
Training Approaches



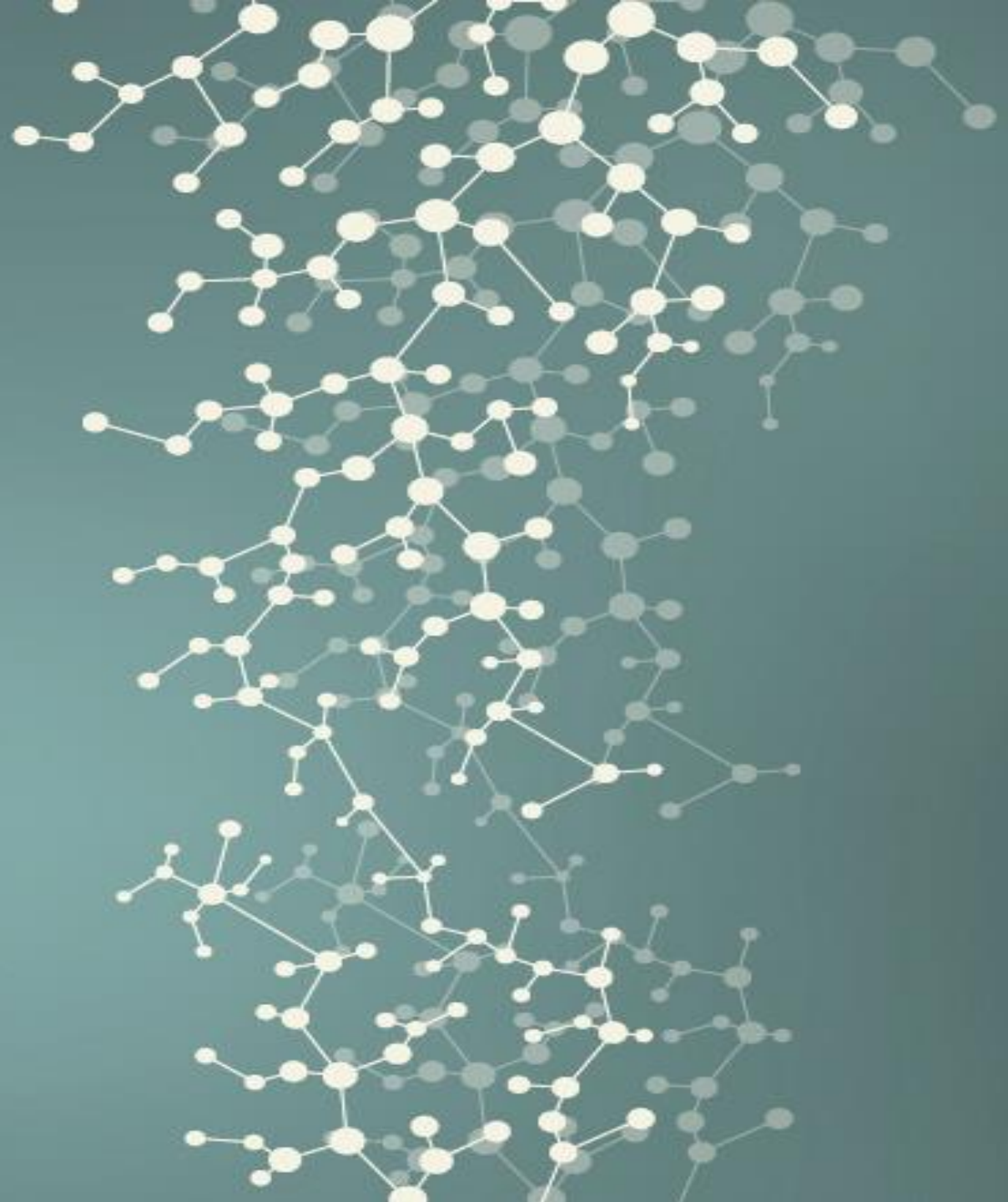
A model: one-on-one, study specific training

- 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



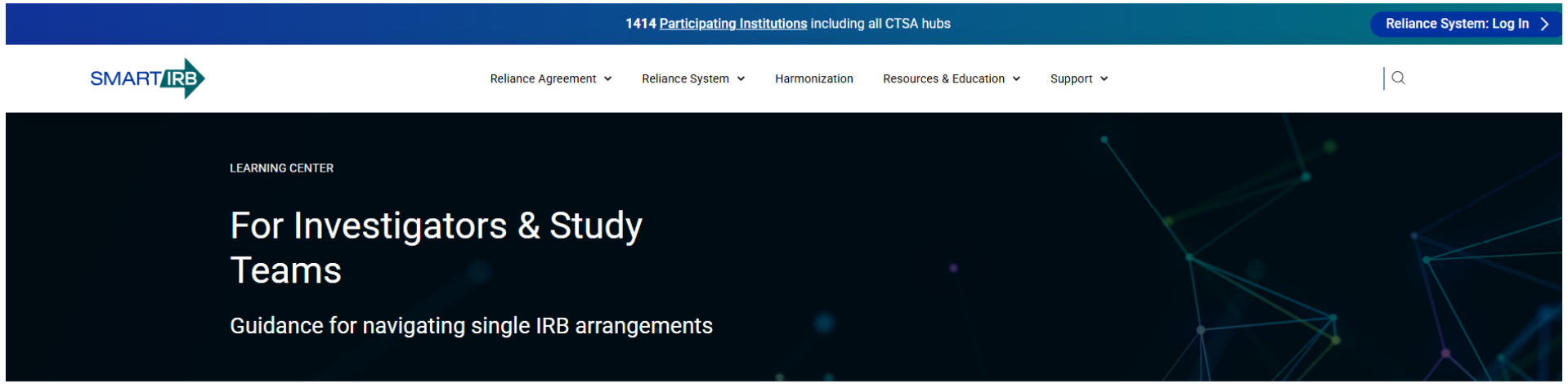
Resources to Support Training

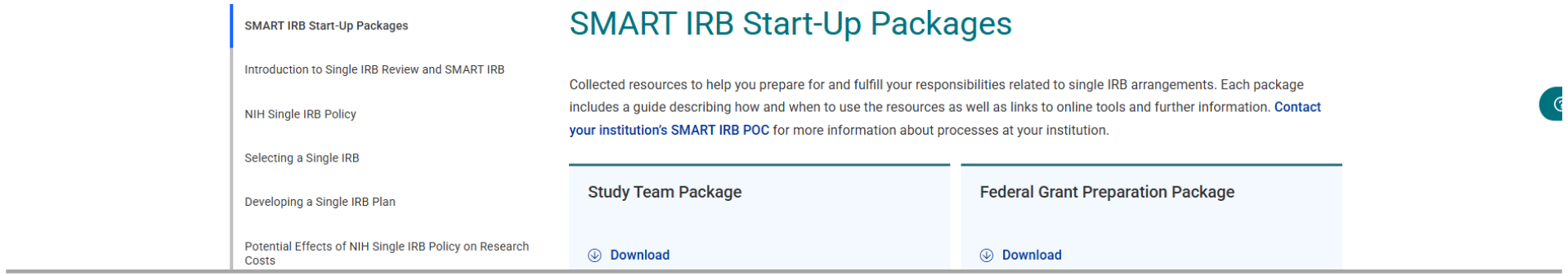


SMART IRB Resources for Study Teams

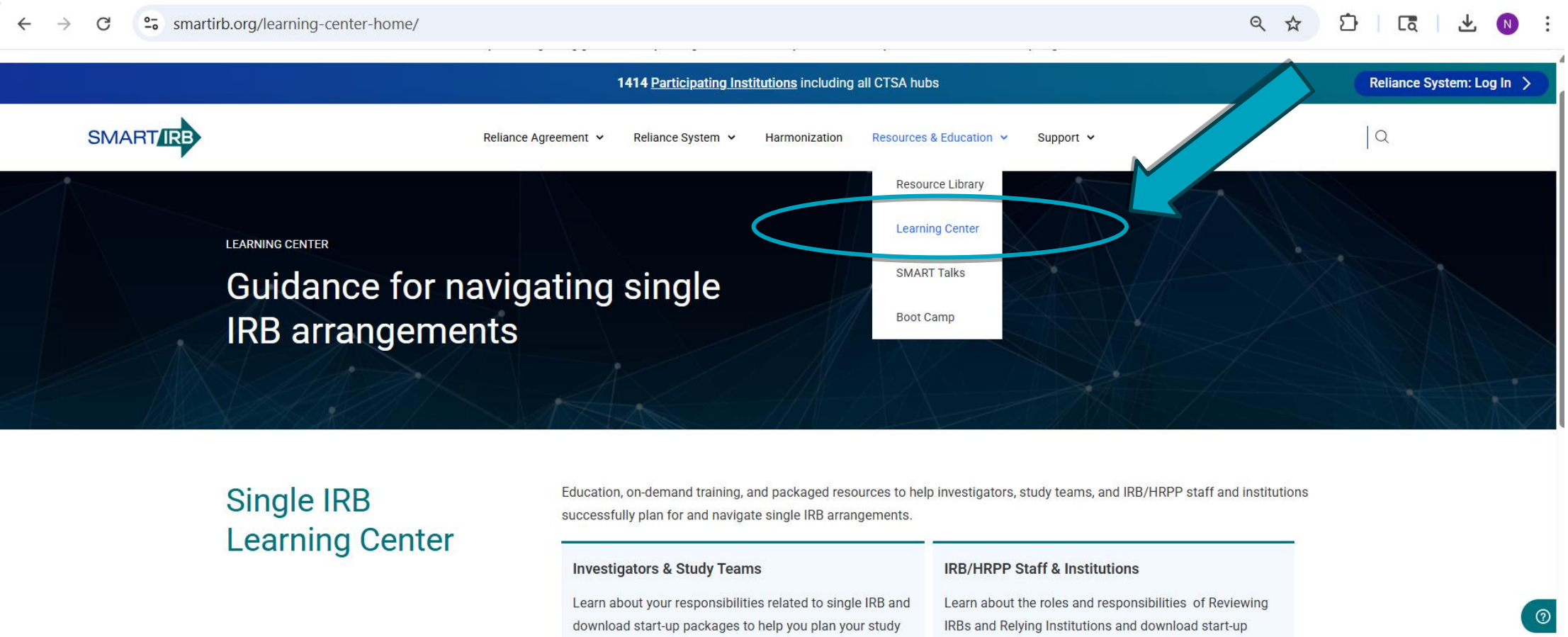
https://smartirb.org/study-teams/

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

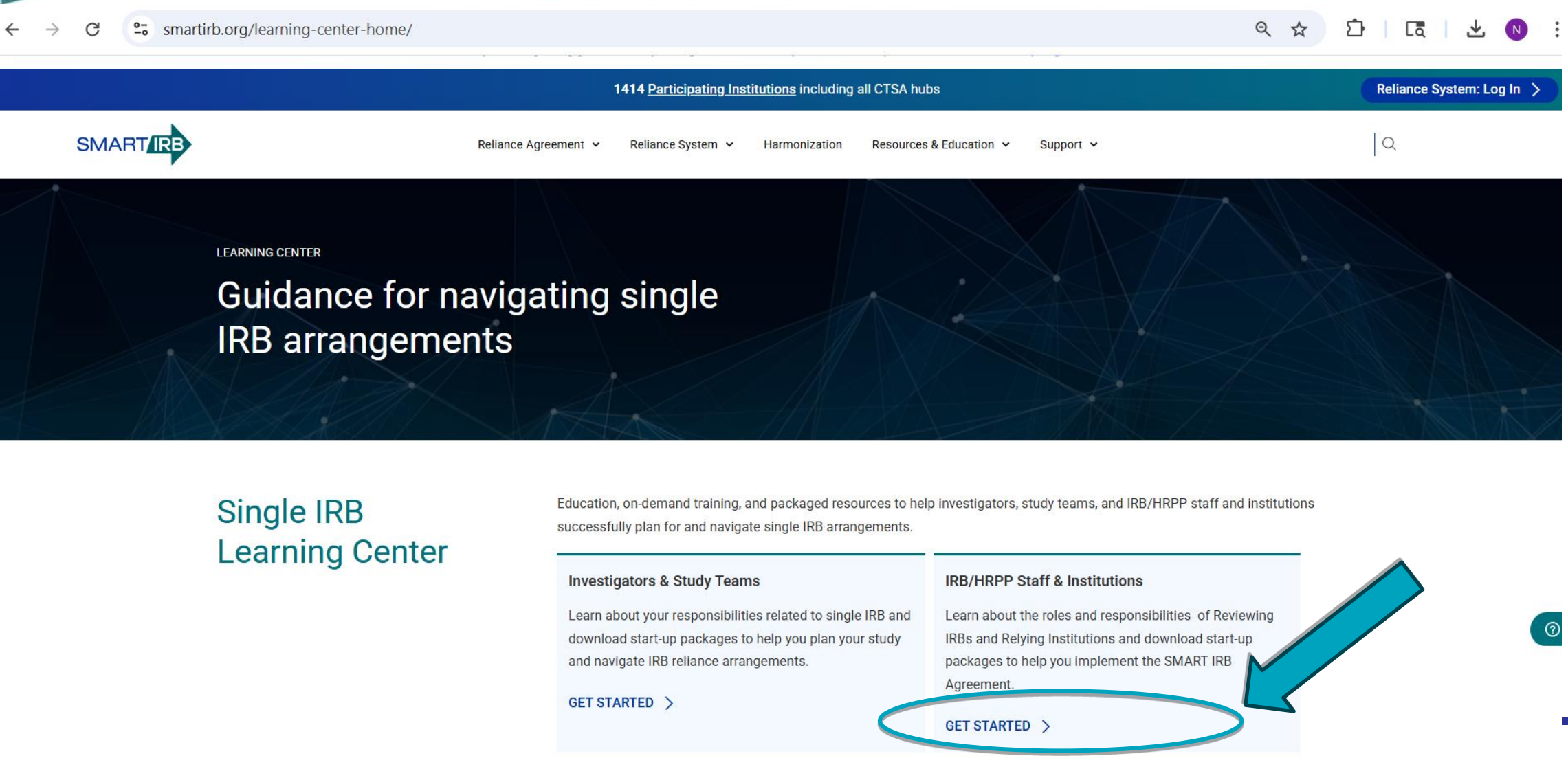




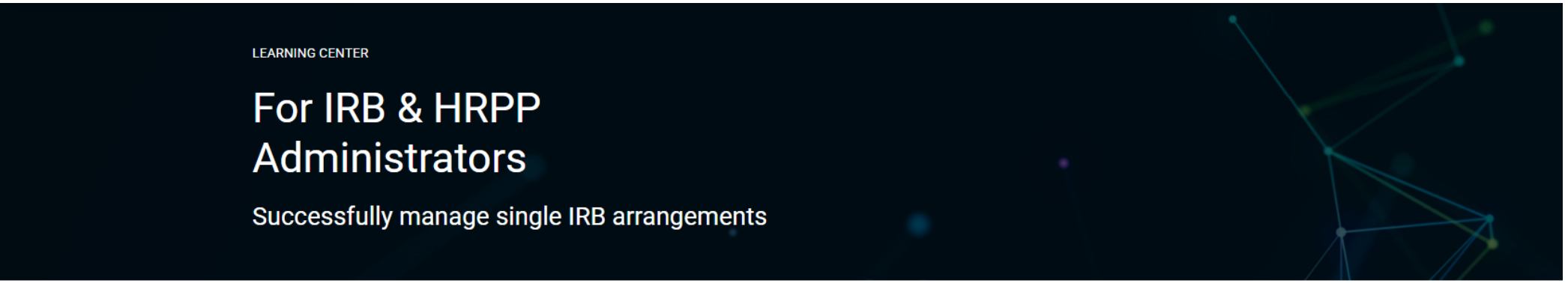
Customizing the Training: Go to smartirb.org

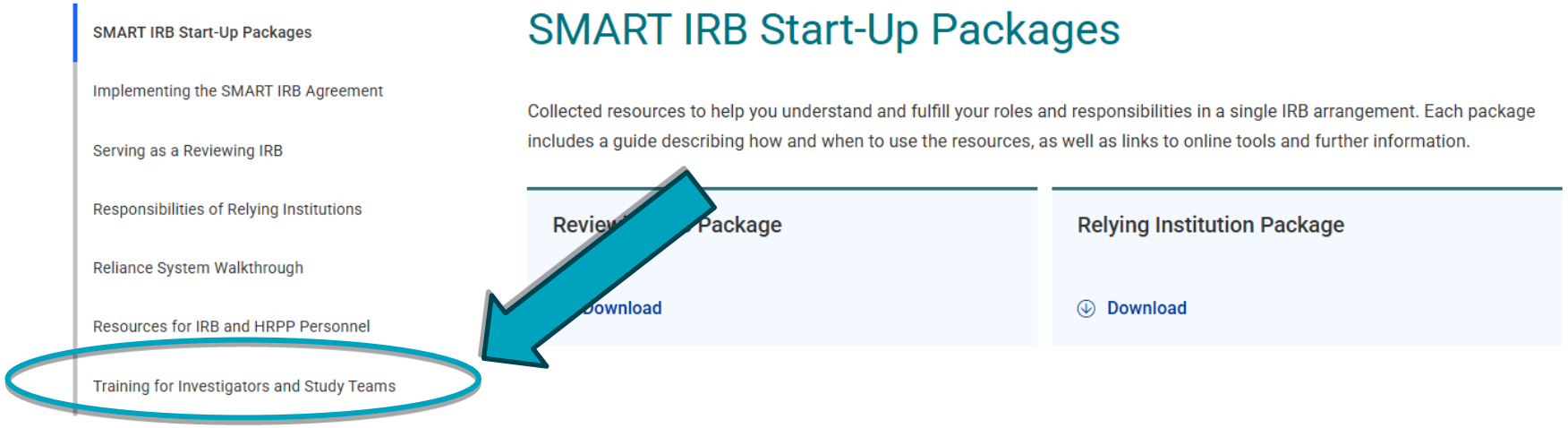


Customizing the Training: Go to smartirb.org



Customizing the Training: Go to smartirb.org





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

Training Study Teams

Kathy Lawry
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

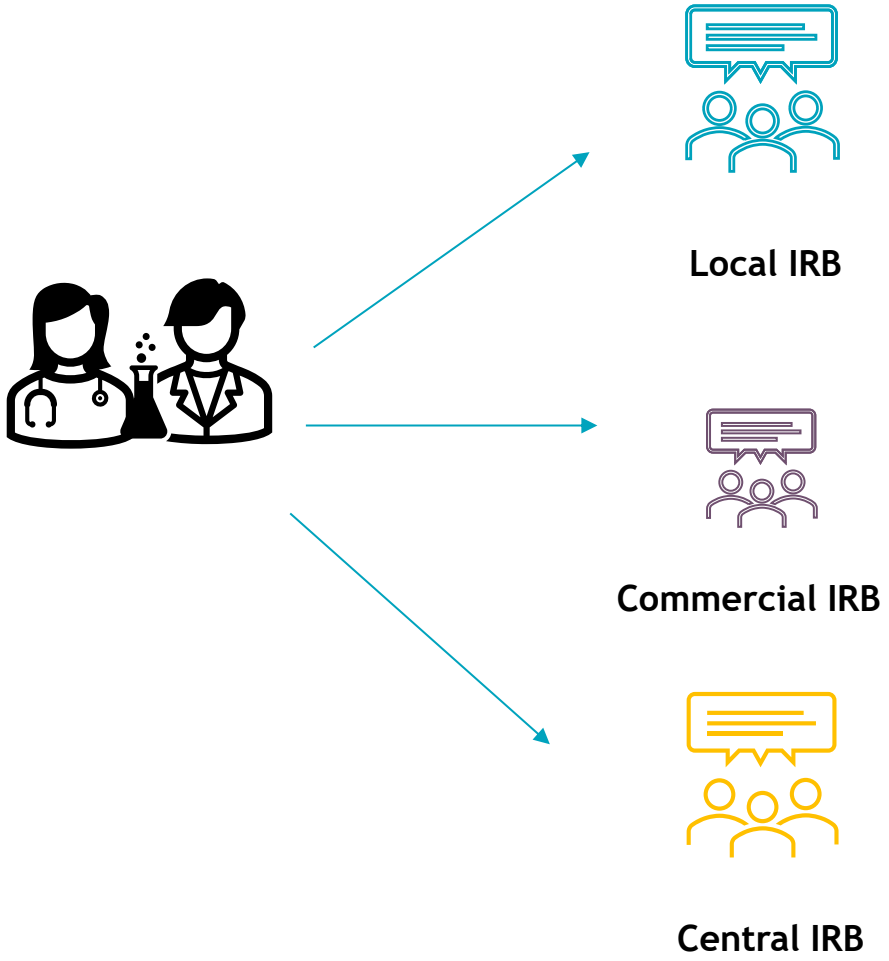
- Overview the effect of single IRB on study teams and impact on training needs
- SMART IRB resources that can be leveraged to train study teams
- Strategies for study team training and education

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



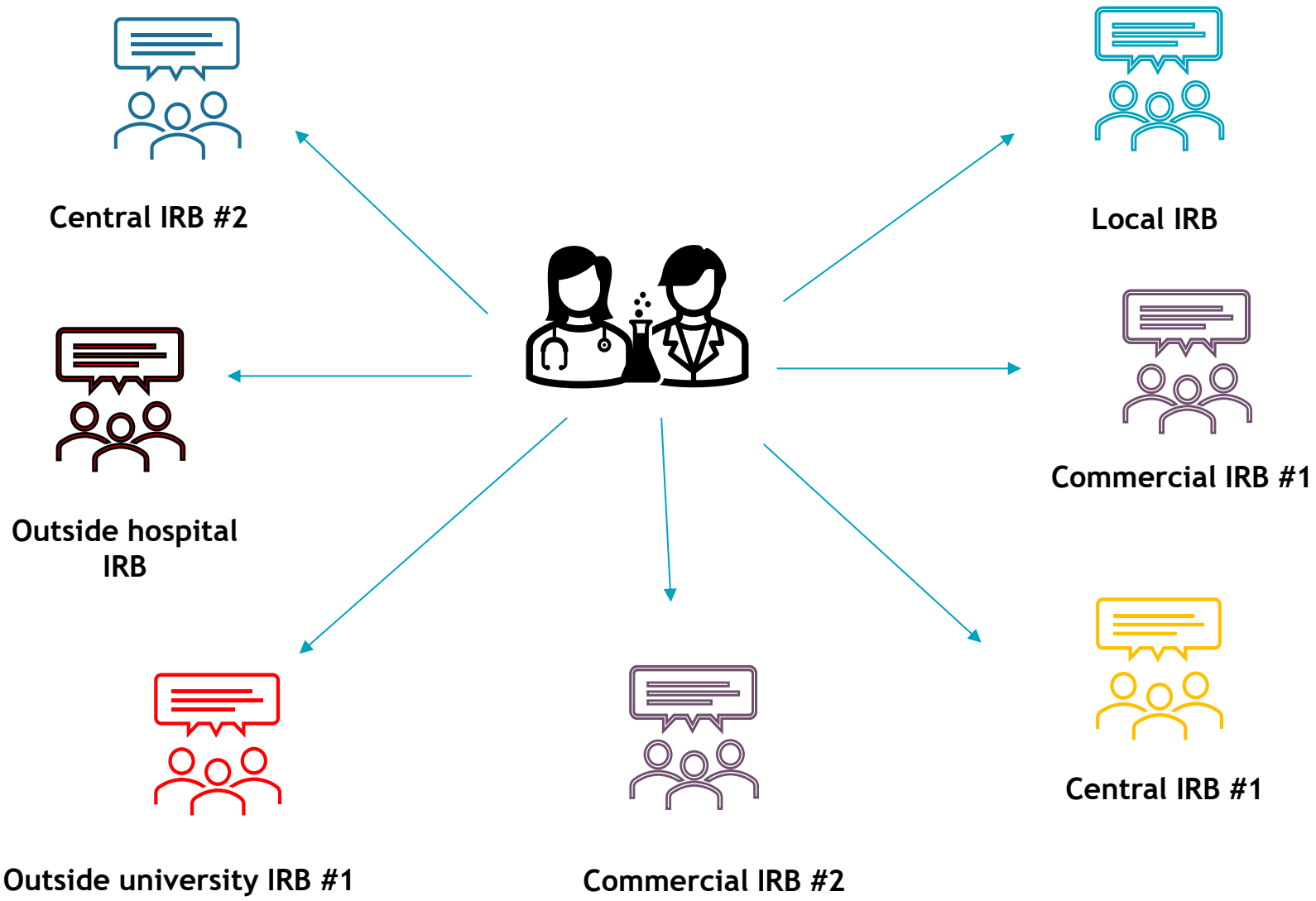
Before Single IRB

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

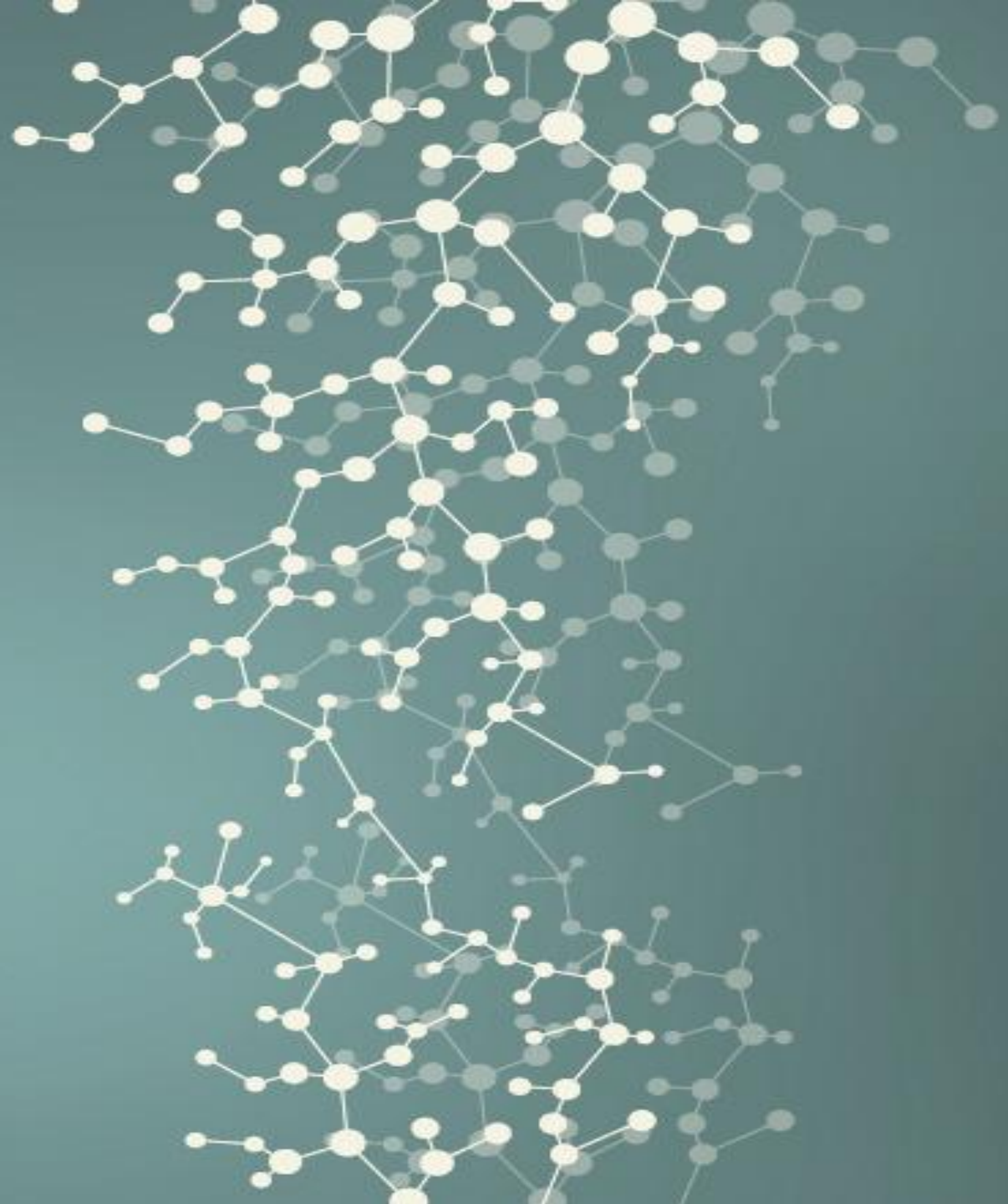
Researchers are working with so many more IRBs



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

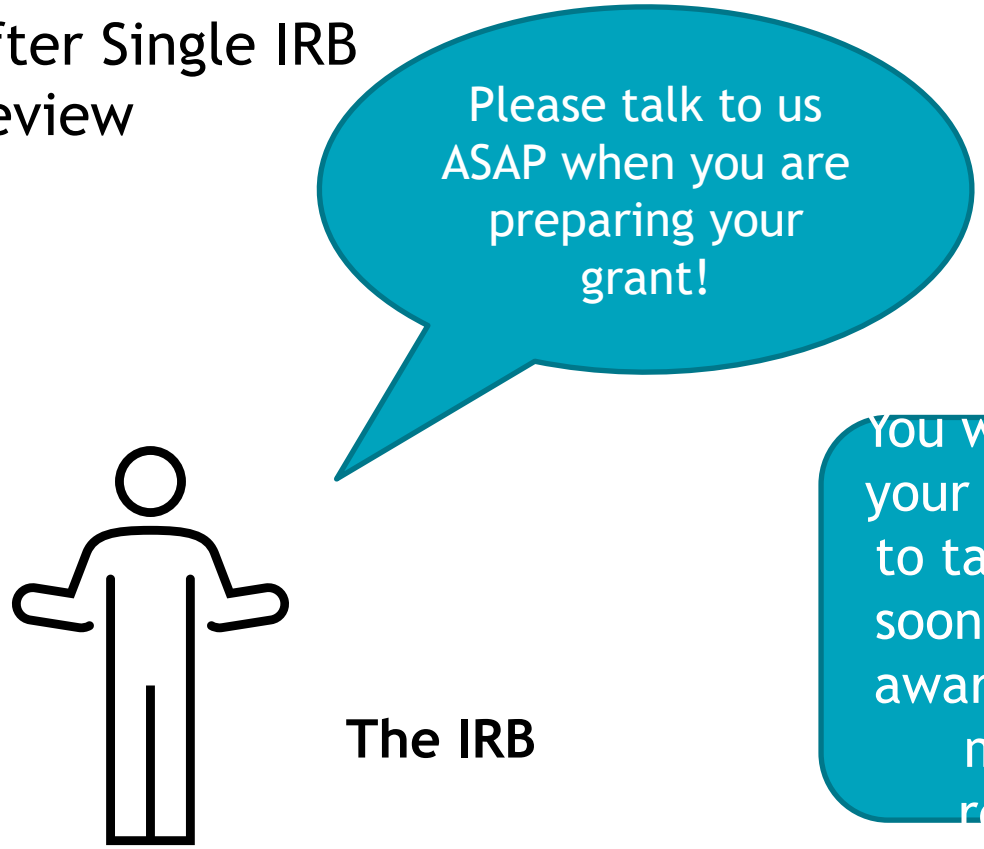
Federal Grants that include Multisite Human Participants Research

What IRBs said to research teams:

Before Single IRB Review



After Single IRB Review

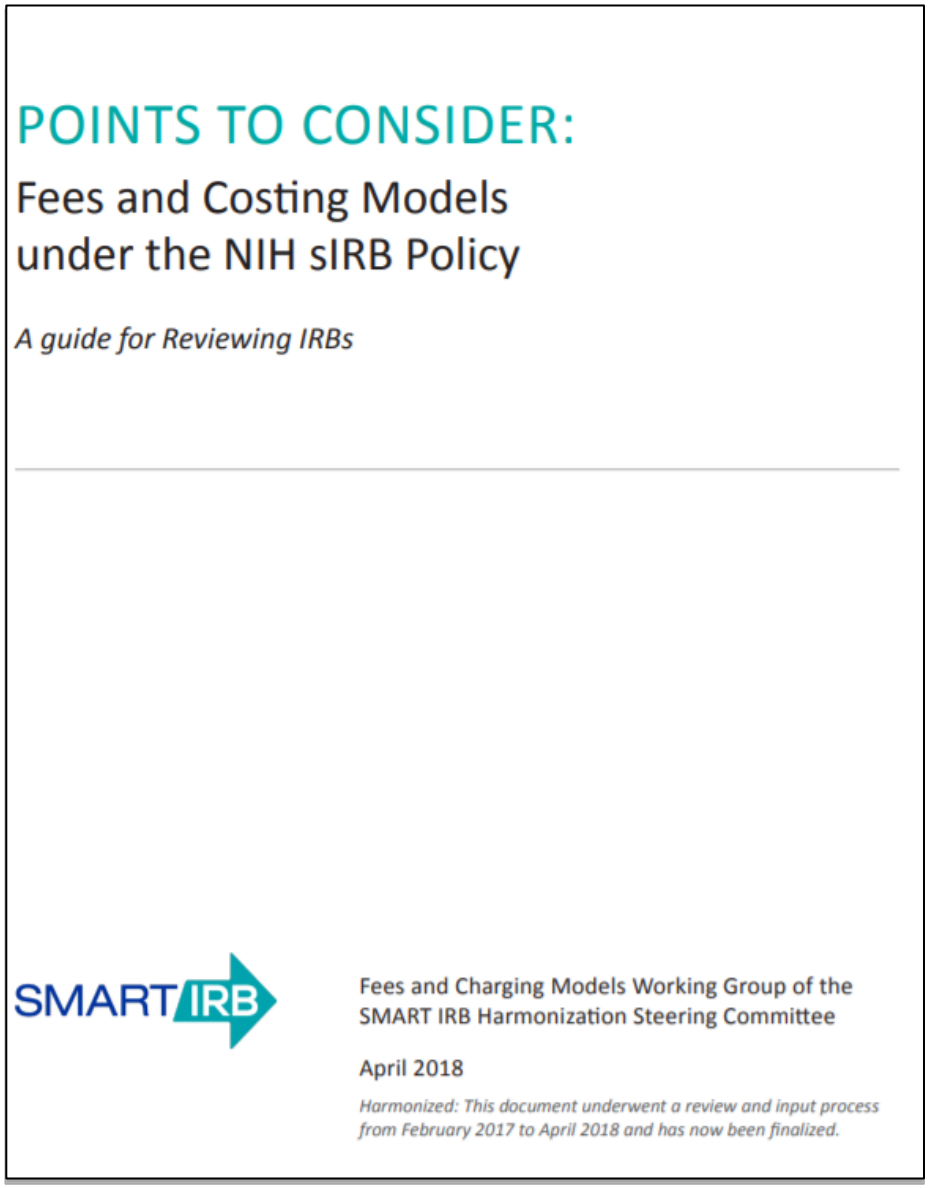


You want to train your study teams to talk to you as soon as they are aware single IRB might be required

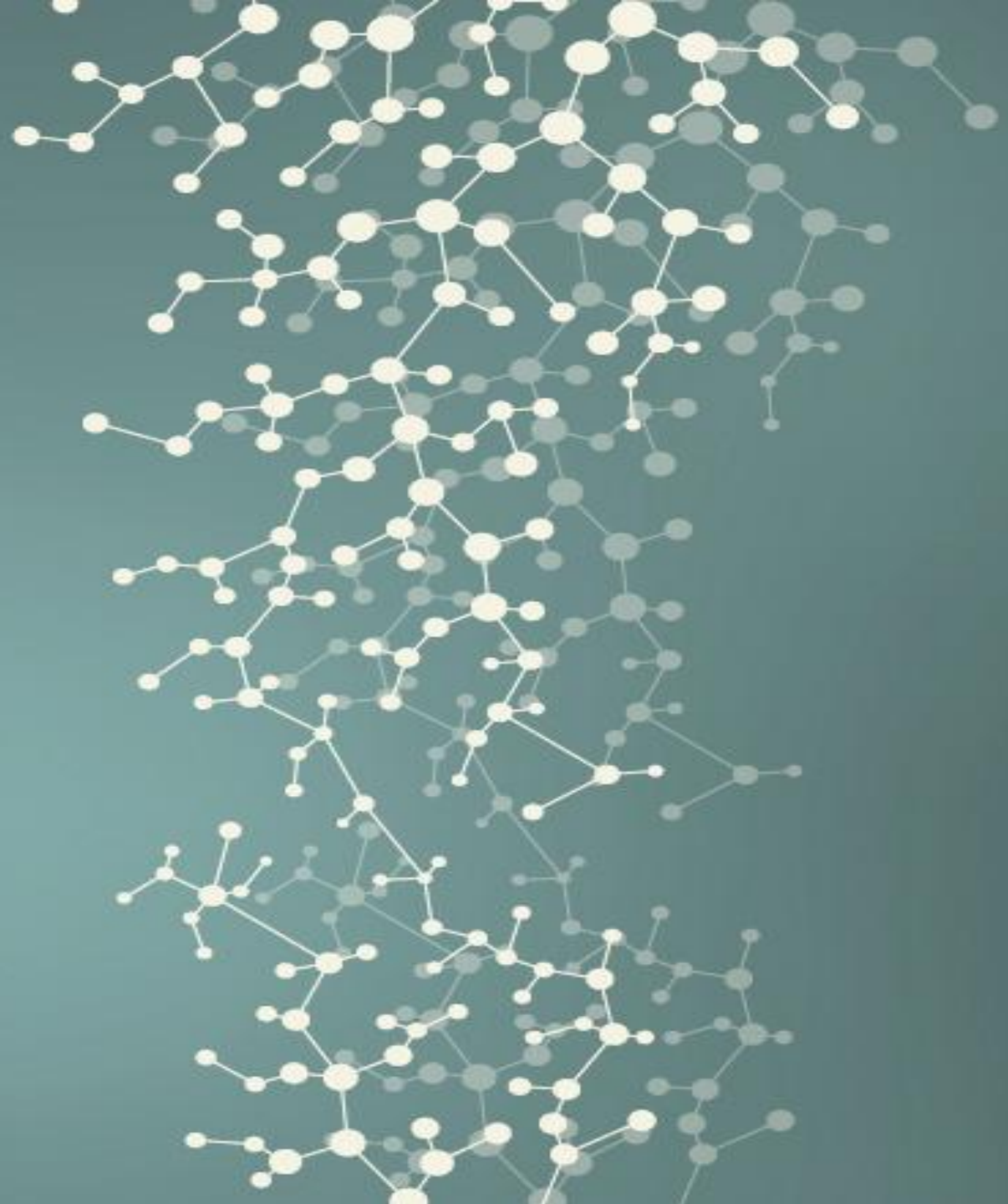
SMART IRB Resource for IRB Fees and Costing Models

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



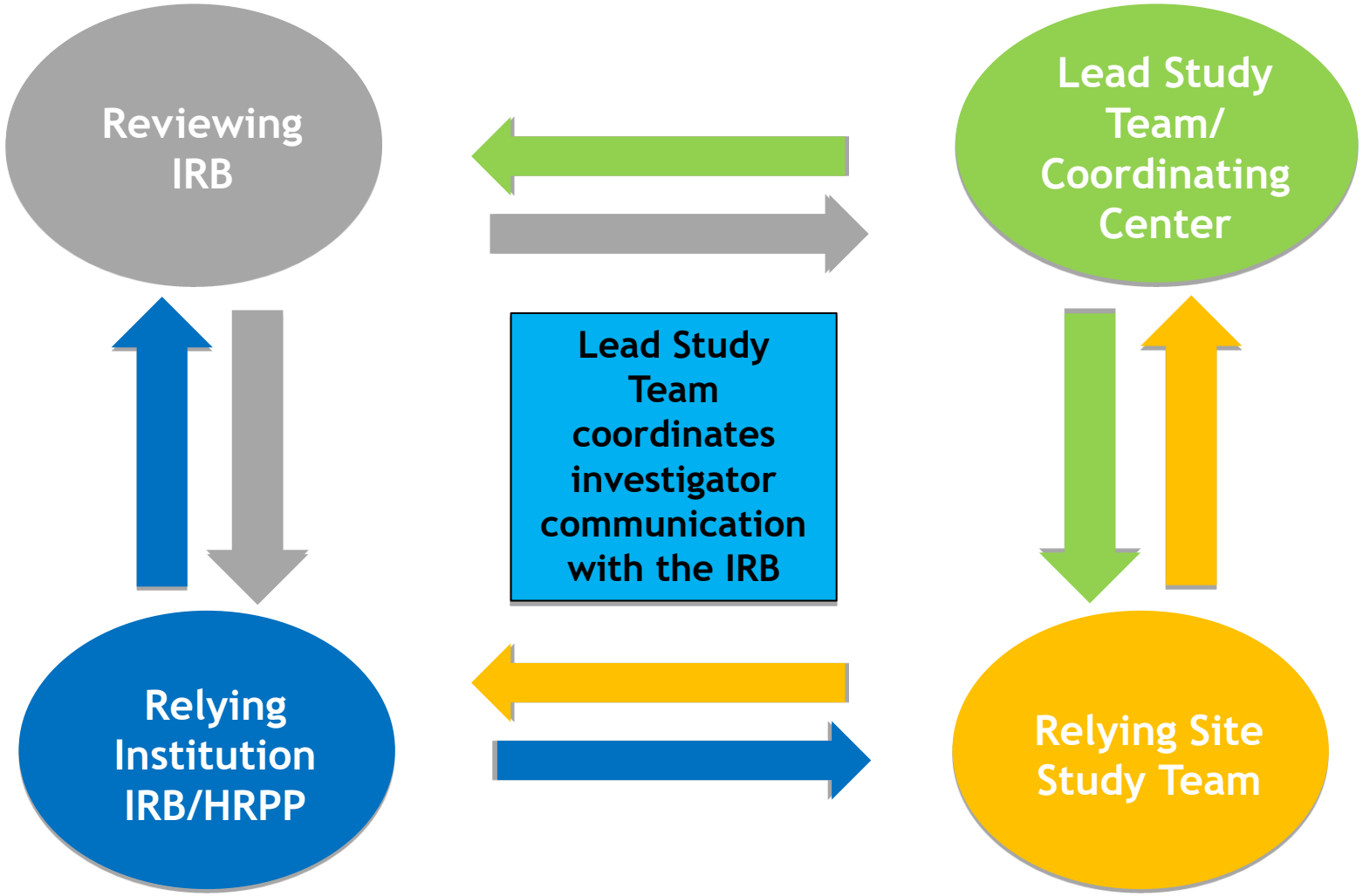
Responsibilities



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.



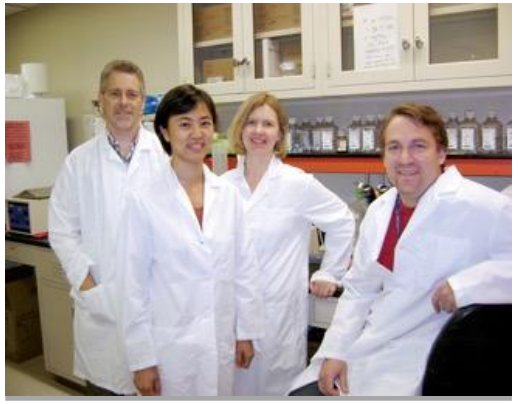
Single IRB Readiness Checklist for Lead Study Teams & Coordinating Centers: Reliance Arrangements

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

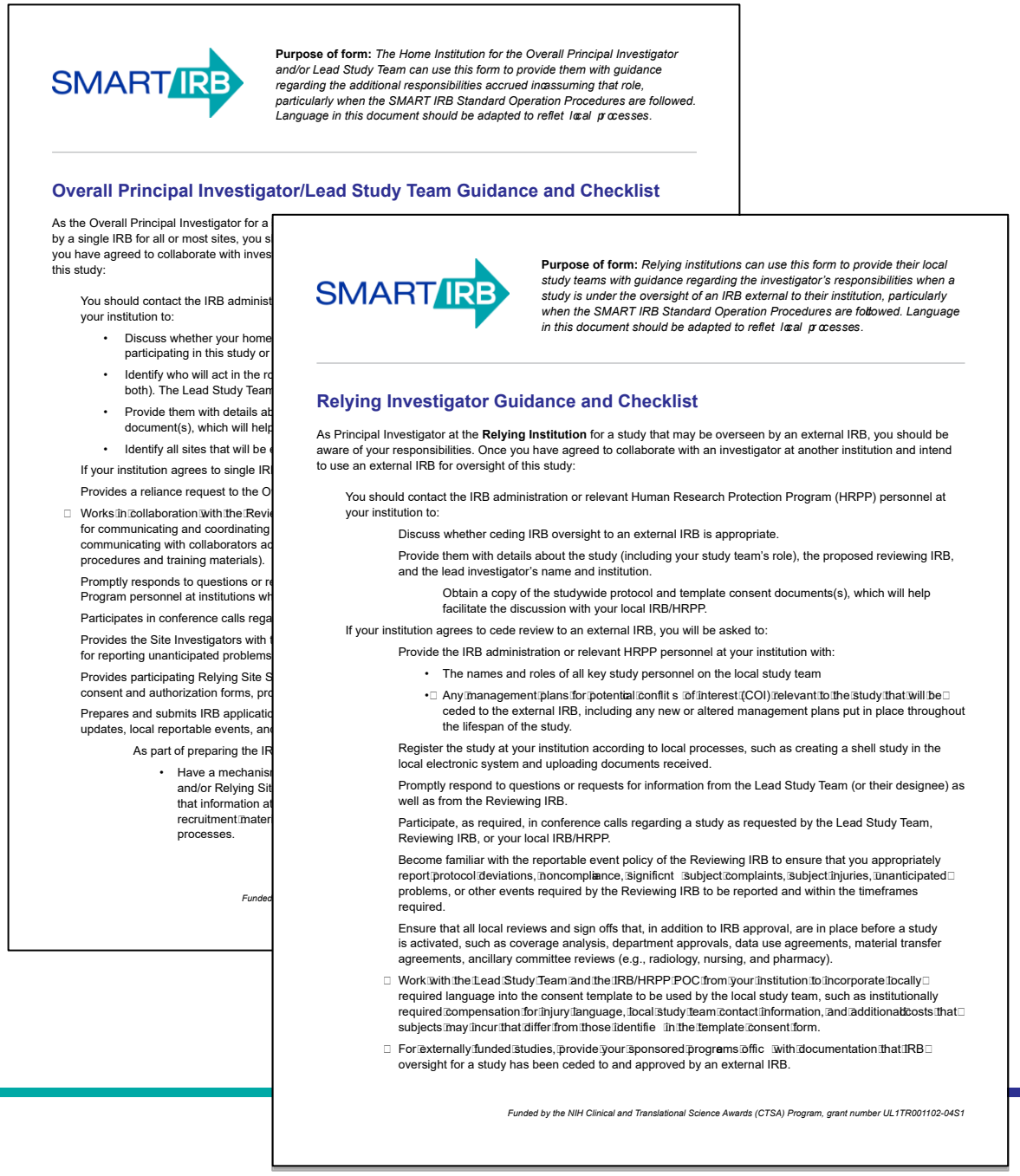
SMART IRB Resource: Investigator Checklists

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 rc
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 progra ms offic with documentation that IRB oversight for a study has been ceded to and approved by an external IRB.

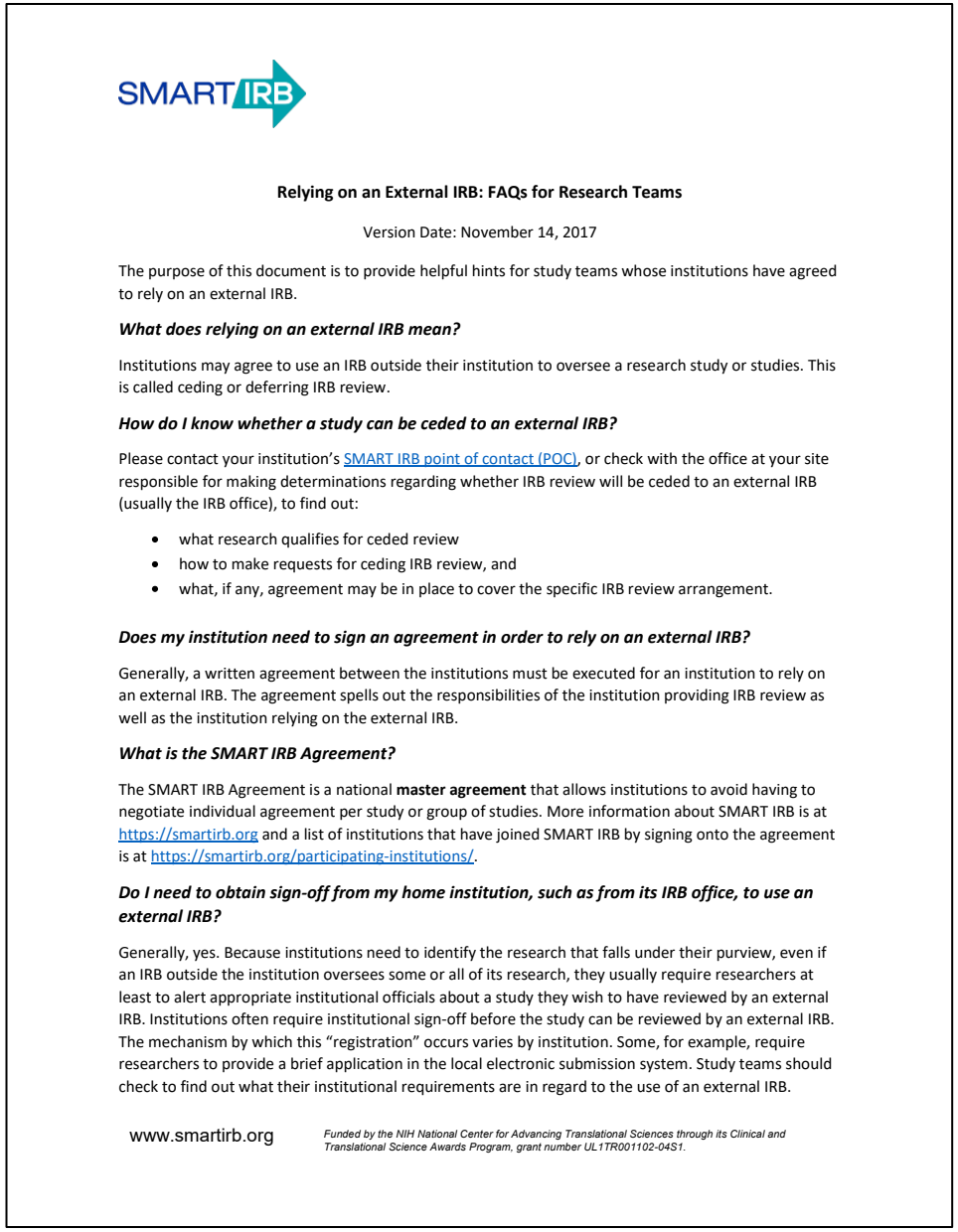
Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR001102-04S1

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.

www.smartirb.org

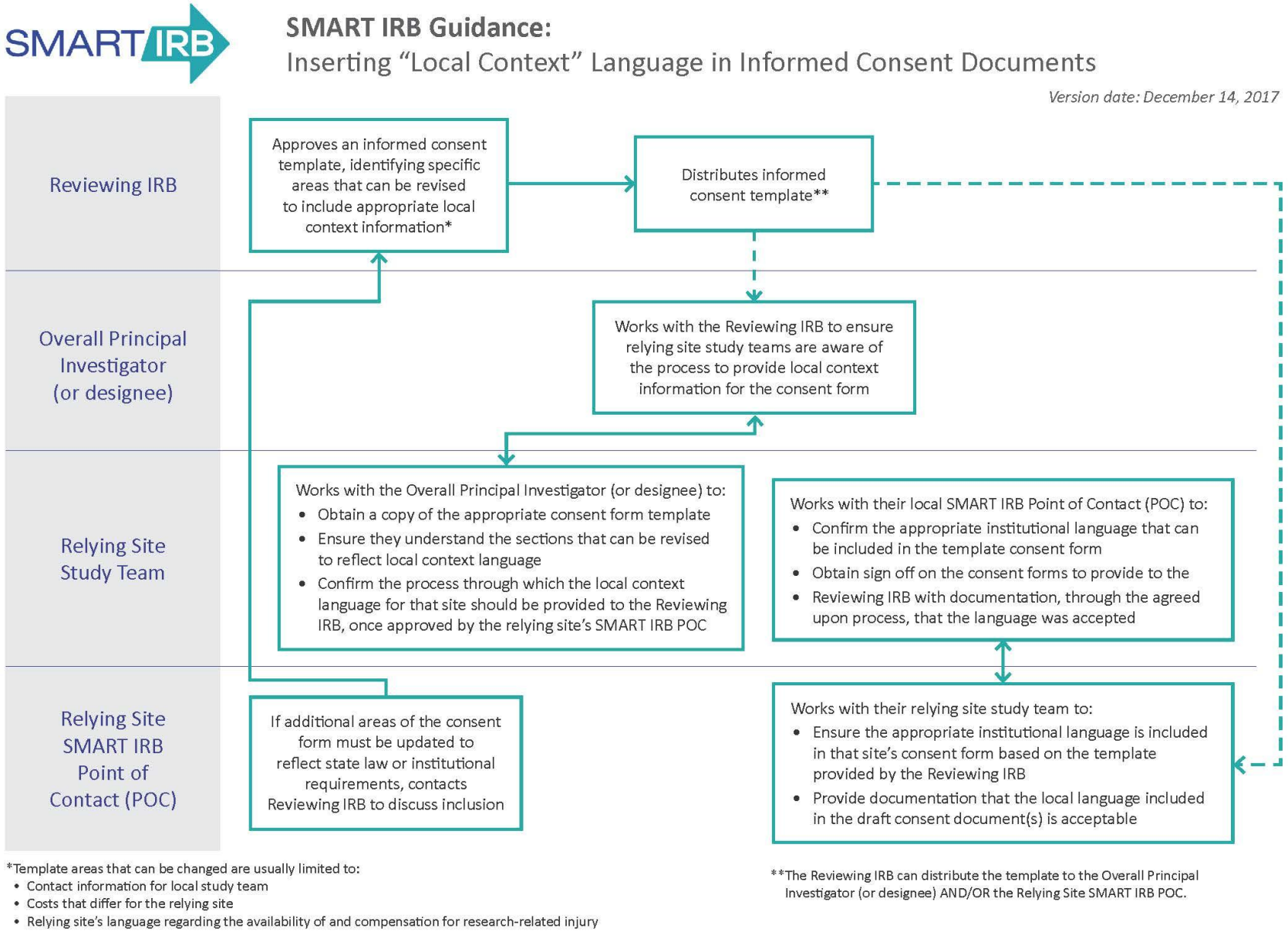
Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

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.

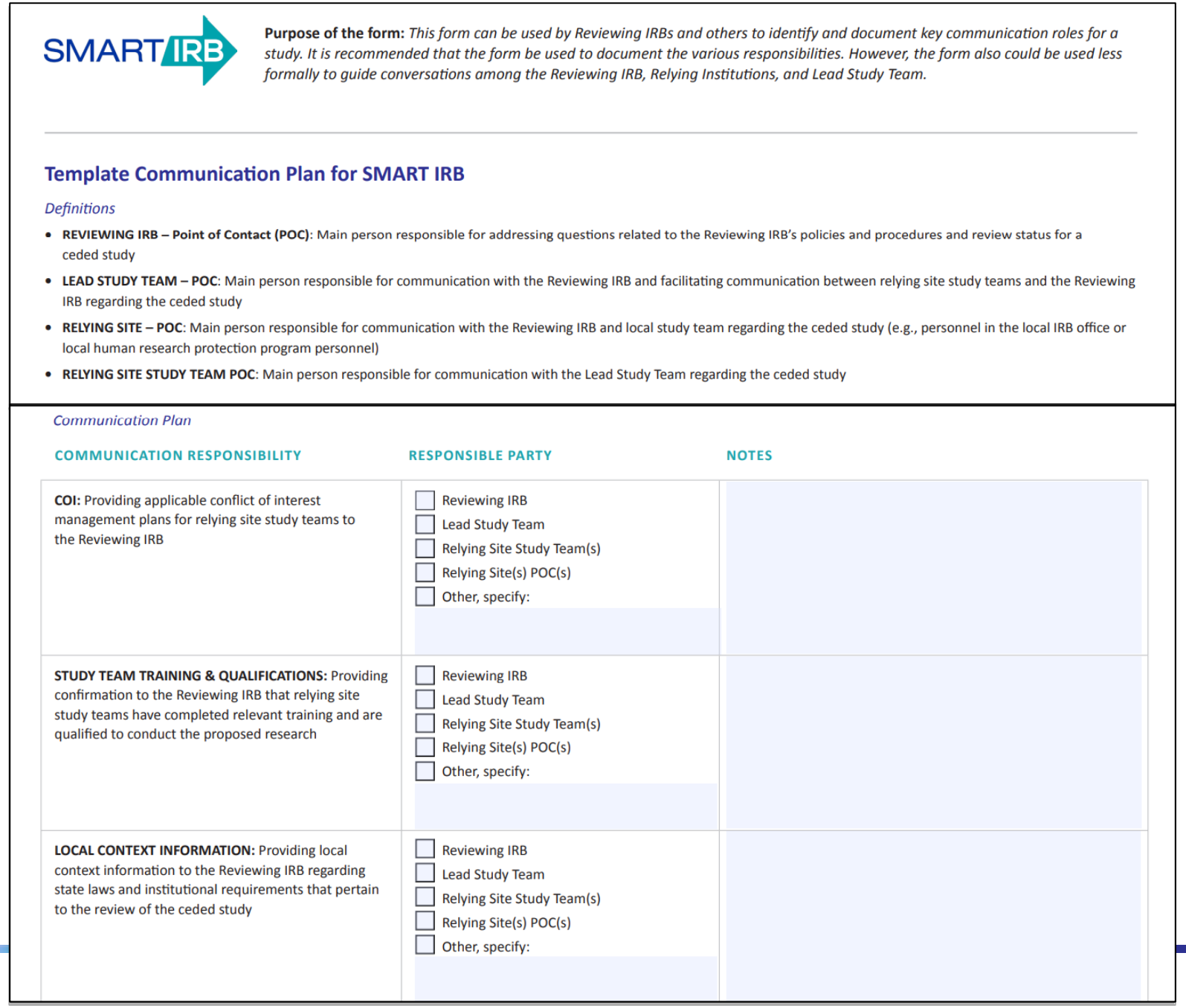


SMART IRB Resource: Communication plan for single IRB review

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

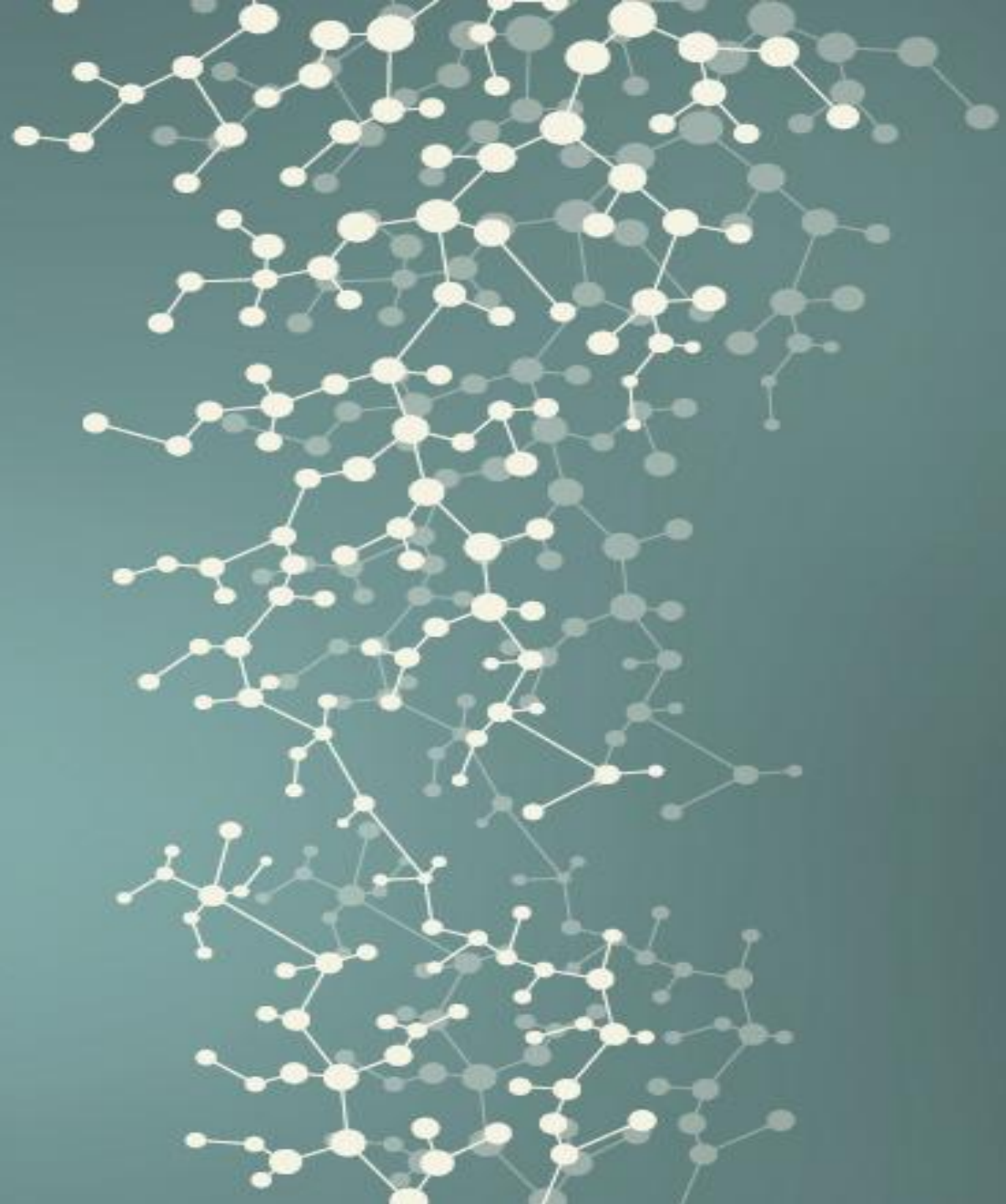
Definitions

- **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:

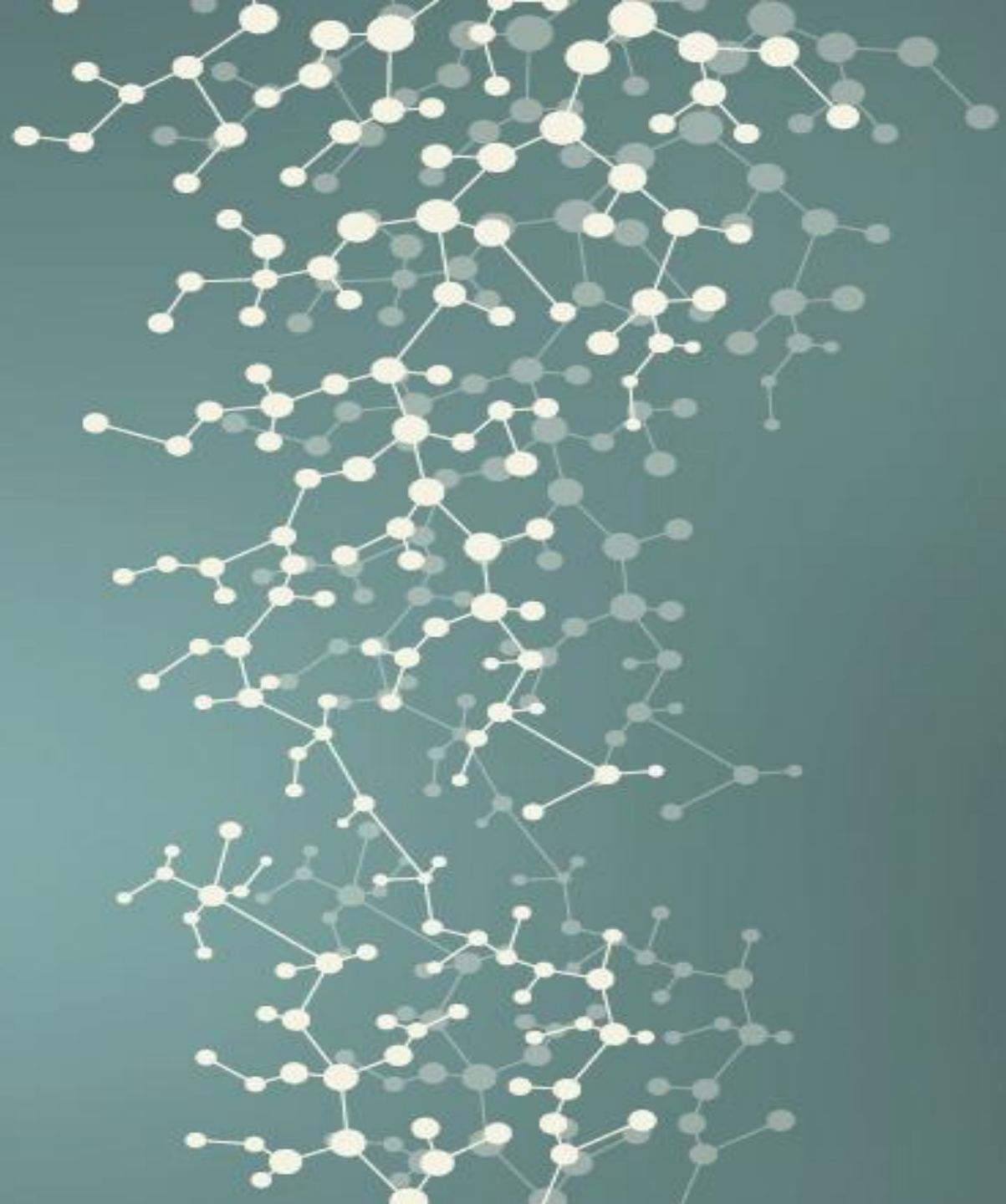
What to report to the Reviewing IRB and adhering to the Reviewing IRB's policies, such as for:

- 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

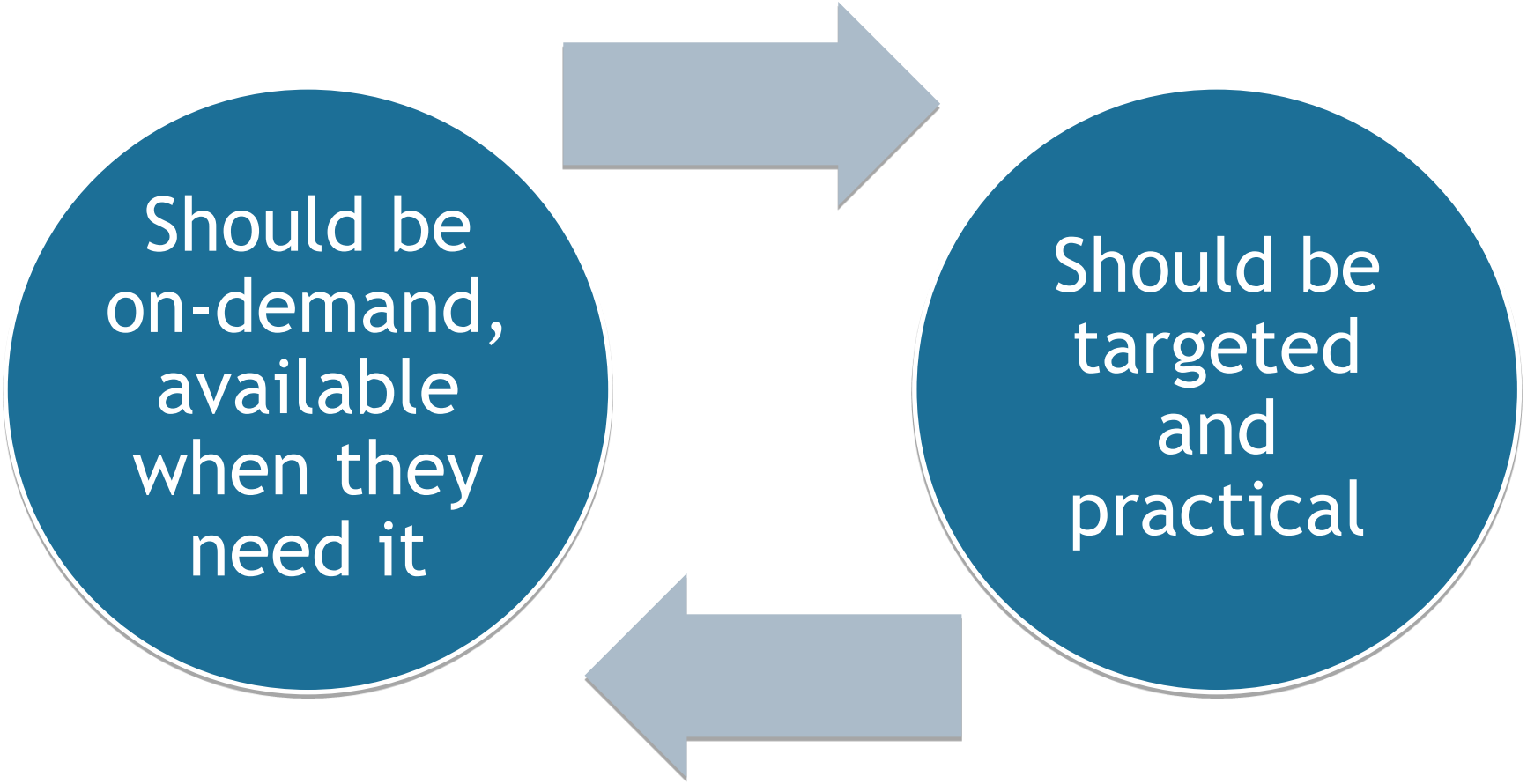
Training Approaches



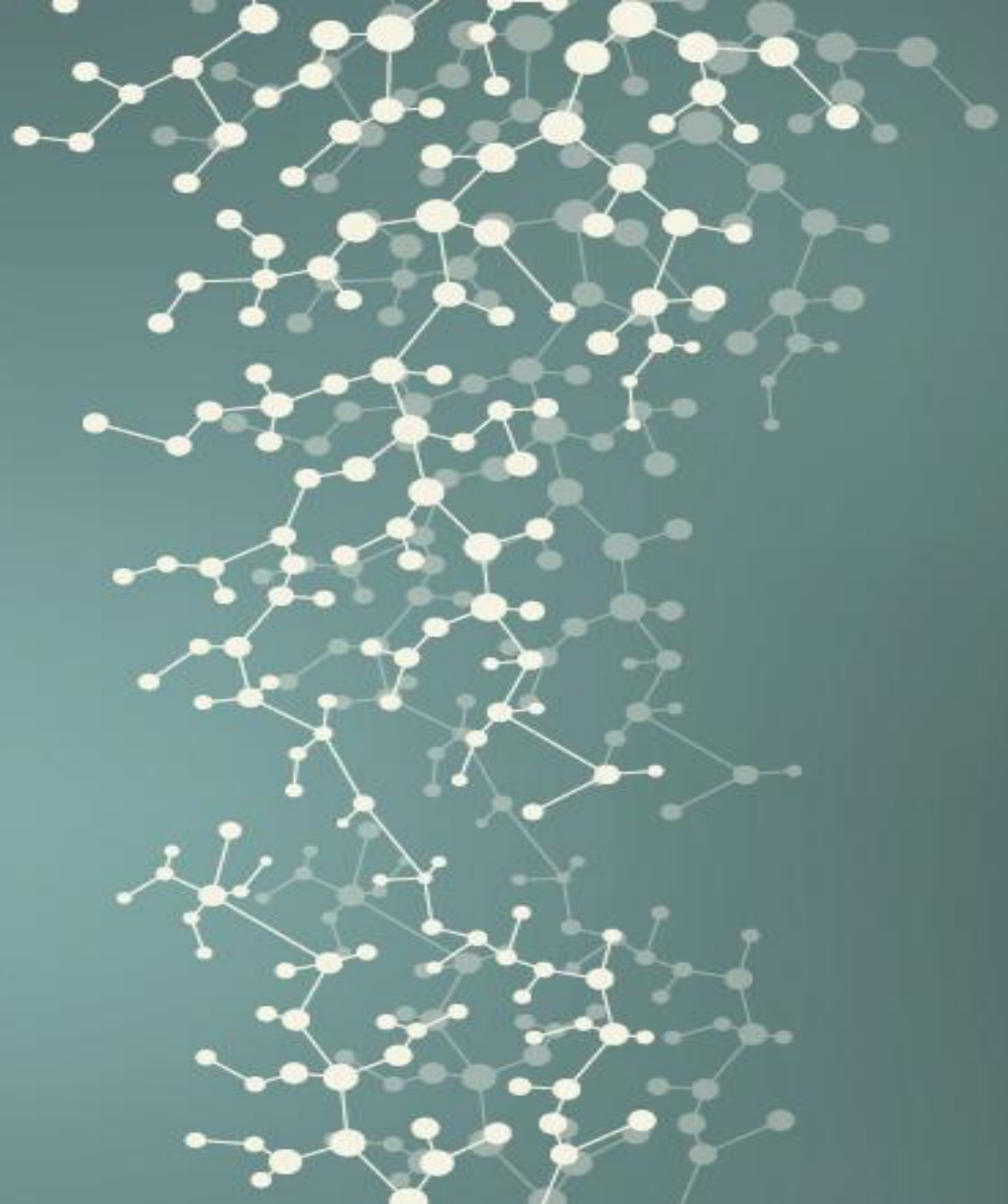
A model: one-on-one, study specific training

- 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



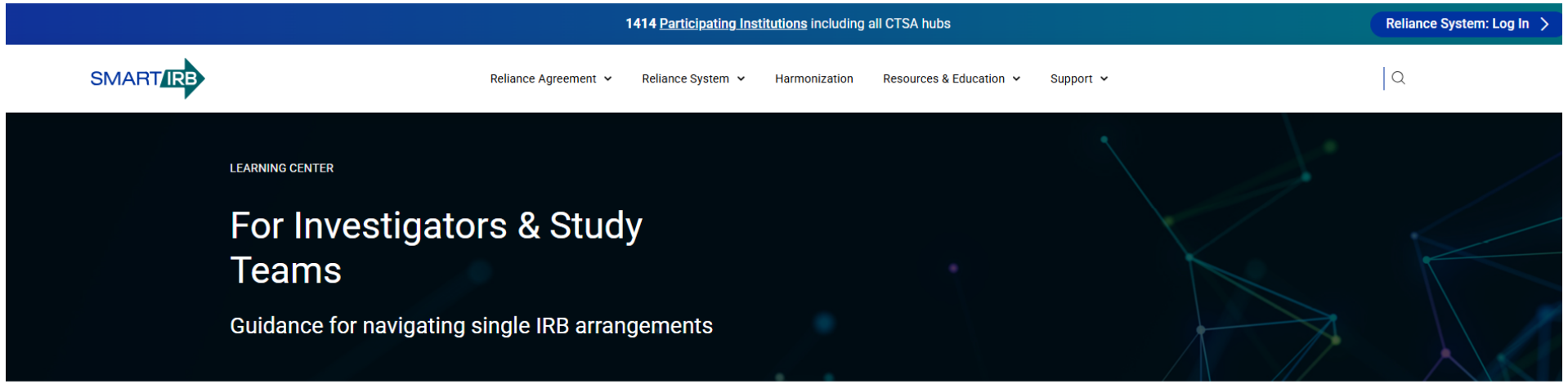
Resources to Support Training

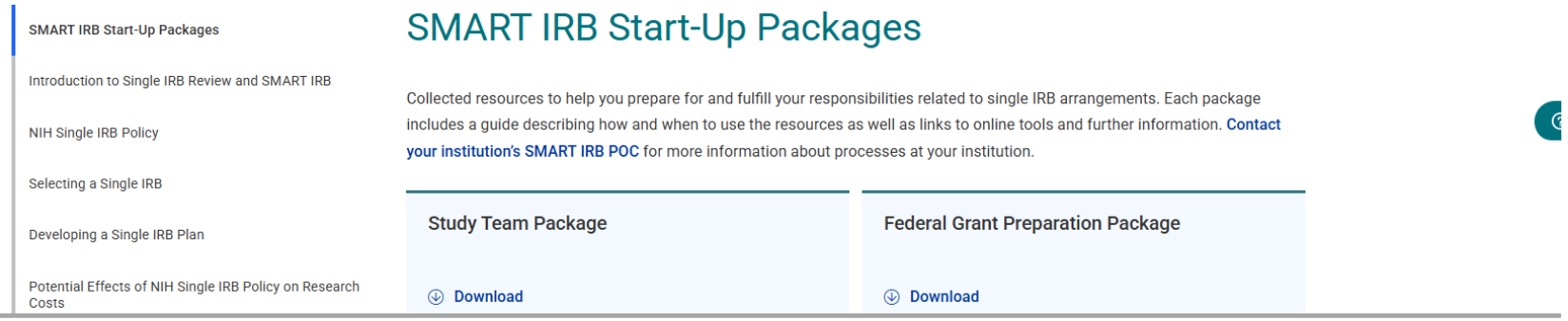


SMART IRB Resources for Study Teams

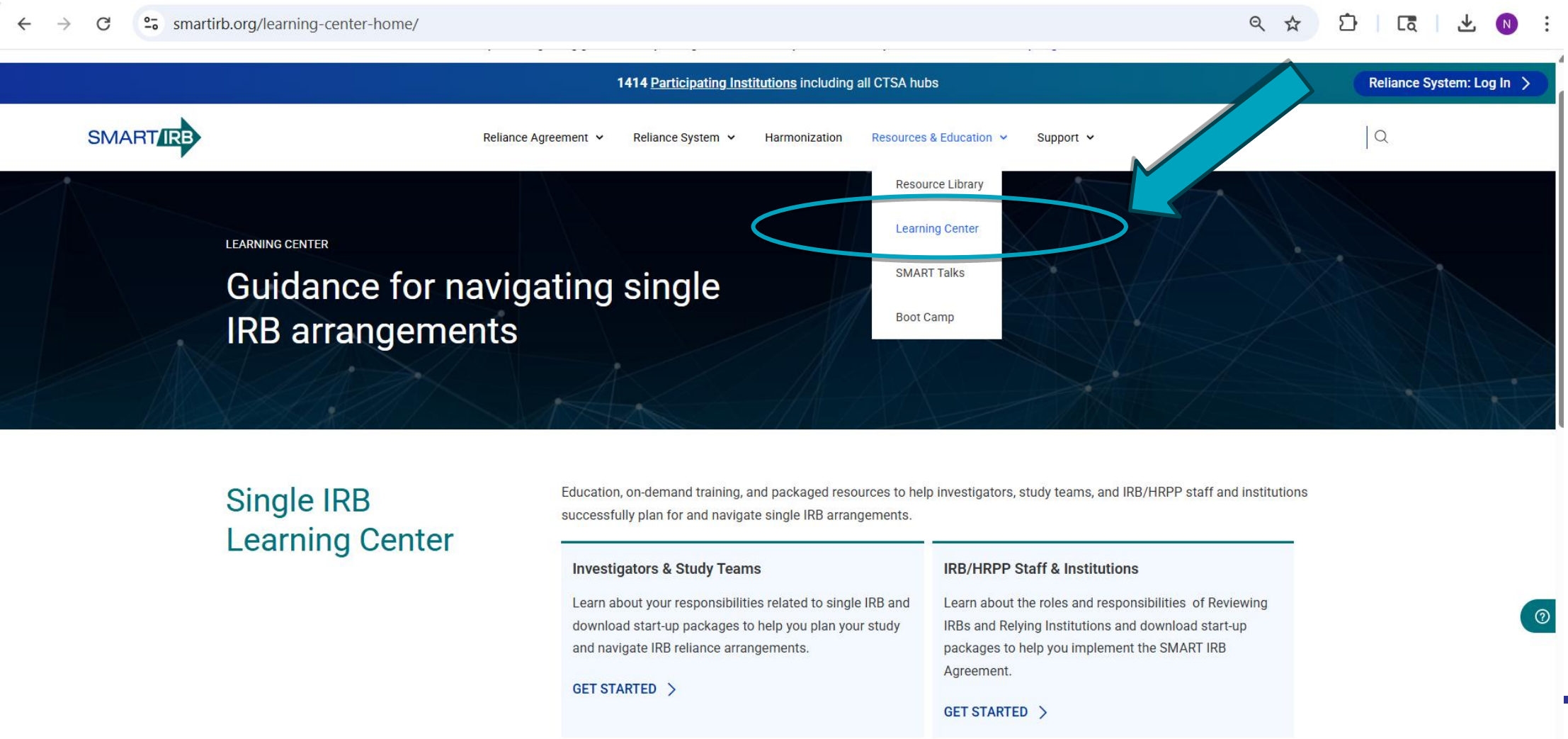
https://smartirb.org/study-teams/

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

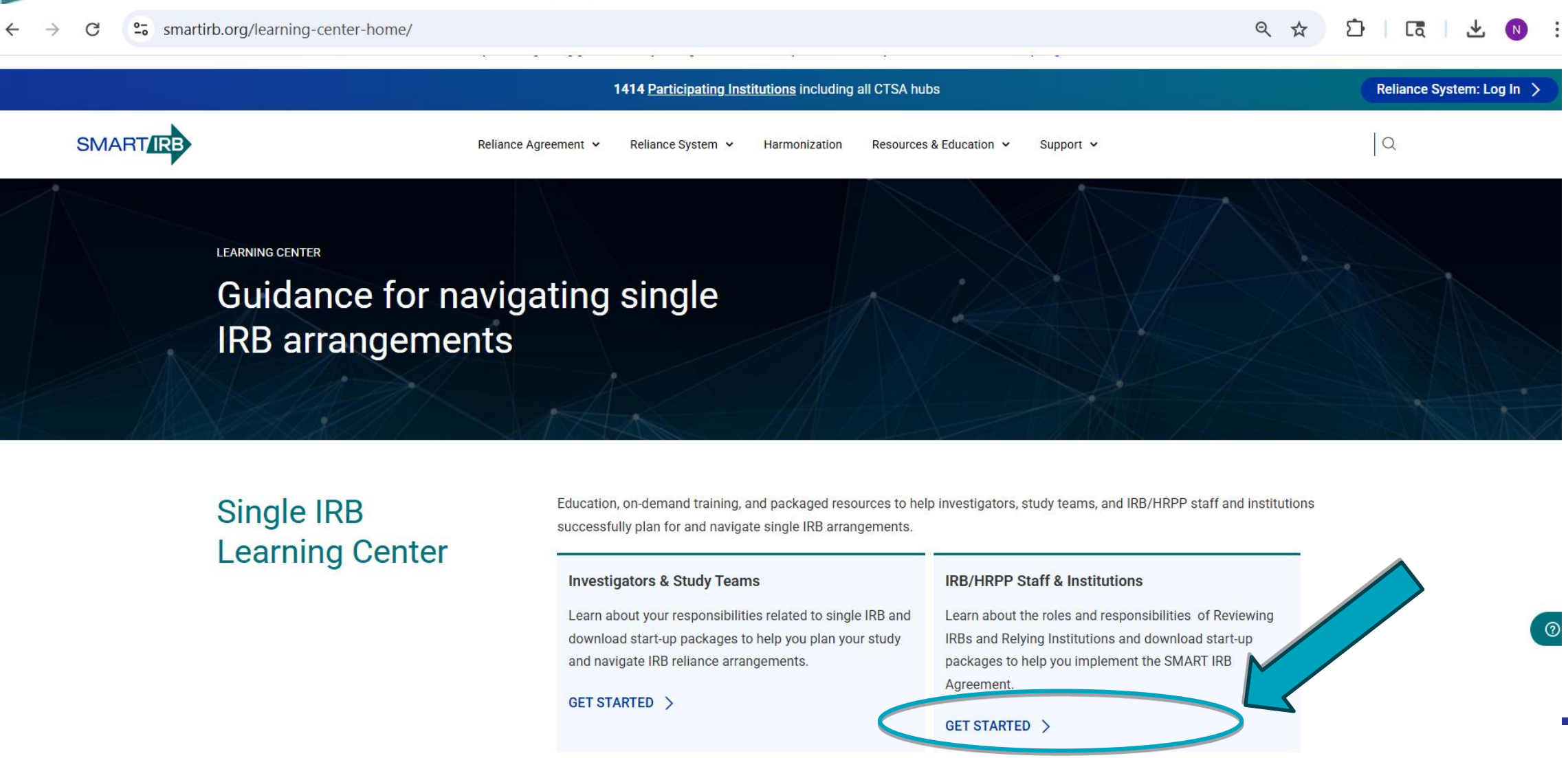




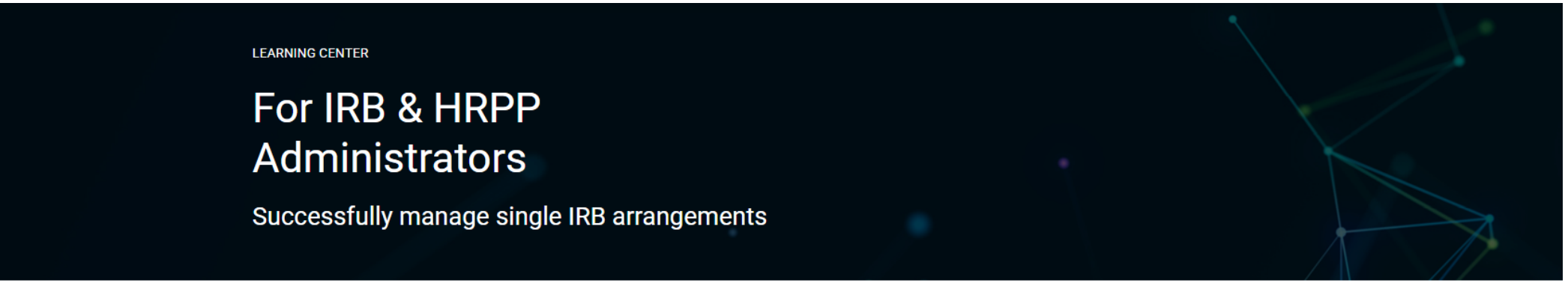
Customizing the Training: Go to smartirb.org

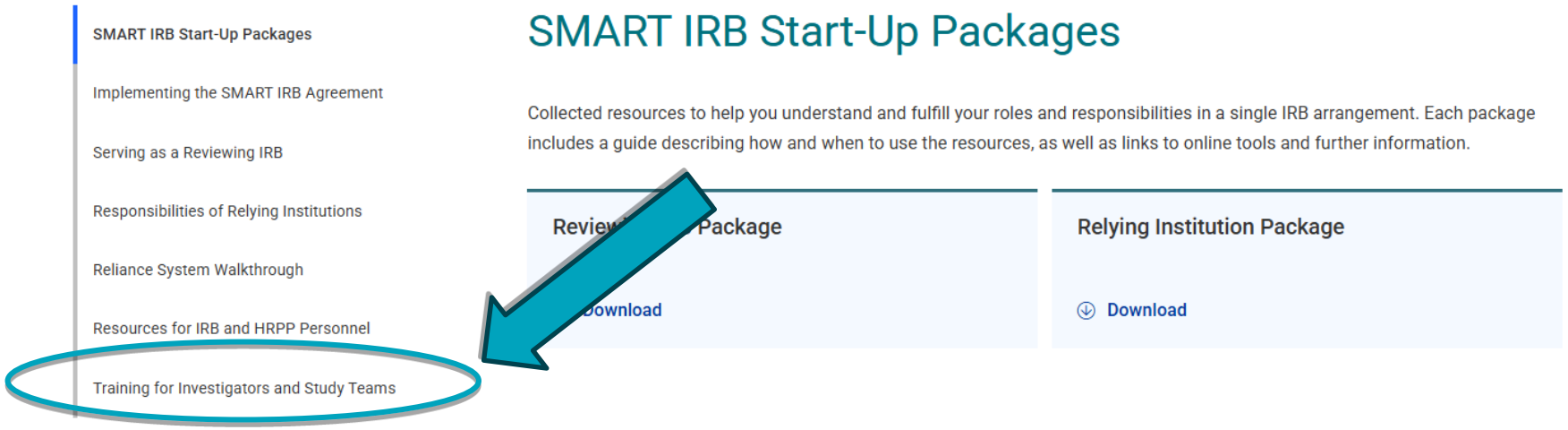


Customizing the Training: Go to smartirb.org



Customizing the Training: Go to smartirb.org





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

Harmonizing Local Considerations

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

What I Will Cover

- Why the recommendations were developed
- Key points about local considerations
- Resources available



What the SMART IRB Agreement Says About 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.

What the SMART IRB Agreement Says About Local and Other 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

Why local context matters

Ensures reviewing IRB conducts an appropriate review for a relying site in terms of ethical issues and compliance with federal regulations and federal and state laws

Institutions vary in their sensitivities, which are a product of their histories

Local context variation

- Variability in:
  - Whether the Reviewing IRB collects the information
  - What information is collected
  - When information is obtained
  - How information is assessed
  - Whose responsibility it is to verify or provide the information
  - If the information is tailored to the study
  - Method of communicating to the Reviewing IRB

Why local context variation matters

- Affects the accuracy and quality of IRB review
  - Recruitment procedures
  - Approaches to informed consent and assent process and language included in forms
  - Risk assessment
  - Consideration of any additional safeguards
  - Privacy and confidentiality measures

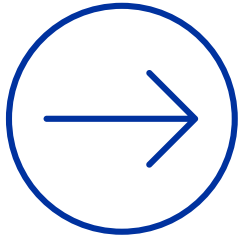
Three Challenge Areas for Local Considerations



Definition of local considerations (aka local context).

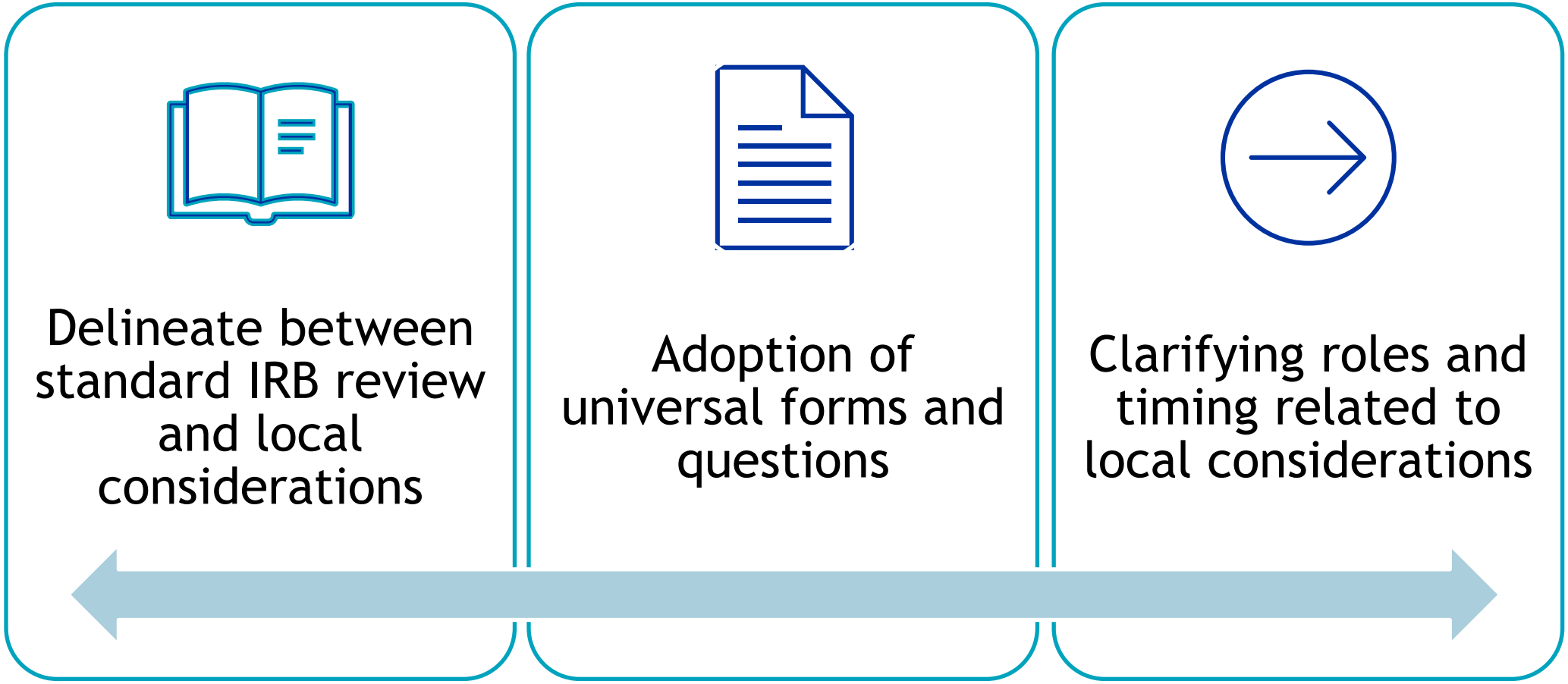


The type and detail of information collected to address local considerations.

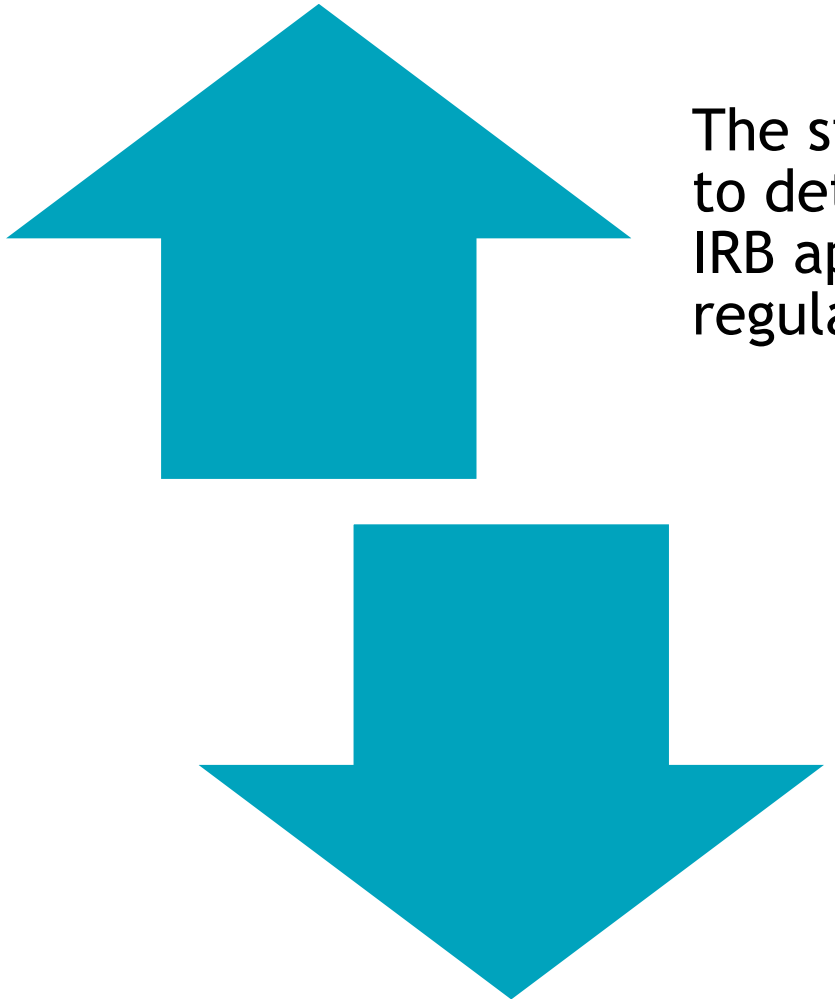


Assessing local considerations throughout the life of a study.

Three Areas for Improvement



Standard IRB review practice vs local considerations



The standard IRB review practice requires IRBs to determine if a study meets the criteria for IRB approval as outlined under applicable regulations

Local considerations are issues that are unique about, or specific to, a Relying Institution that the Reviewing IRB needs to be aware of in order to conduct an adequate review of that site as opposed to what a Reviewing IRB should take into account to assess the study as a whole (i.e., standard IRB review practice)

Examples of Standard IRB Review Practice vs. Local Context Consideration

EXAMPLE	STANDARD IRB REVIEW PRACTICE	LOCAL CONTEXT CONSIDERATION
Research study includes experimental drugs that could adversely affect a pregnancy. Determining how to minimize reproductive risks from drugs that can affect pregnancy, such as what forms of contraception would be acceptable	Determining how to minimize reproductive risks from drugs that can affect pregnancy, such as what forms of contraception would be acceptable	Any limits a Relying Institution may impose on what contraception it would be willing to provide to research subjects enrolled at its site (e.g., because of religious beliefs or practices) and what language it requires to be included in the informed consent about contraception
Informed consent content	When informed consent is required, determining the information that must be provided to research subjects as part of the informed consent Process (e.g., the required and additional elements of informed consent)	Specific language or format (e.g., font size) required by institutional policy (e.g., compensation for injury language) or State law (e.g., California Experimental Participants Bill of Rights)

Key recommendations

- Adopt a Harmonized Definition of Local Considerations
- Harmonize the Type and Detail of Information Collected to Address Local Considerations
- When Local Considerations Should be Addressed and Responsibilities for the Collection and Provision of Local Considerations



SMART IRB proposed definition of local considerations (aka local context)

A local consideration is an aspect about the Relying Institution which could affect the Reviewing IRB's determinations, including the criteria for IRB approval.

SMART IRB proposed definition of local considerations (aka local context)

A local consideration is an aspect about the Relying Institution which could affect the Reviewing IRB's determinations, including the criteria for IRB approval.

Local considerations may include:

- State and local laws or Relying Institution policies relevant to the study or subject population.
- Customs, beliefs, values, or practices of a distinct subject population(s) that a Relying Institution could expect to be enrolled or included (such as records or biospecimens used for the research) in a study and that may have an impact on IRB review.
- Variations in how a study will be implemented across sites, including differences in standard of care (i.e., routine care).

More on *customs*, *beliefs*, *values*, and *practices*

- The concepts of *customs*, *beliefs*, *values*, and *practices* cover a range of considerations that could be relevant to research, such as:
  - Expectations around decision-making – whether it is done as a family, a community, or individually
  - Whether oral is emphasized over written communication, which can affect how information is conveyed and understood
  - The level of comfort with documents being signed, especially those that appear to be official
  - Prohibitions on the use of certain technologies, which may limit transportation modes or use of any devices used in a study either as the focus of the research or to support participation in the research
  - Forms of contraception permitted by a belief system, which may affect eligibility requirements for a study or the description of birth control within a consent document
  - Use of health insurance, which can influence informed consent language

Institutional Profile

Static Information

- Identify any affiliations this site has, such as university, clinic, or hospital. If any of the sites are within a network or system, identify all sites with separate Federal Assurances.
- Does your state law or institution require you to apply the Common Rule to all studies?
- Does your state law or institutional policy require you to apply any of the subparts (B, C, or D) of the HHS regulations at 45 CFR part 46 that provide additional protections for certain populations in research to all studies, when applicable?
- Is your institution willing to serve as an IRB of record (Reviewing IRB) for other institutions?

vs

Study Specific Information

Dynamic Information

- Will the study be implemented differently at your site due to a limited role (e.g., your site serves as a data analysis center or biospecimen repository)?
- Are there any site-specific ancillary reviews that could have an impact on the IRB review and/or approval at your site and need to be addressed by the reviewing IRB?
- Does the Relying Institution consider this study to fall under the HIPAA Privacy Rule? If yes, does the institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects (e.g., the institution does not consider this a “Preparatory to research activity")?

Adoption of Universal Forms and Questions

SMART IRB

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):	

INSTITUTIONAL PROFILE

SMART IRB

Institutional, Local, a
Working Group of th
Steering Committee

July 2018

*Harmonized: This documen
from February 2017 to July*

SMART IRB

STUDY-SPECIFIC DOCUMENT

Institutional, Local, and State Requirements
Working Group of the SMART IRB Harmonization
Steering Committee

Roles & Timing

Study Development

- Researchers develop protocols that take into account the differences at each participating institution

Initial IRB Review of a Site

- Relying Site PIs/Relying Site Study Teams & Relying Institutions work together to provide the Reviewing IRB with accurate local considerations information

After Initial IRB Approval

- Reviewing IRBs identify categories of changes that should trigger a review & Relying Institutions develop guidance for their study teams regarding what changes in research, events, and other information may impact local considerations and may require input from their institution's HRPP

Resources

- Appendices in the recommendations document
  - Institutional Profile
  - Study-specific Document
  - Local Considerations Information Guidance Table
  - Local Considerations Throughout the Life of a Study
  - Local Considerations Responsibilities By Reliance Stage
  - Considerations for Investigators Writing Multi-Site Protocols
  - Single IRB Review Case Study: Addressing Variation in Institutional Assent Policies
  - Template Checklists for Reviewing IRBs and Relying Institutions to Identify When to Address Local Considerations after Initial Approval of a Study



Document focus

- Responsibilities (Reviewing IRB vs Relying Institution) for local considerations by reliance stage
  - Feasibility
  - Reliance execution
  - After initial IRB approval
  - Local considerations review
  - After site approval

Appendix 5: Local Considerations Responsibilities By Reliance Stage

Role	Feasibility	Reliance Execution	Local Considerations Review	After Site Approval
Reviewing IRB	Ensure you can meet the requirements of the Relying Institution by reviewing their Institutional Profile.	▸ Create a reliance package: – Collect local considerations using the Study-Specific Document. – Identify how you will implement the flexible terms of the SMART IRB Agreement using the Implementation Checklist. – Create a Communication Plan.	Review Study-Specific Document received from Relying Institution.	▸ Identify categories of changes that should trigger a review of local considerations. ▸ If a change or reportable event occurs, determine whether additional information is needed from the Relying Institution.
Relying Institution	Ensure Institutional Profile is up to date.	▸ Review all reliance documents. ▸ Provide institutional local considerations in consultation with local study team.	Answer Reviewing IRB questions about local considerations, if requested.	▸ Answer Reviewing IRB questions about local considerations, if requested. ▸ Monitor and communicate to the Reviewing IRB and study teams any updates to local considerations that could impact research review by an external IRB or research conduct by study team(s)

Document focus

- Types of local considerations
- Responsibilities
- When information collected/provided
- Relevant SMART IRB resource

Appendix 3. Local Considerations Information Guidance Table

This table identifies responsibilities related to providing various types of local considerations, and describes the level of detail that should be provided, as well as when and how that information should be communicated. All constituents must work together to ensure accurate local consideration information is provided. The Relying Institution Principal Investigator (PI) should work in consultation with the Relying Institution. Thus, when the table references Relying Institution PI, it assumes they have consulted with the appropriate person at the Relying Institution, as applicable. It is especially critical that Relying Institution PIs review the protocol or study plan and communicate to the Lead Study Team, Reviewing IRB, and Reliance Point of Contact (POC) any differences in local protocol implementation or study conduct throughout the life of the project. Relying Institutions will need access to an IRB-approved or near-final protocol or study plan in order to provide local considerations information to the Reviewing IRB.

Local Considerations	Who is responsible for providing local consideration information to the Reviewing IRB?	When should the local consideration information be provided to the Reviewing IRB?	Which SMART IRB resource(s) can I use?
Available resources and facilities to conduct the study	Relying Institution PI should consider whether they have the resources and facilities required to participate in the research at the time of deciding to be involved in this study. Relying Institutions should confirm whether their study team has adequate resources and facilities to perform the research through their internal formal review process.	Prior to or during initial IRB review for a site.	**Resource**: Use SMART IRB Study-Specific Document.

Document focus

- Local considerations by study stage
  - Study Development
  - Initial IRB review of a site
  - After initial IRB approval

Appendix 4. Local Considerations Throughout the Life of a Study

STAGE: STUDY DEVELOPMENT

RESPONSIBILITIES

- The investigator(s) developing a protocol or study plan should consider the compatibility of study procedures and planned participant population with potential participating sites.
- Investigators at potential participating sites should evaluate protocols or study plans to determine whether their site is a good candidate for the research and, if so, identify any differences that may need to be incorporated into study documents and communicate them to the Overall PI (and, if applicable, the Lead Study Team).
- Institutions should provide protocol or study plan templates (similar to the protocol-specific addenda that some institutions have developed) and guidance for their research teams that take into account multi-site research and single IRB review (e.g., how to address variations in recruitment approaches across institutions or study procedures).

KEY LOCAL CONSIDERATIONS INFORMATION AT THIS STAGE

- Protocols and study plans should be written to take into account variations across participating sites, including: institutional standards of care, available equipment and facilities, study population likely to be enrolled, recruitment process and materials, informed consent process, and data security.
- When informed consent is required, template consent documents should accommodate language affected by institutional policy (e.g., compensation for injury, contraception permitted), differences in study costs, variations in study procedures across sites (e.g., differences in equipment, devices, or drugs used), and study team contact information.

Document focus

- Guidance for investigators writing multi-site protocols
  - Likely types of variations to proactively address

Appendix 6. Considerations for Investigators Writing Multi-Site Protocols

When writing multi-site protocols, researchers are encouraged to take into account potential variation across participating sites to ensure that the protocol accurately reflects how the study will be implemented. Protocols and study plans should be written broadly to account for variability in what study procedures will be performed at participating sites, any differences in how sites perform certain procedures (e.g., subject recruitment or the informed consent process), and any differences in subject populations that will be recruited (e.g., to achieve diversity, equity, and inclusion).

The following list reflects key areas of potential variability across sites that should be considered when developing protocols. Not all areas apply to all studies. Research teams might also build questionnaires that can be provided to sites to capture differences in implementation based on the potential variations identified.

Potential Variation	Examples of Questions to Capture Differences Between Sites
Recruitment procedures	▸ How will subjects be identified? ▸ Who will approach potential subjects? ▸ How will potential subjects be approached? ▸ Are there any restrictions on who can be recruited for this study? ▸ Are there any restrictions about who can approach some or all research participants? ▸ Are there any restrictions on language that is permitted in recruitment materials?
Informed consent and assent processes	▸ Are there any languages other than English that potential subjects might read and speak that could influence translations of informed consent documents that may be required? ▸ Are there any restrictions or requirements regarding who can obtain informed consent? ▸ Are there any specific requirements or restrictions regarding electronic informed consent platforms that can be used?

Document focus

- Case study on assent to explore
  - Reviewing IRB and Relying Institution roles related to local considerations
  - Areas where Reviewing IRBs can be more flexible related to potential policy and procedure variations

Appendix 7. Single IRB Review Case Study: Addressing Variation in Institutional Assent Policies

The Working Group considered how sIRB review related to assent for minors determinations differs from when a local IRB reviews a study on behalf of its research team. What follows is an analysis of what are local considerations vs. standard IRB review practice for determining whether assent is required, and if so, how variations in institutional assent policies and practices can be addressed on a study-wide basis, rather than through site-specific determinations.

What is the local considerations challenge?

Institutions vary in their assent policies and practices, such as when it is required and whether it is documented, the content and format of assent forms, and the expected assent process by child's age, which can affect IRB review.

What local considerations for assent should be collected from Relying Institutions and/or study teams?

- State and local laws that establish age of majority.
- Institutional policies that affect any applicable assent process.
- Populations likely to be enrolled at a site or by a study team that could affect the assent process, such as in terms of language or religious or cultural considerations.

What are the Reviewing IRB's responsibilities related to assent?

- Determining whether assent will be waived for a study or a specific site(s).
- If assent is not waived, determining whether any children who may be enrolled in a study are capable of providing assent.
- Collecting and considering local consideration information provided by Relying Institutions.

How can Reviewing IRBs proactively address a range of institutional policies and practices?

Document focus

- Potential triggers for
  - Reviewing IRBs to confirm or collect additional local context information
  - Relying Institutions to communicate updated local considerations information to the Reviewing IRB

Appendix 8. Template Checklists for Reviewing IRBs and Relying Institutions to Identify When to Address Local Considerations after Initial Approval of a Study

These template checklists serve as guides for Reviewing IRBs and Relying Institutions to identify when amendments, events, or other updates might trigger a local consideration that could affect IRB review for a specific site. When events or amendments identified in the checklists occur:

a) Reviewing IRBs may need to review local considerations they collected (e.g., via the Institutional Profile, Study-Specific Document, and Implementation Checklist) to ensure they are taking into account relevant information in their review of that site; and

b) Relying Institutions need to determine whether they must communicate new or updated local considerations information to the Reviewing IRB.

Reviewing IRB

	Amendment Content
☐	Addition of a new subject population, especially children, pregnant women, prisoners, individuals with impaired decision-making capacity, LGBTQIA, other potentially vulnerable subject populations
☐	Addition of non-English speakers
☐	Significant change in recruitment method
☐	Addition of genetic testing
☐	Addition of testing for an infectious disease
☐	Addition of pregnancy testing or collection of information about pregnancy status

Local Considerations Takeaways

- Start early – encourage research teams to build in local considerations in their protocols or study plans
- Reviewing IRBs need to collect and take into consideration local considerations
- Relying Institutions need to help Reviewing IRBs by providing better-tailored local considerations information
- Collection of local considerations occurs throughout the life of a study
- Harmonizing the local considerations information would make life easier for Reviewing IRBs, Relying Institutions and Research Teams

Questions?

Resources Recap and Frequently Asked Questions

Polly Goodman, CIP
Sr. Associate Director, SMART IRB

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

RESOURCES

Library

Flexible, ready to use, and easy to adapt

Discover SMART IRB Resources

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Filter by

Topic

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

Role

- IRB/HRPP Staff
- Relying Institutions

Showing 1 - 20 of 105

Sort by Name (A-Z)

Agreement, The SMART IRB (Version 3.0; finalized March 17, 2025)

Word

Review the SMART IRB Reliance Agreement, which may be used to facilitate IRB reliance arrangements among Participating Institutions. As of March 17, 2025, all new SMART IRB reliance arrangements must be on Version 3.0. **Learn more** about the development and background of the Agreement.

Agreement, The SMART IRB (Version 3.0) – Related Documents

ZIP

A summary of key changes and operational differences from prior versions of the Agreement (V1.0/2.0), as well as other related resources to assist institutions in reviewing and joining SMART IRB Reliance Agreement V3.0.

Need help?

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.

SMART IRB encourages use and distribution of this content. If you extract any language, please cite SMART IRB as follows, "This information was obtained from [doc name] as part of SMART IRB, which is funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number 3UL1TR002541-01S1."

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	

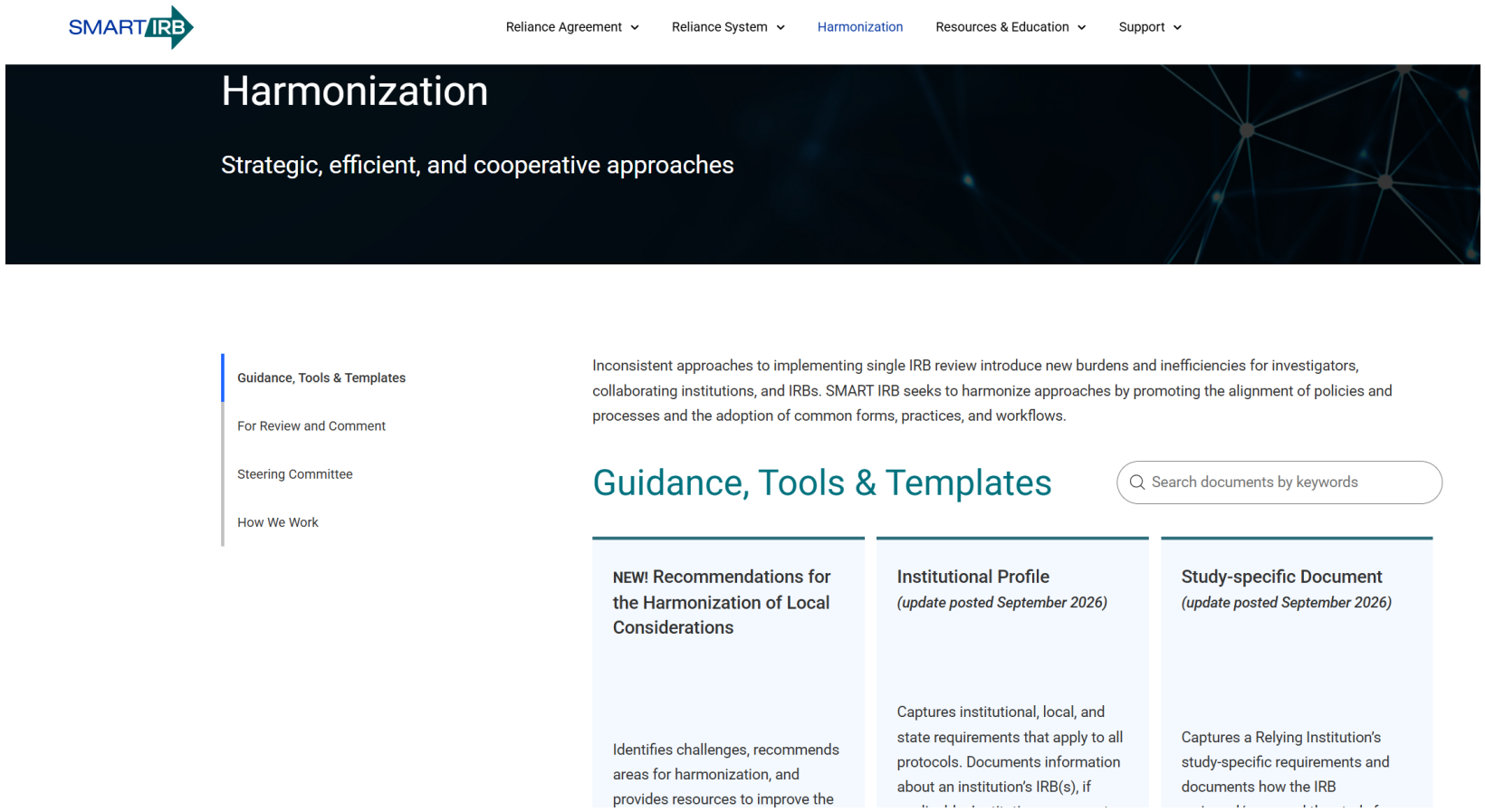
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Harmonization

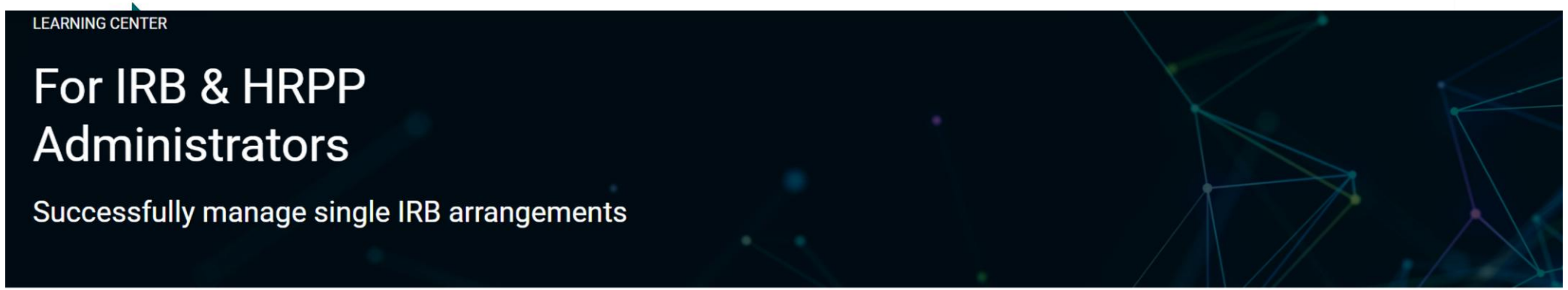
Learn from IRB/HRPP experts across the US!
Topics include

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

Soon: 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.

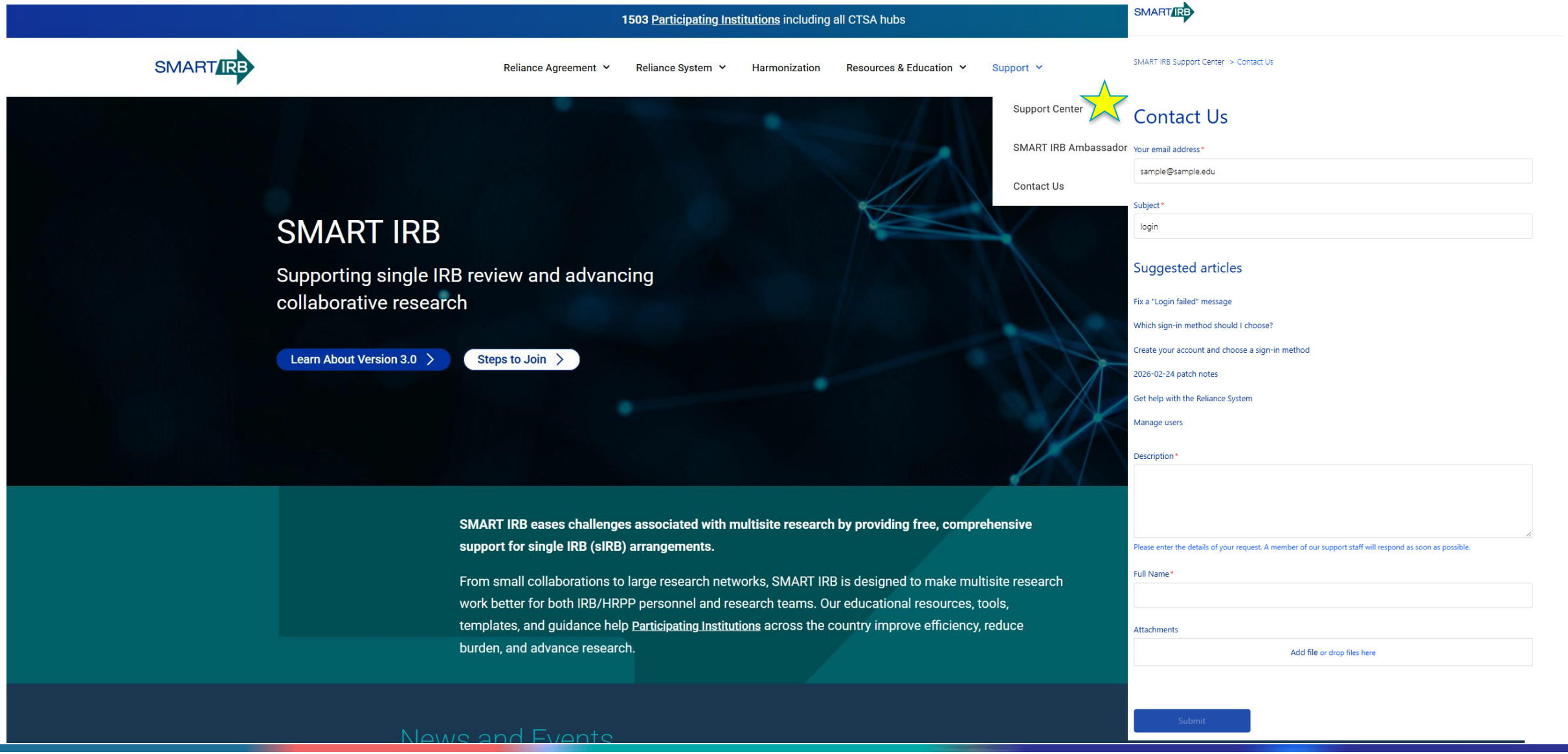
Reviewing IRB Package

Download

Relying Institution Package

Download

Support Center



Questions? We Are Here To Help!

SMART IRB fields over **1000+** help tickets per year, including a wide range of questions on:

- Reliance System
- SMART IRB Resources
- Agreement
- sIRB consultations
- And more!

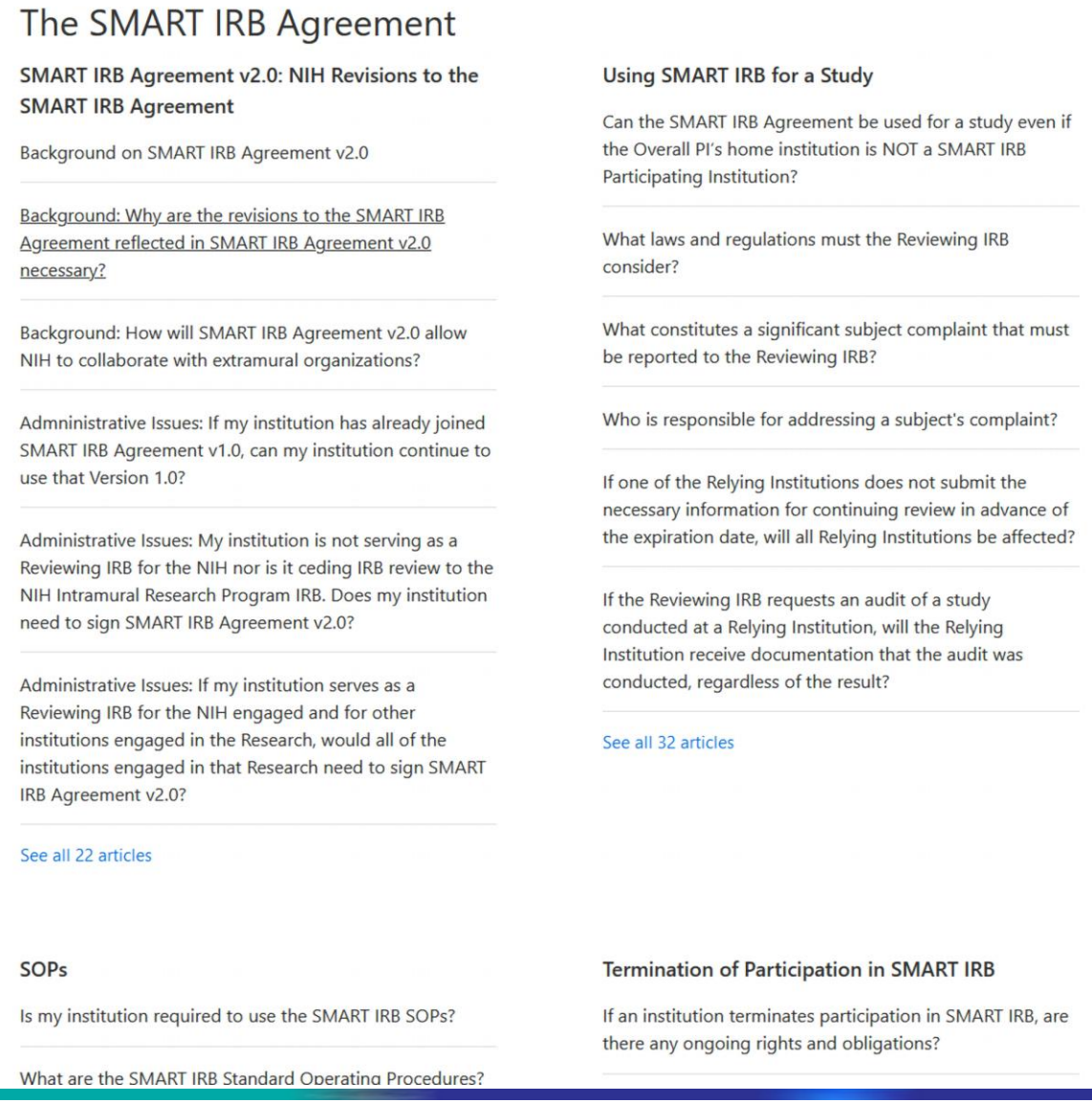
Contact us today: Help@smartirb.org

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



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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.

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 received a 'Login failed' message. 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?