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

Day 2 - February 9, 2023

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

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Welcome and Overview

Welcome!

You will gain a better understanding of:

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

Logistics

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

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

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

Please feel free to take breaks as needed.

Day 2 Overview

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

Onward!

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

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

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

Acknowledgements

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

What we will discuss in this session

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

Key Players

- Lead Institution

- Reviewing IRB

- Lead/Overall PI

- Relying PI

- Relying Institution

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

Two Popular Communication Models

- Lead PI Communication Model: All Study team information flows to the Reviewing IRB through the Lead/Overall PI; Relying PIs send information to Lead PI
- Relying PI Communication Model: Relying PIs work directly with Reviewing IRB and copy Lead/Overall PI
- Smart IRB Agreement allows either model, but the Smart IRB Resource documents are usually based on the Lead PI Communication Model

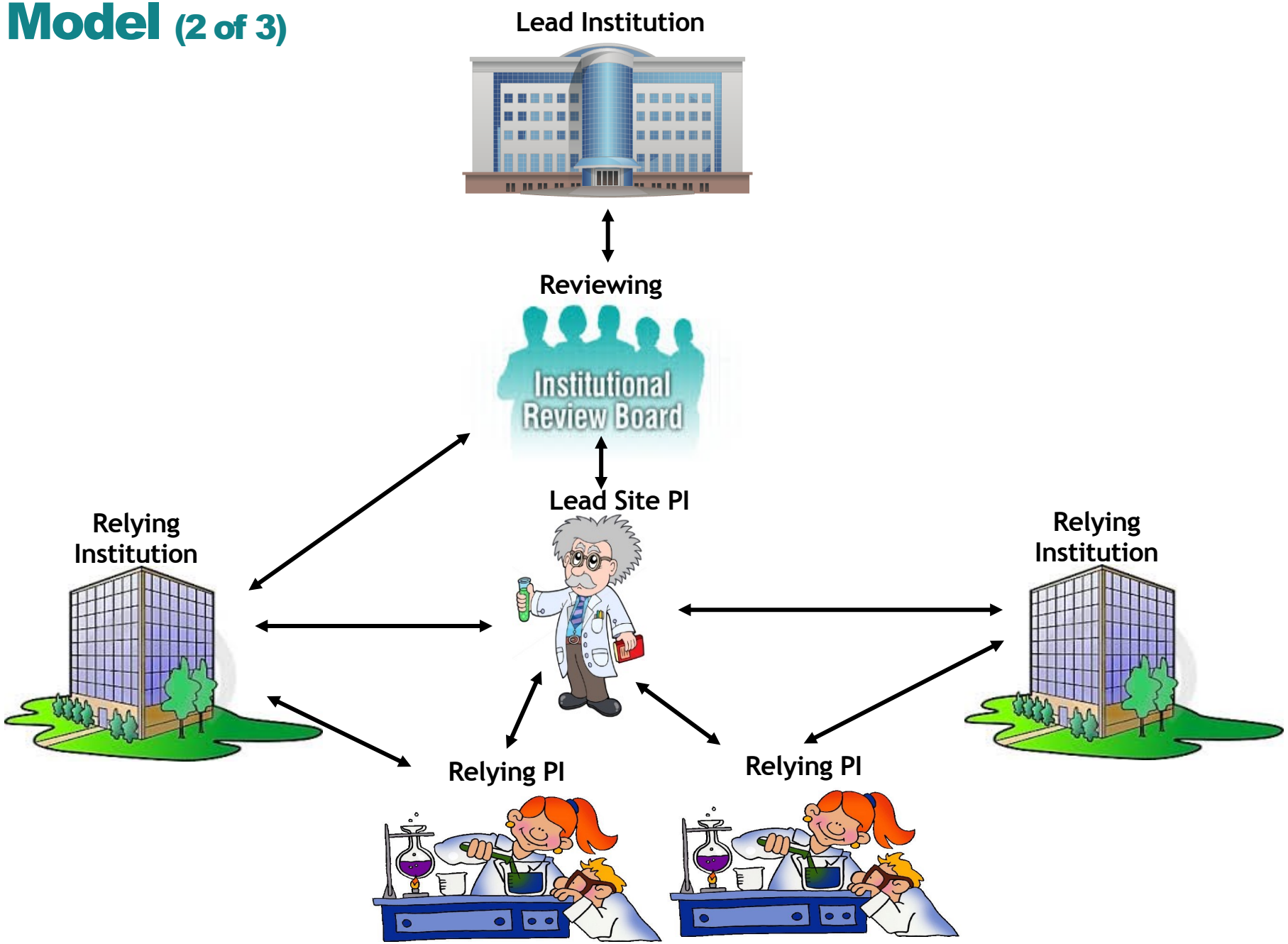
Lead PI Model (1 of 3)

Lead Institution

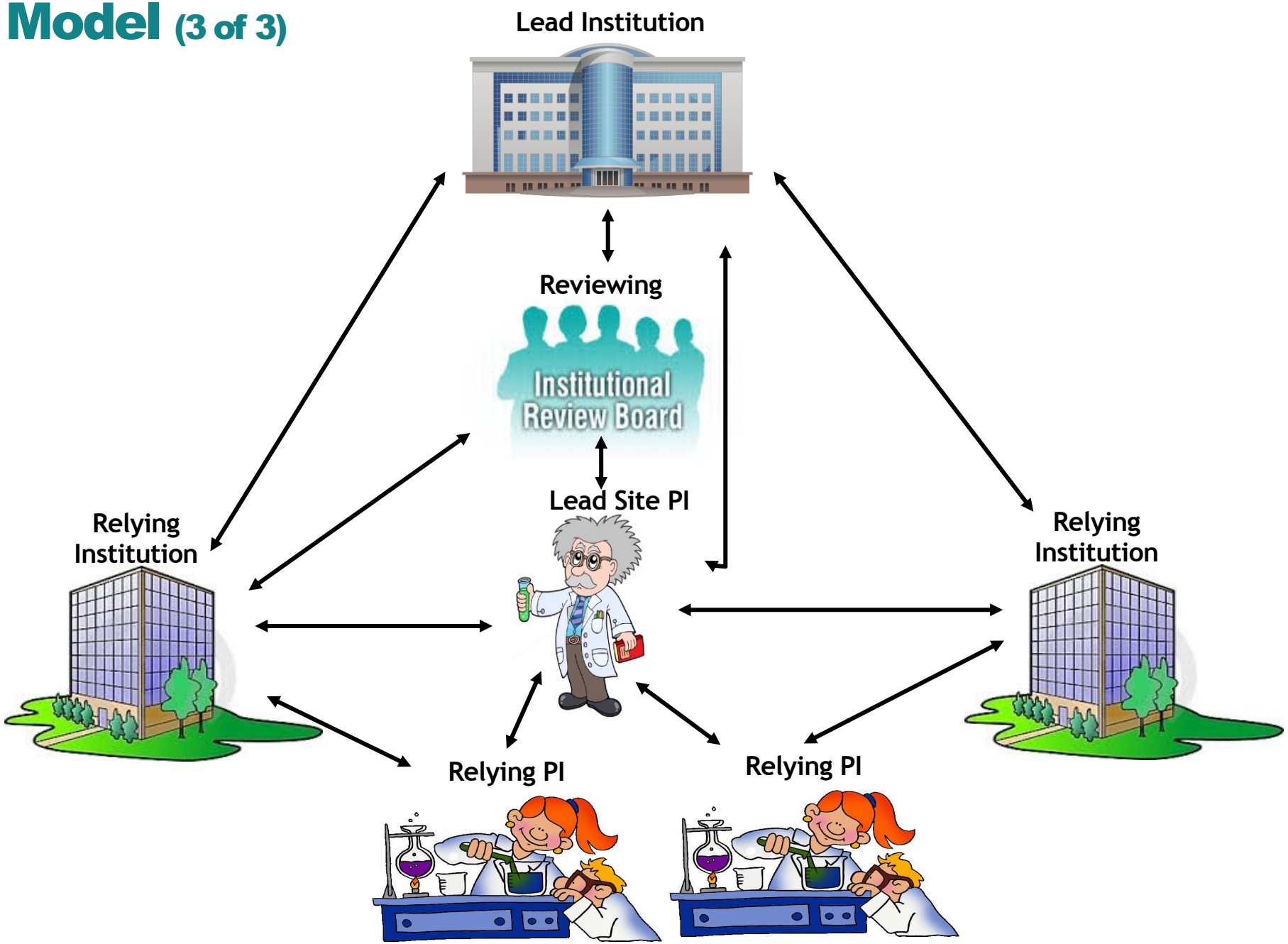
Reviewing

Lead Site PI

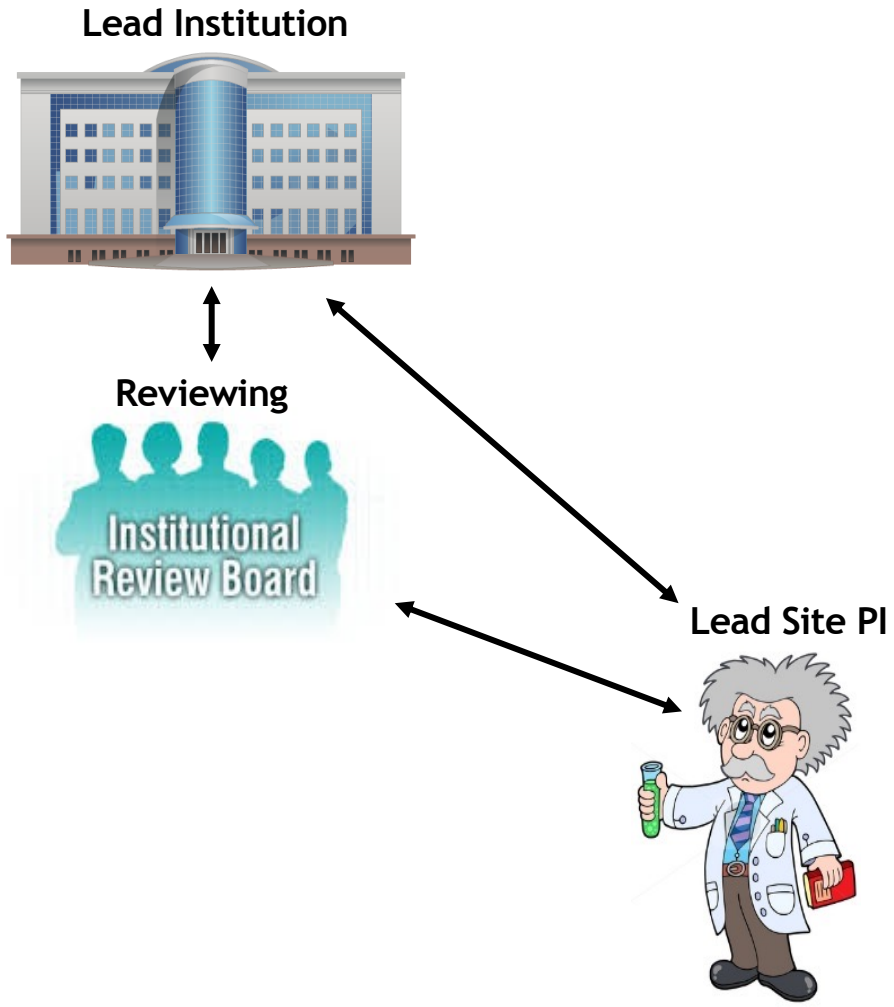
Lead PI Model (2 of 3)



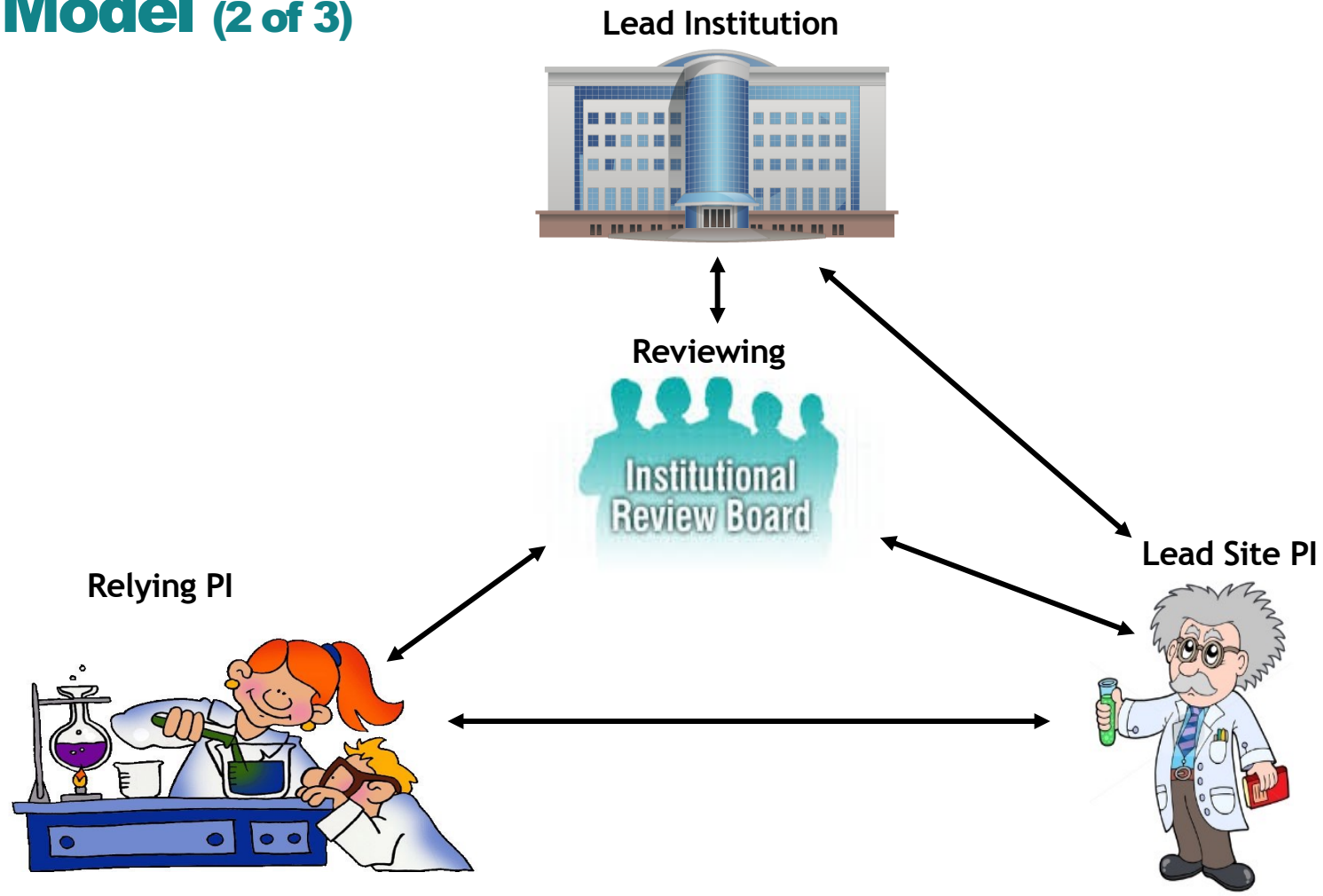
Lead PI Model (3 of 3)



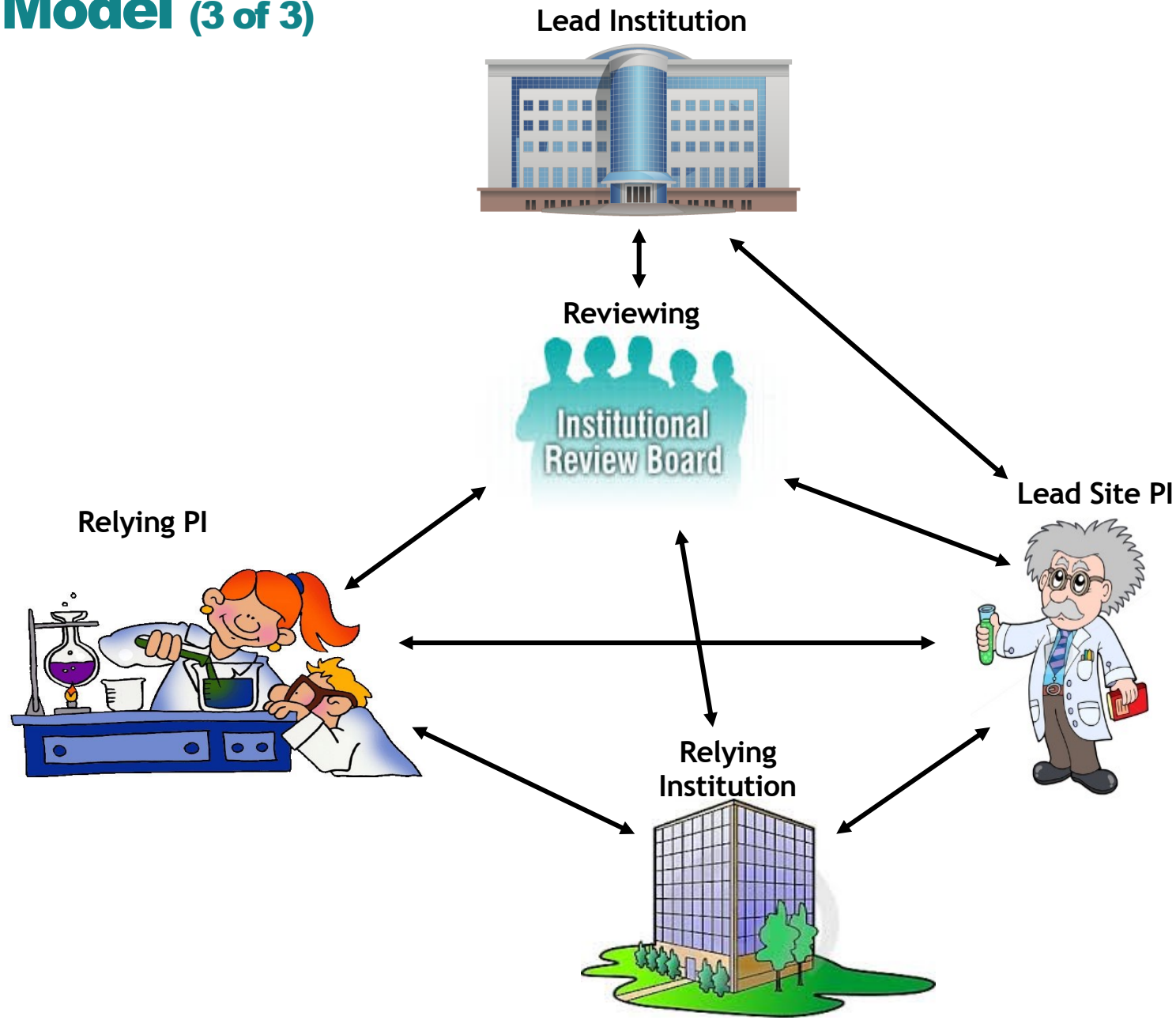
Relying PI Model (1 of 3)



Relying PI Model (2 of 3)



Relying PI Model (3 of 3)



Hint: Critical that you know what type of communication model will be used

- Challenge: The agreement may not specify type of flow. What do you do in that case?
- Challenge: The Reviewing IRB may not communicate their expectations for communication! What do you do in that case?

What do you do?

- If Relying (Institution or PI), ask the Reviewing IRB!
- If Reviewing IRB, work it out!
  - Have a mechanism in place
  - Be clear on expectations and communication flow
  - Be flexible
- To assist in developing communication plan, use Smart IRB Resources (e.g., Implementation Plan, Template Communication Plan, Overall and Relying Site PI Checklists)

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 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 regarding any standard issues not outlined specifically in the agreement such as HIPAA review etc.)
- Request for Local Context/Consideration Information (e.g., applicable state or local laws, regulations institutional policies, local factors)
- Request for Select Ancillary Reviews such as Conflict of Interest Management Plan
- Approved Consent Template including site-specific information/identified in customizable sections of the consent form such as compensation for research related injury, payment of research costs, local contact information
- Request documentation or Assurances for research personnel education, training, & qualifications
- IRB Determinations, Review Decisions for all types of review (initial, continuing, amendment etc.), Lapses of Approval and Applicable Corrective Action Plans
- IRB Findings and Actions related to reportable issues (e.g., unanticipated problems, serious or continuing noncompliance, suspension or termination, significant subject complaints, subject injuries, unanticipated problems involving risks to subjects or others, reports to federal, state or funding agencies)

RELYING INSTITUTION Communication Responsibilities: Provide

- To Local Relying PI/Study Team
  - Relying Institution policies and procedures regarding use of an external IRB and the relying institution's expectations for communication with them and with the reviewing IRB
- To Reviewing IRB promptly respond to requests for the following:
  - Local Context/Consideration Information such as state and local laws and regulations, institutional policies, local factors)
  - Consent Form with customized site-specific information addressed
  - If separate HIPAA authorization form is used, provide site-specific authorization language
  - Request for Ancillary Review information such as Conflict of Interest Management Plan
  - Documentation or Assurances for research personnel education, training, & qualifications
  - Ensures the Relying Study Team notifies the Reviewing IRB of unanticipated problems, potential noncompliance, suspension or restriction, significant subject complaints

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 context information for each site, local amendments, personnel updates, local reportable events, study wide information for continuing review and amendments)
  - Lead Study team should have mechanism for obtaining and collating information from Participation Site and/or Relying Site POC

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.)

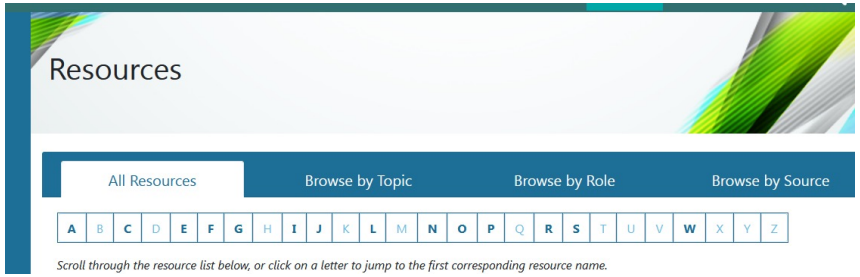
If the institution does not have any assigned HRPP/IRB Reliance staff, then the Relying PI will have increased responsibilities for communication.

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

- Overall Principal Investigator/Lead Study Team Guidance and Checklist
  https://smartirb.org/assets/files/PI_checklist.pdf
- Relying Site Investigator Guidance and Checklist
  https://smartirb.org/assets/files/Relying_institution_checklist.pdf
- Potential Relying Site Study Team Survey document
  https://smartirb.org/assets/files/Relying-Site-Team-Survey.pdf

Smart IRB Resources for all Key Players

- https://smartirb.org/resources/



- Implementation Checklist (pdf)
- Communication Plan for Single IRB Review (pdf)

Implementation Checklist and Documentation Tool

SMART IRB

SMART IRB Agreement Implementation Checklist and Documentation Tool

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

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

Instructions:

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

Template Communication Plan for SMART IRB (1 of 2)

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

Template Communication Plan for SMART IRB (2 of 2)

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:	
IRB APPLICATION – STUDYWIDE: Preparing and submitting the studywide application for initial IRB review and studywide amendments to the Reviewing IRB	☐ Reviewing IRB ☐ Lead Study Team ☐ Relying Site Study Team(s) ☐ Relying Site(s) POC(s)	

Example Communicating Conflict of Interest

Determine who will perform the conflict of interest analysis

Relying Institution?

Reviewing IRB?

Implementation Checklist

5. Conflicts of interest *SMART IRB Agreement Sections 5.8 and 6.6*	☐ **OPTION 1 – Relying Institution(s) will perform conflict of interest analyses under their policies** The Relying Institution(s) will perform their own analyses under their relevant policy(ies) with respect to disclosure and management of their Research Personnel's conflicts of interest in connection with the identified study(ies). The Relying Institution's(s') resulting determinations, prohibitions, management plans, and any updates will be provided to the Reviewing IRB. Note that the Reviewing IRB has the right to impose additional prohibitions or conflict management requirements. ☐ **OPTION 2 – Reviewing IRB will perform conflict of interest analyses 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 study(ies). The Reviewing IRB will notify the Relying Institution(s) of the IRB's resulting determinations, prohibitions, management plans, and any changes thereto. Note that the Relying Institution(s) may propose additional prohibitions or conflict management requirements to the Reviewing IRB for approval. ☐ **OPTION 3 – Relying Institution(s) and Reviewing IRB have agreed on an alternate plan for conflict of interest analyses** [DESCRIBE THE ALTERNATE PLAN]

Communication Plan

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:	

Relying Institution Responsibilities for Conflict of Interest

- The relying institution communicates their COI process to the relying site PI.
- The relying institution performs the COI analysis under their policies.
- The relying institution communicates the COI management plan to the relying site PI.

How does the Site PI’s conflict of interest management plan get communicated to the Reviewing IRB?

Reviewing IRB/Institution Responsibilities for Conflict of Interest

- The reviewing IRB communicates the process to receive information about COI and associated management plans from relying institutions.
- Examples of how reviewing IRBs collecting this information from relying sites might include the use of:
  - Local Context Forms
  - SMART IRB Protocol-Specific Document

Resource: Protocol-Specific Document


PROTOCOL-SPECIFIC
DOCUMENT

To Collect Institutional Requirements from Relying Institutions

- https://smartirb.org/assets/files/Protocol-Specific-20180726.pdf

Protocol-Specific Document

17. Did the organization determine there is a relevant individual or institutional financial **conflicts of interest (COI)** for this protocol?

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

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

b. If yes, provide the name and contact information for the appropriate POC for questions related to the determination and/or local management plan.

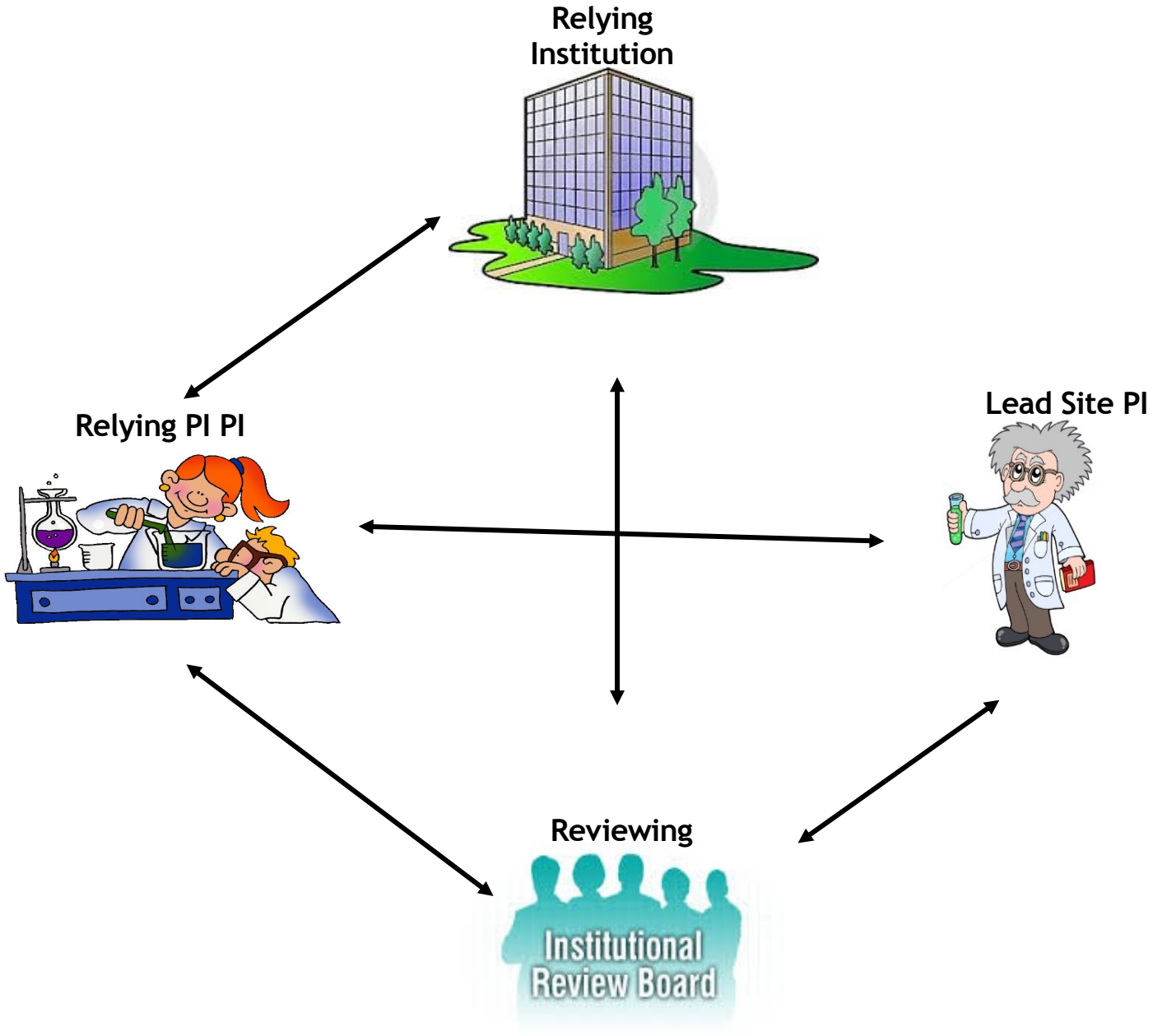
Lead PI Responsibilities for Conflict of Interest

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

Reviewing IRB Responsibilities for Conflict of Interest

- Reviews conflict of interest management plan from relying institution.
- If additional changes or strategies are needed, reviewing IRB communicates according to original plan established for communication.
  - *Note! In the earlier example using the "Protocol Specific Document" to collect COI information, there is a designated area to provide the contact information for POC at the relying institution.*

Conflict of Interest - Lead PI Model



Smart IRB Resources

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

https://smartirb.org/harmonization/

Harmonized Documents

Recommendations for the Harmonization of Ancillary Reviews NEW!

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

Download Document

Best viewed in Adobe Reader.

Conflict of Interest Review Processes for sIRB Review

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

Download Document

Best viewed in Adobe Reader.

Post-Approval Auditing for Studies Subject to Single IRB Review

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

Download Document

Best viewed in Adobe Reader.

Communicate Early and Often!

Things have to be very clear from the beginning.

Tip

Use and understand the agreement

Use the implementation checklist

Use the template communication plan

What to do when there are disagreements or miscommunications

He said / She Said - A Case Example
(1 of 2)

- Reviewing IRB sends out a template consent form with sections marked for site specific language.
- Relying Site Investigator sends back to the Reviewing IRB a consent form with lots and lots of changes and says her IRB requires all this. But the local context form submitted from the Relying Institution doesn't mention it…..

What should the Reviewing IRB do?

He said / She Said - A Case Example
(2 of 2)

What should Reviewing IRB do?

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

Communication breakdown – A Case Example

- Early in the process the Reviewing IRB & Relying Institution agrees to pursue reliance
- Time goes by …
- The Reviewing IRB inquires with the Lead PI if he has heard anything
- Lead PI contacts the Relying PI

- Relying PI produces a letter from 6 months prior from the Relying Institution indicating they have agreed to rely
- Nothing was documented between the Reviewing IRB and Relying Institution

Reviewing IRB Position

- Reach Out!
  - Get to the root of the issue
  - Don’t assume
- Be Flexible!
  - Can you accept something different?
- Be Nice!
  - It’s a small world
- Start and end on a positive note

Relying Institution Position

- Ask for options!
  - Can you provide the information another way?
  - Do we have to do reliance?
- Roll with it!
  - Sometimes, you just have to get through
- Be Nice!
  - It's still a small world
- Start and end on a positive note

Pro Tips on Communication (1 of 2)

Be Willing to Talk

To other IRBs, to PIs, to anyone.

Don’t be Shy

Ask, Be responsive, Keep it short

Pro Tips on Communication (2 of 2)

Assume Good Intentions

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

Ask yourself, does this matter?

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

Gratitude

- If you have a positive interaction with another IRB, a relying PI, anyone, let them know
- If you have a PI/Study Team that is really on top of sIRB procedures, share your appreciation
- If your IRB Chair and members have a terrific handle on sIRB, say thank you

In summary, what did we discuss today?

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

Training Study Teams

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

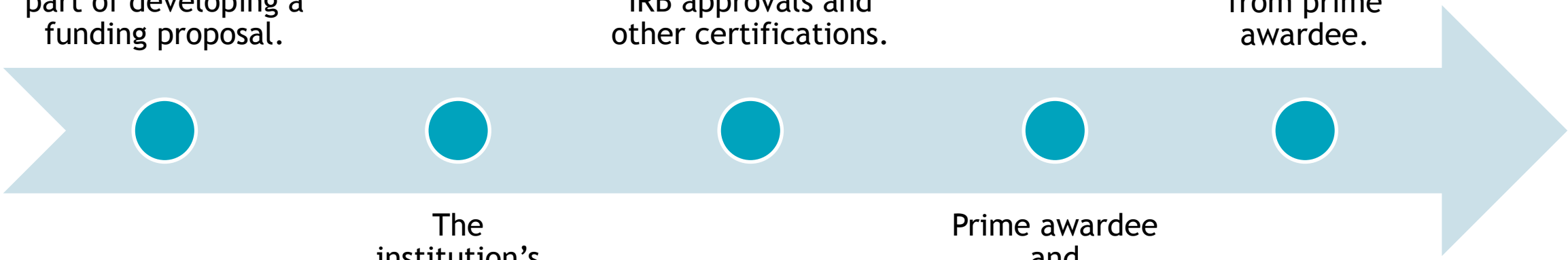
Kathy Lawry, MSSA, CIP
SMART IRB Ambassador; Senior Consultant, Association for the Accreditation of Human Research Protection Programs (AAHRPP)

What We Will Cover

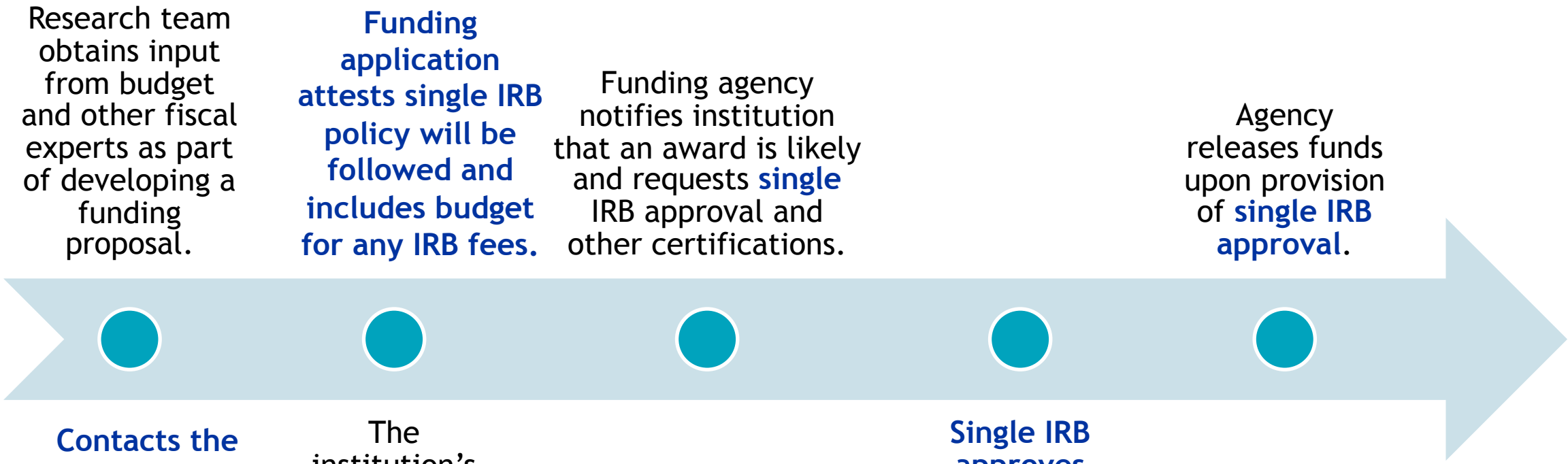
- Overview the effect of single IRB on study teams and impact on training needs
- SMART IRB resources that can be leveraged to train study teams
- Strategies for study team training and education

Impact of Single IRB on the Funding Process

Funding Application Process Before the Single IRB Requirement



Funding Application Process After the Single IRB Requirement (1 of 2)



Funding Application Process After the Single IRB Requirement (2 of 2)

Research team obtains input from budget and other fiscal experts as part of developing a funding proposal.

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

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

Agency releases funds upon provision of **single IRB approval**.

Although NIH no longer requires the single IRB to be identified in the grant application, we recommend ensuring who will act as the Reviewing IRB is known before a grant application is submitted because of the potential effect on budget and to eliminate delays.

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

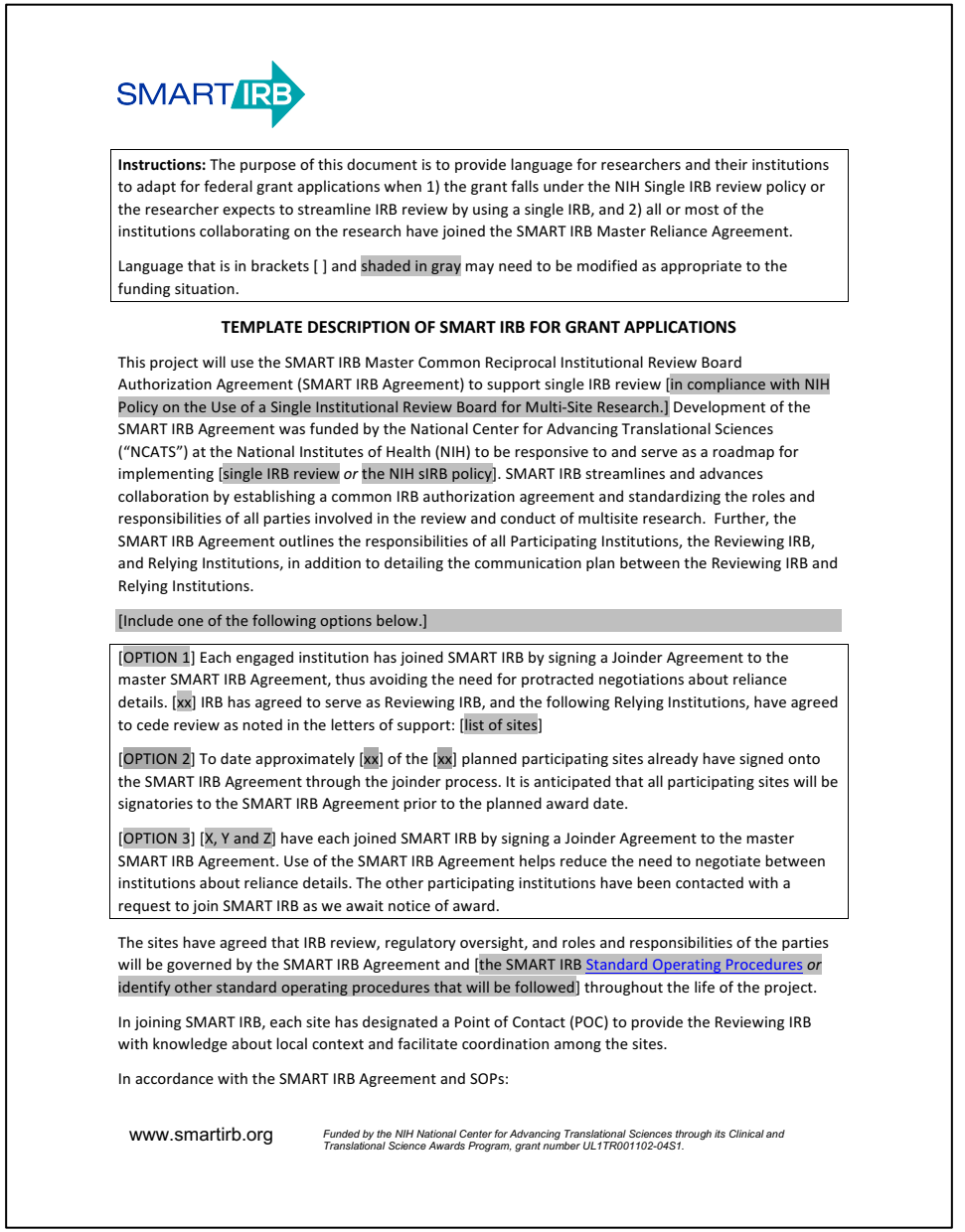
The institution's sponsored programs office submits the proposal to the funding agency.

Single IRB approves study for prime awardee and subawardees.

Resource: Grant Application Language

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

https://smartirb.org/assets/files/Template_Description_SMART_IRB_for_grant_applications.docx



SMART IRB

Instructions: The purpose of this document is to provide language for researchers and their institutions to adapt for federal grant applications when 1) the grant falls under the NIH Single IRB review policy or the researcher expects to streamline IRB review by using a single IRB, and 2) all or most of the institutions collaborating on the research have joined the SMART IRB Master Reliance Agreement.

Language that is in brackets [ ] and shaded in gray may need to be modified as appropriate to the funding situation.

TEMPLATE DESCRIPTION OF SMART IRB FOR GRANT APPLICATIONS

This project will use the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (SMART IRB Agreement) to support single IRB review [in compliance with NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research.] Development of the SMART IRB Agreement was funded by the National Center for Advancing Translational Sciences ("NCATS") at the National Institutes of Health (NIH) to be responsive to and serve as a roadmap for implementing [single IRB review *or* the NIH sIRB policy]. SMART IRB streamlines and advances collaboration by establishing a common IRB authorization agreement and standardizing the roles and responsibilities of all parties involved in the review and conduct of multisite research. Further, the SMART IRB Agreement outlines the responsibilities of all Participating Institutions, the Reviewing IRB, and Relying Institutions, in addition to detailing the communication plan between the Reviewing IRB and Relying Institutions.

[Include one of the following options below.]

[OPTION 1] Each engaged institution has joined SMART IRB by signing a Joinder Agreement to the master SMART IRB Agreement, thus avoiding the need for protracted negotiations about reliance details. [xx] IRB has agreed to serve as Reviewing IRB, and the following Relying Institutions, have agreed to cede review as noted in the letters of support: [list of sites]

[OPTION 2] To date approximately [xx] of the [xx] planned participating sites already have signed onto the SMART IRB Agreement through the joinder process. It is anticipated that all participating sites will be signatories to the SMART IRB Agreement prior to the planned award date.

[OPTION 3] [X, Y and Z] have each joined SMART IRB by signing a Joinder Agreement to the master SMART IRB Agreement. Use of the SMART IRB Agreement helps reduce the need to negotiate between institutions about reliance details. The other participating institutions have been contacted with a request to join SMART IRB as we await notice of award.

The sites have agreed that IRB review, regulatory oversight, and roles and responsibilities of the parties will be governed by the SMART IRB Agreement and [the SMART IRB Standard Operating Procedures *or* identify other standard operating procedures that will be followed] throughout the life of the project.

In joining SMART IRB, each site has designated a Point of Contact (POC) to provide the Reviewing IRB with knowledge about local context and facilitate coordination among the sites.

In accordance with the SMART IRB Agreement and SOPs:

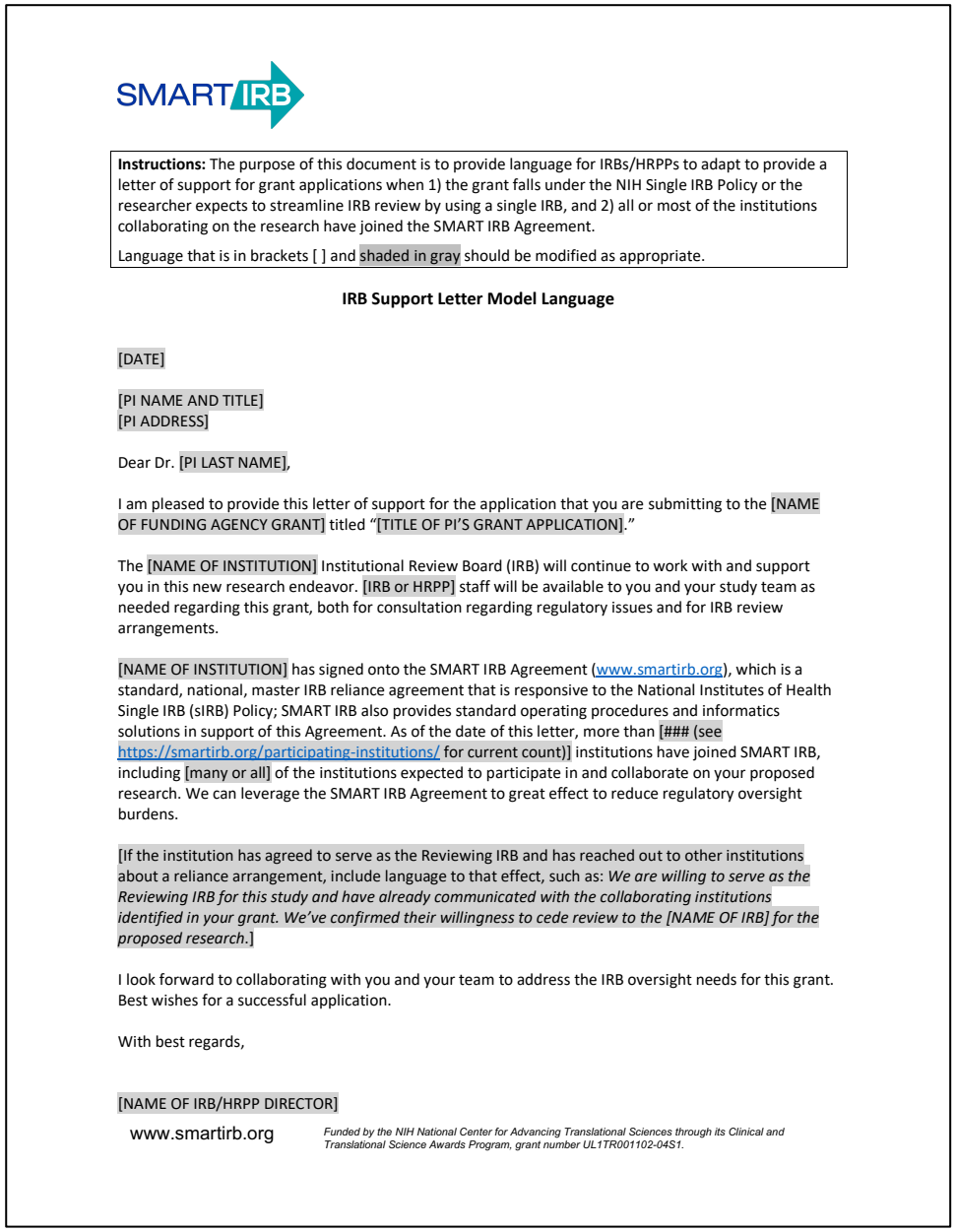
www.smartirb.org

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

SMART IRB Resource: IRB Letter of Support for Grants

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

https://smartirb.org/assets/files/IRB-support-letter-model-language.docx



SMART IRB

Instructions: The purpose of this document is to provide language for IRBs/HRPPs to adapt to provide a letter of support for grant applications when 1) the grant falls under the NIH Single IRB Policy or the researcher expects to streamline IRB review by using a single IRB, and 2) all or most of the institutions collaborating on the research have joined the SMART IRB Agreement.

Language that is in brackets [ ] and shaded in gray should be modified as appropriate.

IRB Support Letter Model Language

[DATE]

[PI NAME AND TITLE]
[PI ADDRESS]

Dear Dr. [PI LAST NAME],

I am pleased to provide this letter of support for the application that you are submitting to the [NAME OF FUNDING AGENCY GRANT] titled "[TITLE OF PI'S GRANT APPLICATION]."

The [NAME OF INSTITUTION] Institutional Review Board (IRB) will continue to work with and support you in this new research endeavor. [IRB or HRPP] staff will be available to you and your study team as needed regarding this grant, both for consultation regarding regulatory issues and for IRB review arrangements.

[NAME OF INSTITUTION] has signed onto the SMART IRB Agreement (www.smartirb.org), which is a standard, national, master IRB reliance agreement that is responsive to the National Institutes of Health Single IRB (sIRB) Policy; SMART IRB also provides standard operating procedures and informatics solutions in support of this Agreement. As of the date of this letter, more than [### (see https://smartirb.org/participating-institutions/ for current count)] institutions have joined SMART IRB, including [many or all] of the institutions expected to participate in and collaborate on your proposed research. We can leverage the SMART IRB Agreement to great effect to reduce regulatory oversight burdens.

[If the institution has agreed to serve as the Reviewing IRB and has reached out to other institutions about a reliance arrangement, include language to that effect, such as: *We are willing to serve as the Reviewing IRB for this study and have already communicated with the collaborating institutions identified in your grant. We've confirmed their willingness to cede review to the [NAME OF IRB] for the proposed research.*]

I look forward to collaborating with you and your team to address the IRB oversight needs for this grant. Best wishes for a successful application.

With best regards,

[NAME OF IRB/HRPP DIRECTOR]

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.

Budgeting for Single IRB Review

IRB Fees

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

New Staff Roles

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

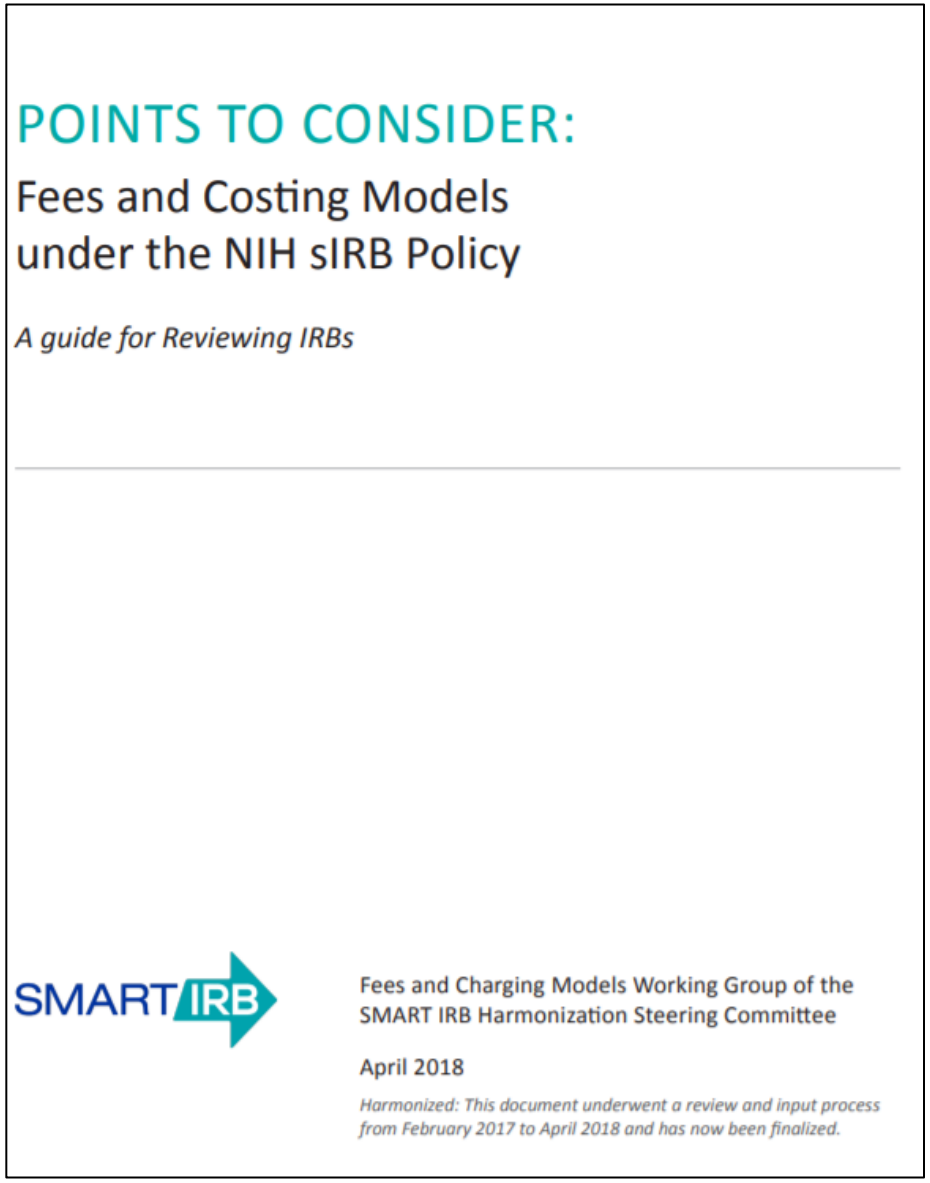
New Resources

May need new platforms to disseminate documents to study teams

SMART IRB Resource for IRB Fees and Costing Models

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

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.

Impact of Single IRB on Protocol and Consent Form Preparation & Review Process

Protocol Content

The protocol should be written in a way that it can be utilized across all sites:

- Describe procedures in a manner that all sites can be compliant
- Give choices of procedures that yield the same outcome when possible (e.g., CT vs MRI)
- Describe sections such as AE reporting and privacy/security of data as general as possible without compromising the integrity of the protocol (e.g., AE reporting according to FDA, or data will be stored in a secure manner and password protected)

Informed Consent

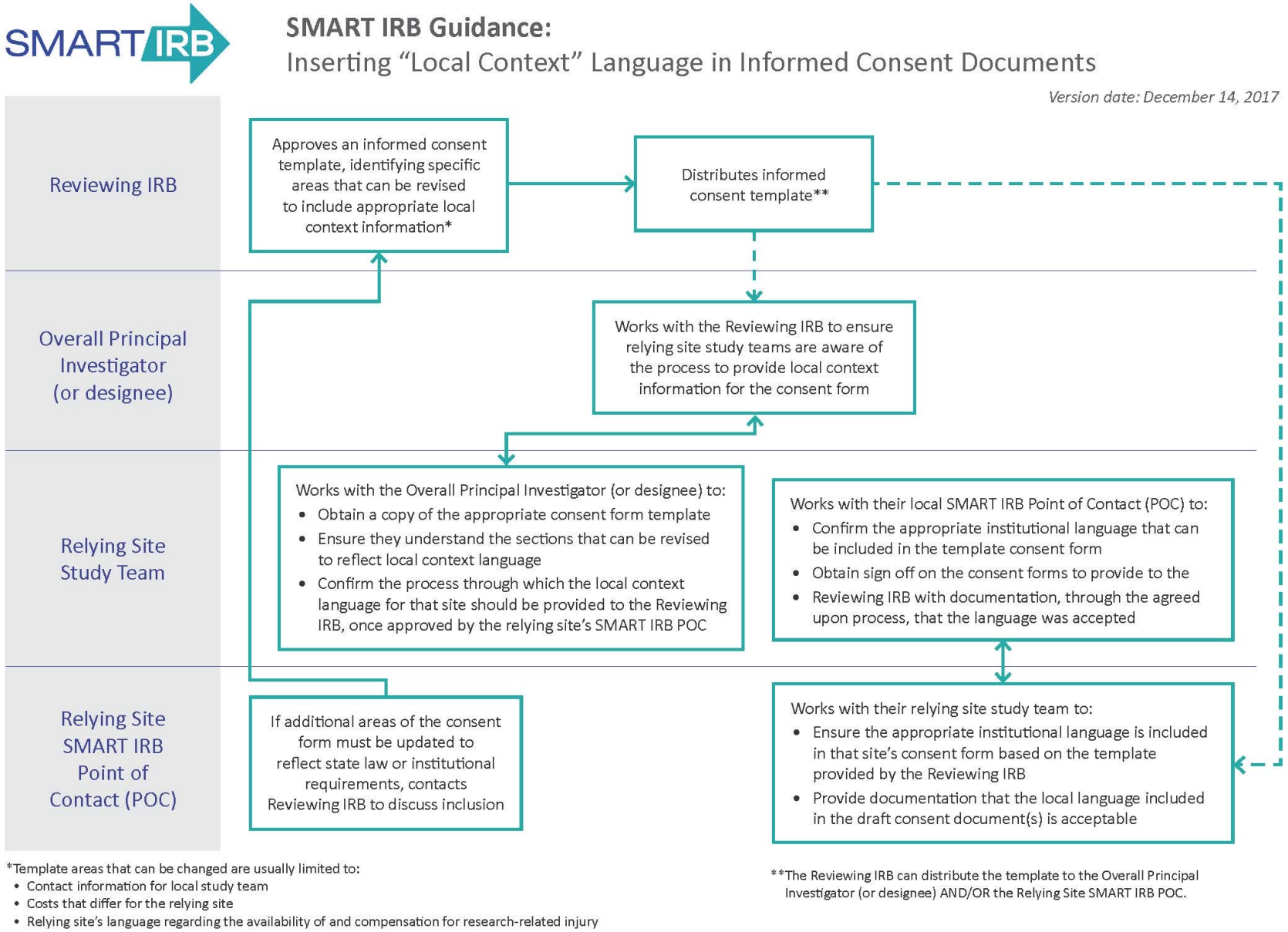
The consent document should have portions that are exactly the same for each site as well as portions that allow local language.

- Lock down study specific information and allow customization only in certain sections for local context
- Another model: a 2-part consent that is merged after review into 1 document

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

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

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



Managing Roles Related to Single IRB

Understanding 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 Overall PI Responsibilities

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

Designates a Lead Study Team*

(can be a coordinating center)

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

Common Lead Study Team Key Responsibilities

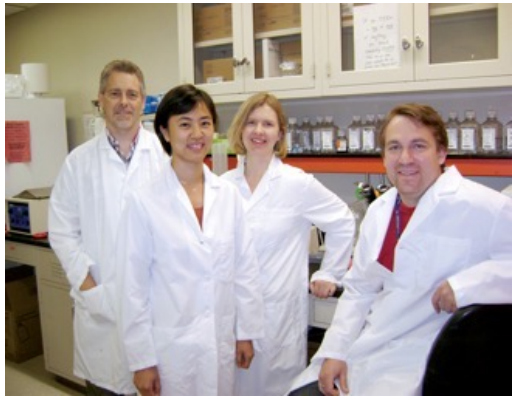
Submit materials to the Reviewing IRB for all sites, including, initial protocol, study-wide and site-specific changes of protocol, continuing reviews, and reportable events (e.g., unanticipated problems, noncompliance, and new information)

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

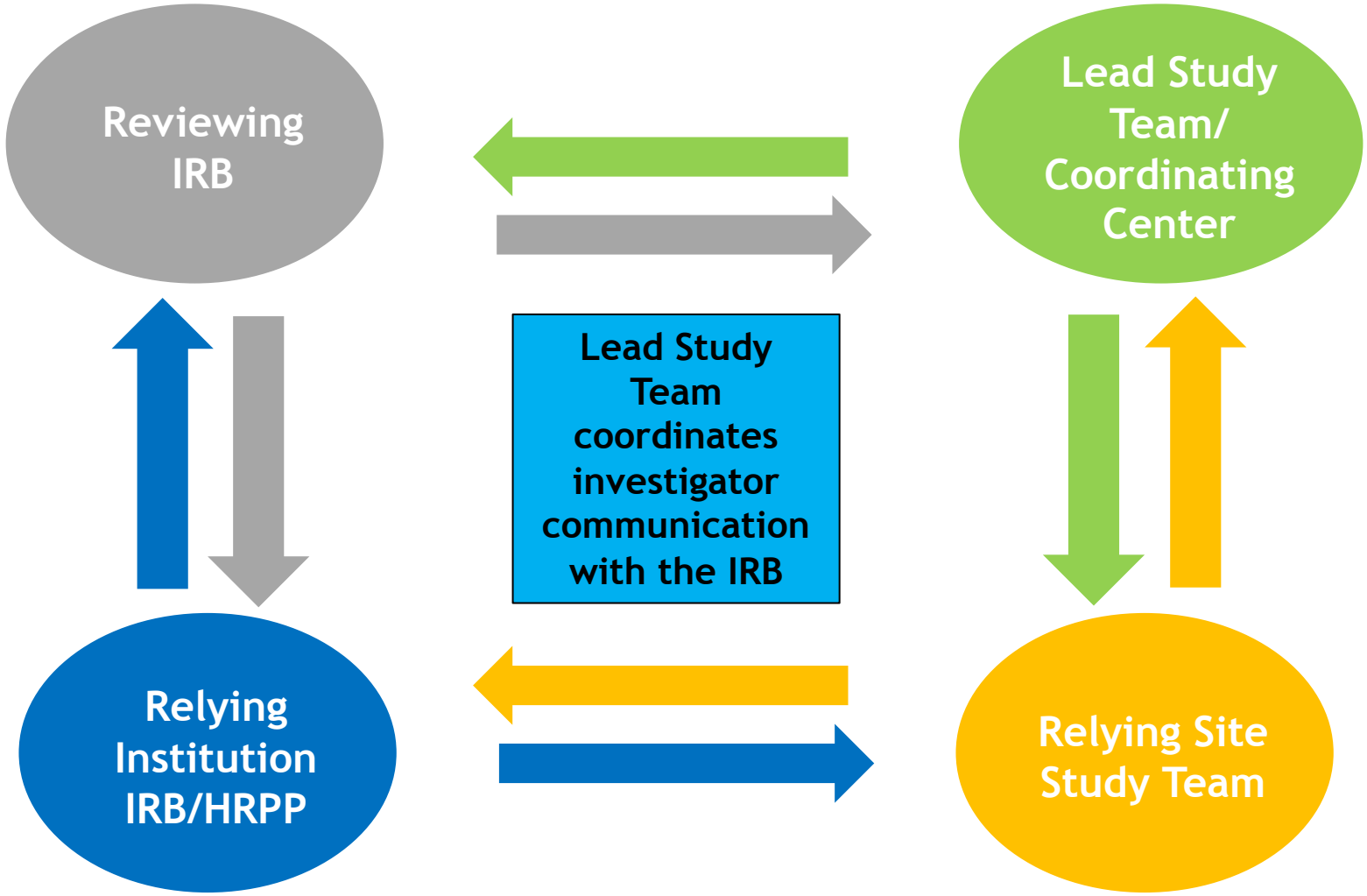
Common Responsibilities for Site PIs & Relying Site Study Teams



*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

Common Single IRB Communication Model



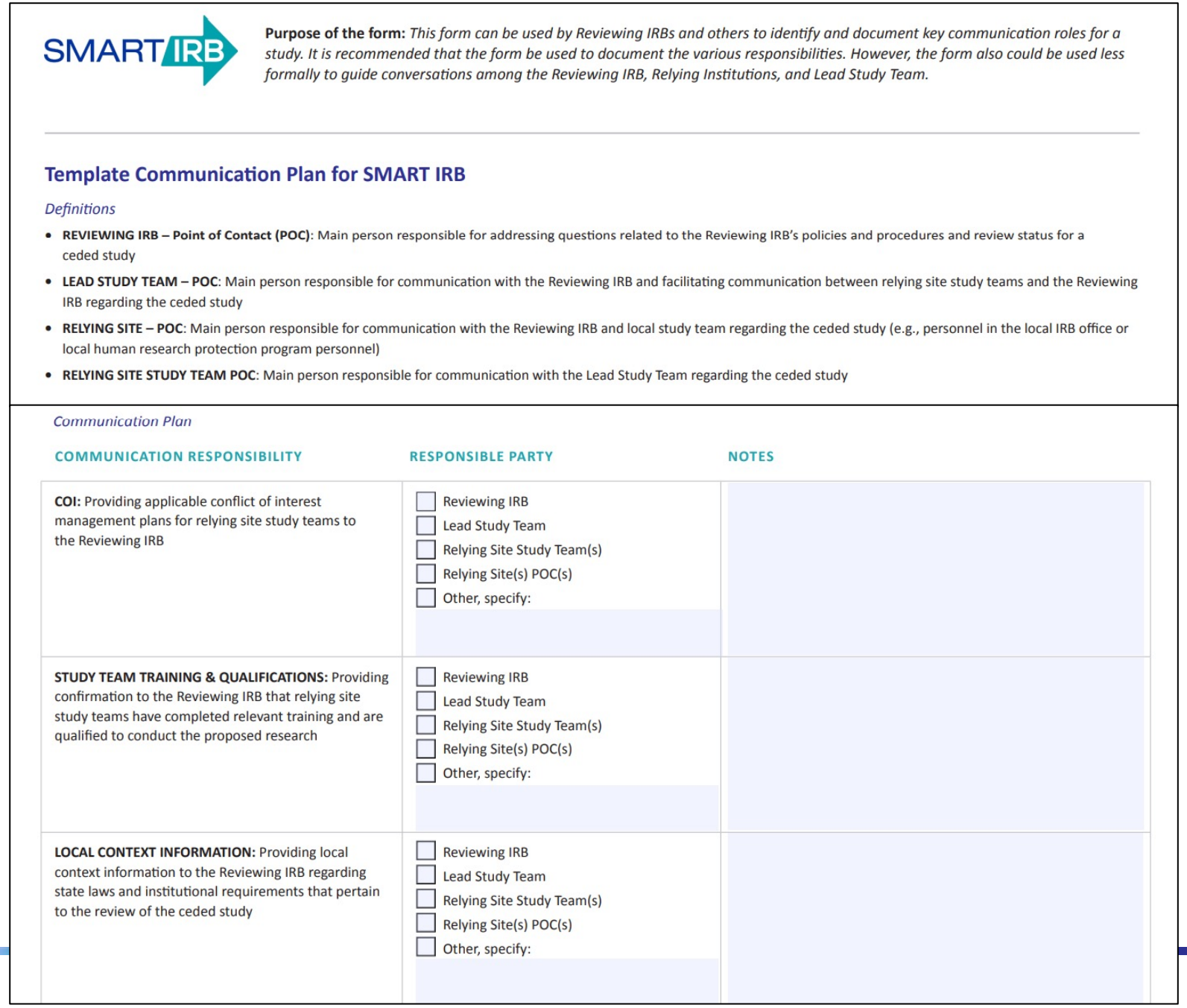
SMART IRB Resource: Communication plan for single IRB review

Document key communication roles, e.g., submitting initial and continuing reviews, amendments, and reportable events; providing conflict of interest management plans; and providing IRB-approved documents and communicating Reviewing IRB determinations.

[Download the Communication Plan (pdf)]

[Download the Communication Plan (customizable Word document]

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



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:

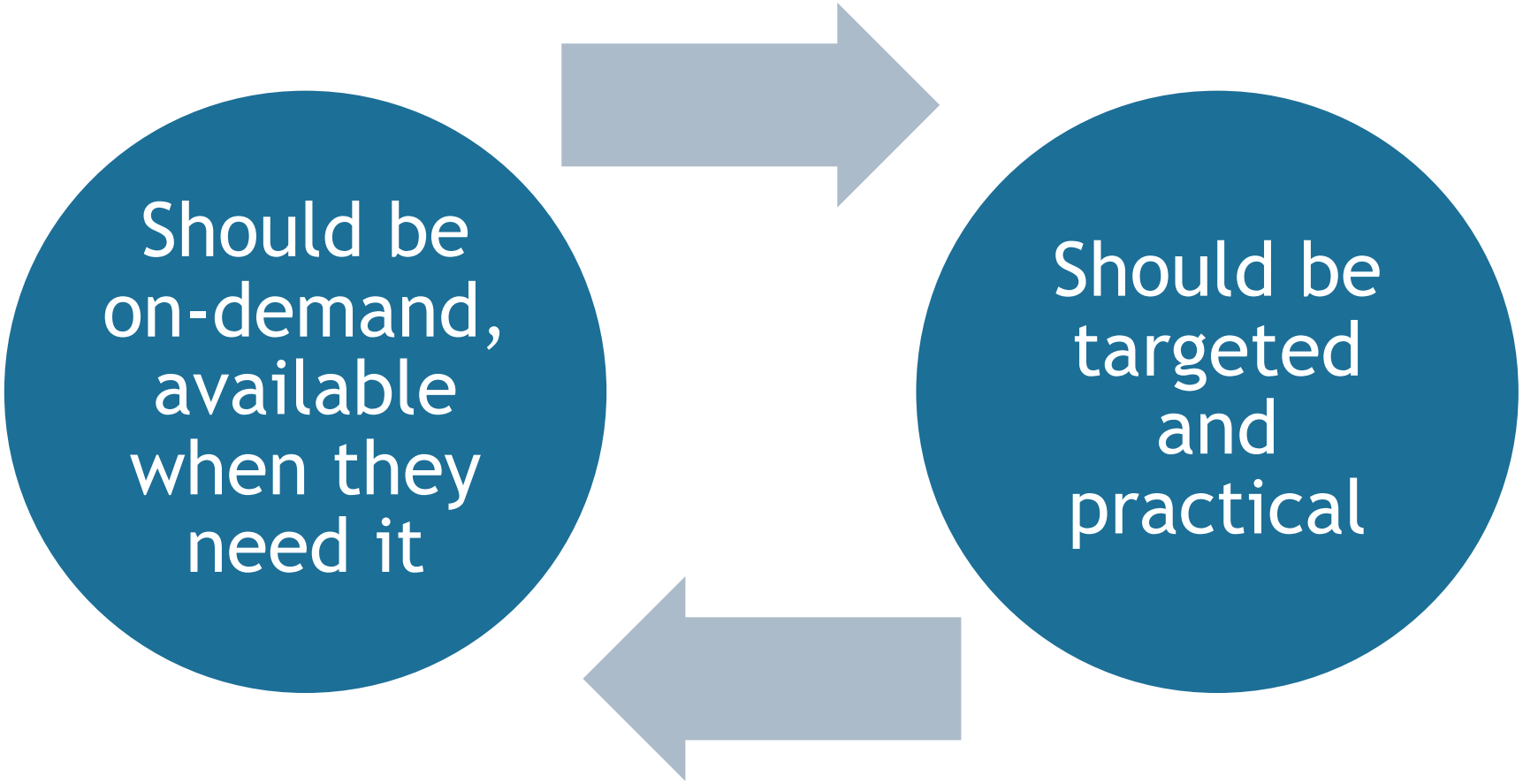
- Reportable events
- Personnel updates, including when they trigger the need to communicate a new or updated conflict of interest management plan

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 Resources

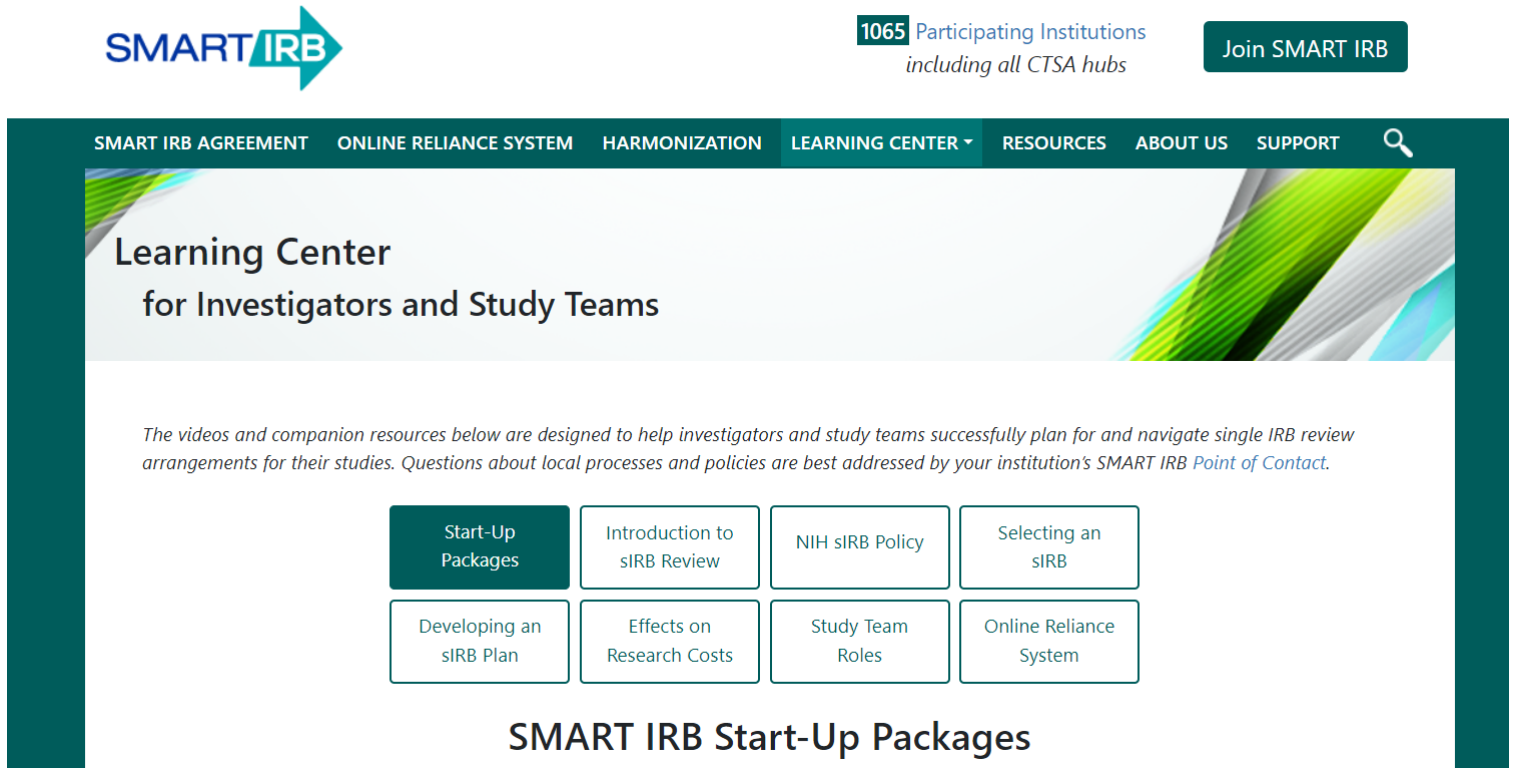
Approach to Study Team Training



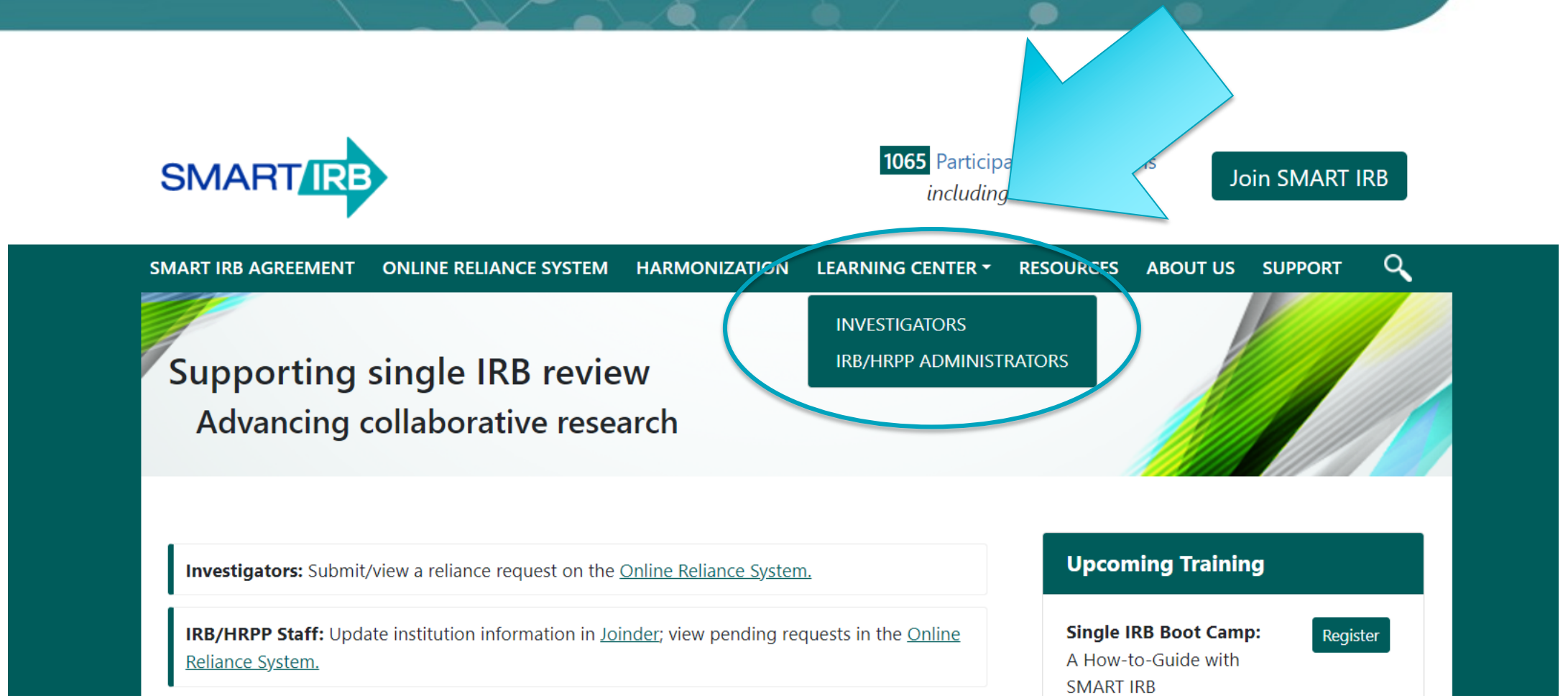
SMART IRB Resources for Study Teams

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



IRB/HRPP Administrators Learning Center Page

Topics for Training Study Teams

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

Download and Edit

Training for Investigators and Study Teams

Use this suite of training videos and resources as is, or customize to reflect local processes and policie

Visit the Investigator and Study Team Learning Center to view available materials; send investigators here for self-guide

Download presentations (no audio) to use for local training sessions or customize to reflect local processes.

To download the presentations with embedded audio, please use the links below:

- Developing a Single IRB Plan
- Overview of the NIH Single IRB Policy for Researchers
- Potential Effects of Single IRB on Research Costs
- Selecting a Single IRB
- Single IRB review and SMART IRB
- Study Team Roles Related to Single IRB

Back to Top

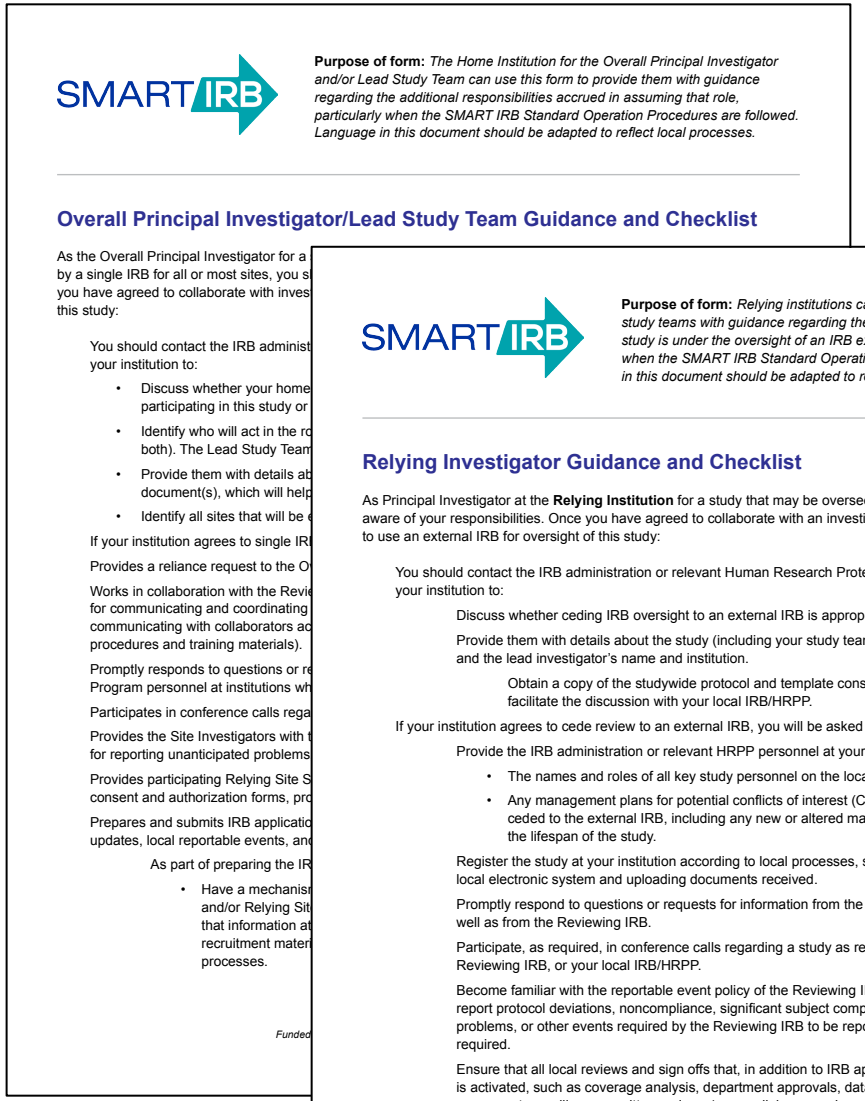
SMART IRB Resource: Investigator Checklists

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 reflect 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 Team
- 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 Revie
for communicating and coordinating
communicating with collaborators ac
procedures and training materials).

Promptly responds to questions or re
Program personnel at institutions wh

Participates in conference calls rega

Provides the Site Investigators with t
for reporting unanticipated problems

Provides participating Relying Site S
consent and authorization forms, pro

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

As part of preparing the IR

- Have a mechanis
and/or Relying Sit
that information at
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 reflect 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 conflicts 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, significant 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 identified in the template consent form.

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

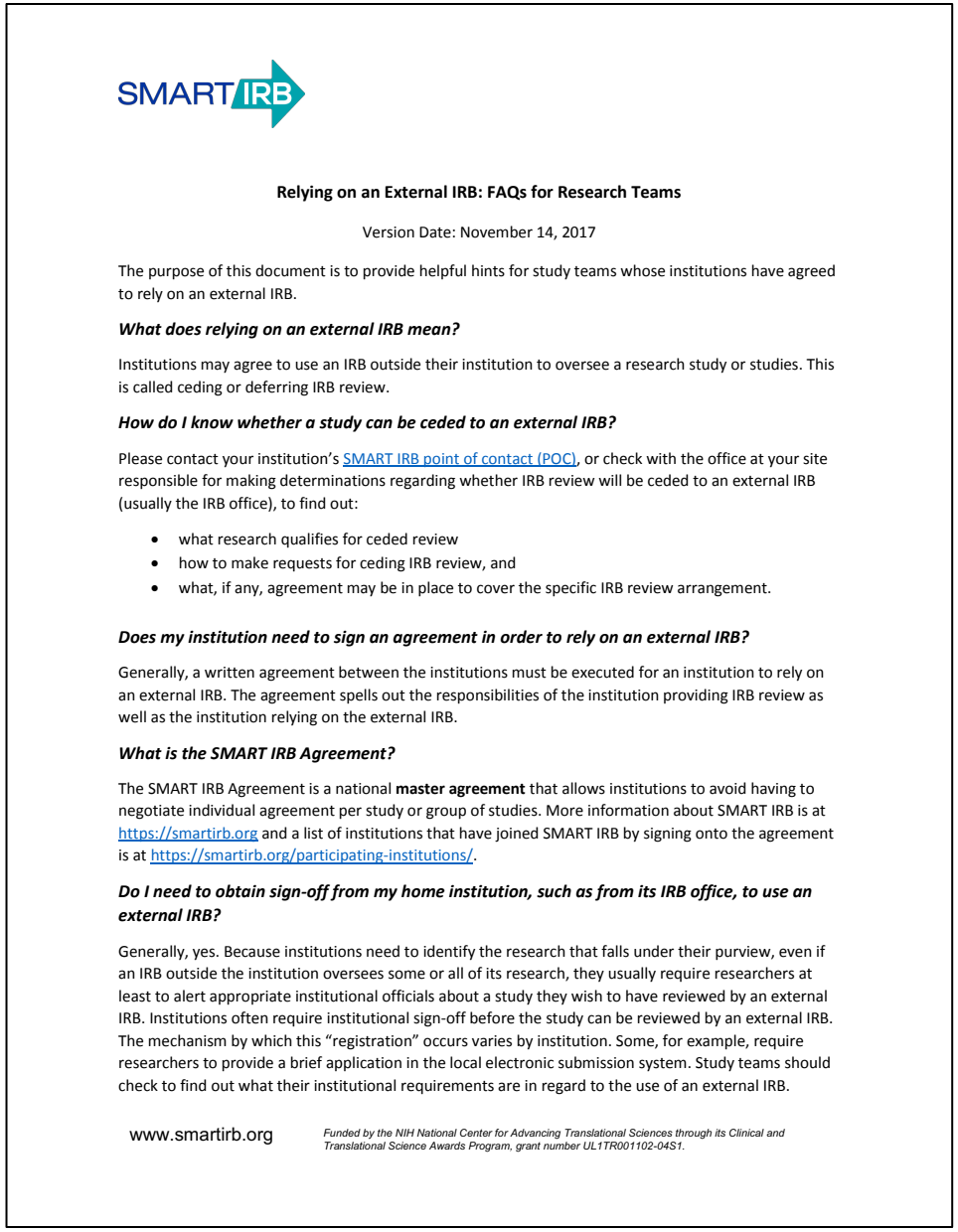
Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR001102-04S1

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.

COMING SOON:
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 assist you to identify the processes and resources you may need to facilitate a single IRB reliance arrangement for your multi-site 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***	☐	☐	Click or tap here to enter text.
2. Have you identified a Reviewing IRB that is willing to serve as the Single Reviewing IRB? ***Often, but not always, the Single IRB is at the Overall Principal Investigator's institution.*** **Link to helpful Resource for Selecting a Single IRB**	☐	☐	Click or tap here to enter text.
3. Have you identified the reliance agreement the Reviewing IRB will use for this study?	☐	☐	Click or tap here to enter text.
4. Will the Reviewing IRB use the SMART IRB Agreement? Link to Smart IRB Agreement	☐	☐	Click or tap here to enter text.
5. Are all Participating Institutions using SMART IRB ?	☐	☐	Click or tap here to enter text.

Questions

SMART IRB

Harmonization Guidance

Barbara Bierer, MD
Director of Regulatory Policy, SMART IRB

Goals of Single IRB Review

- NIH Single IRB policy
  - "**enhance and streamline the IRB review process** in the context of multi-site research so that research can proceed as effectively and expeditiously as possible."
- Common Rule
  - "Mandated single IRB review would ultimately **decrease administrative burdens** and **inefficiencies** for investigators and institutions."

Feedback from Investigators, Study teams & HRPPs

Challenges Encountered

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

Harmonization

Harmonization Steering Committee (HSC)

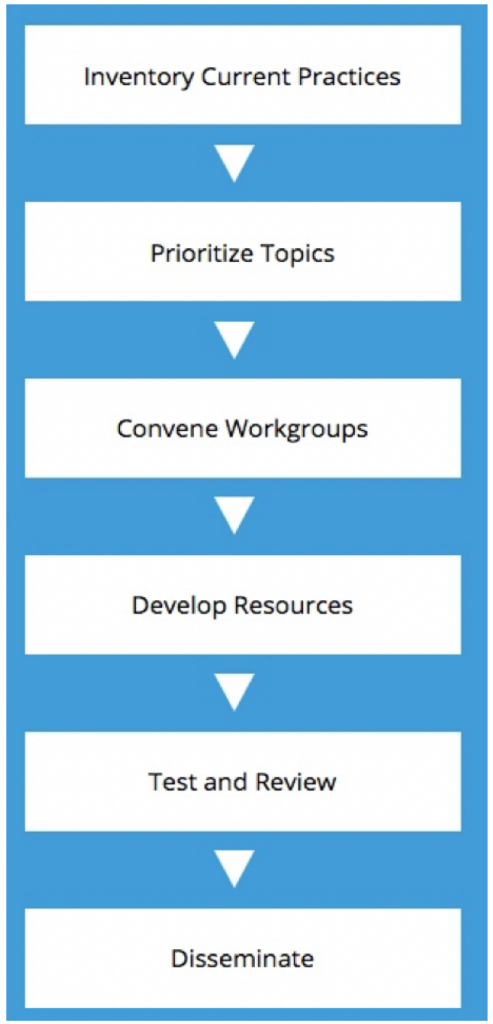
- To promote a more strategic, effective, efficient and cooperative approach to policies, processes and procedures related to single IRB review of multisite studies

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

Josh Fessel, MD, PhD
Senior Clinical Advisor, Division of Clinical Innovation, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health

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

HSC: Iterative development cycle



Finalized:

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

In Progress:

- Local Context

Subcommittees' focus:

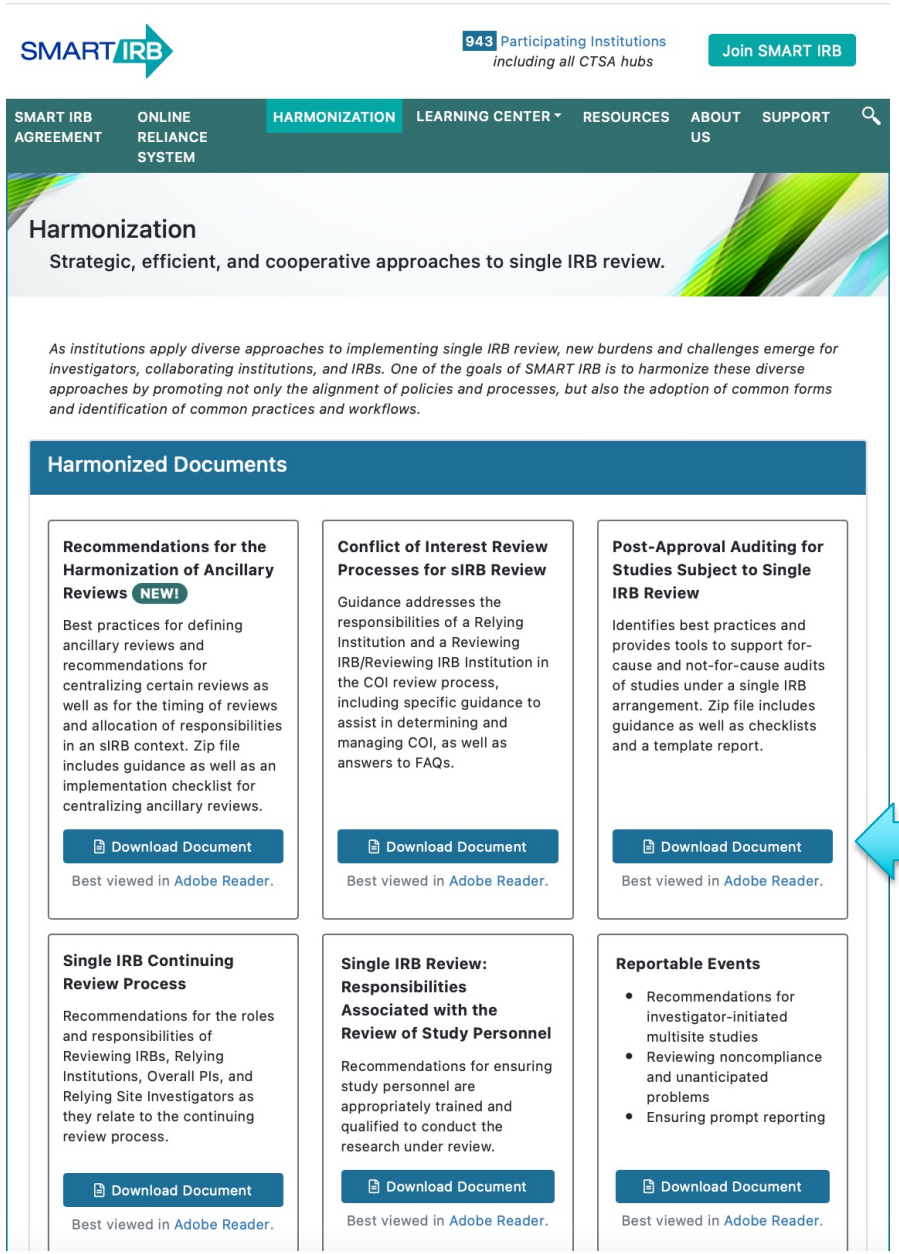
- Through "Emerging Issues Workshop" to HSC for selection

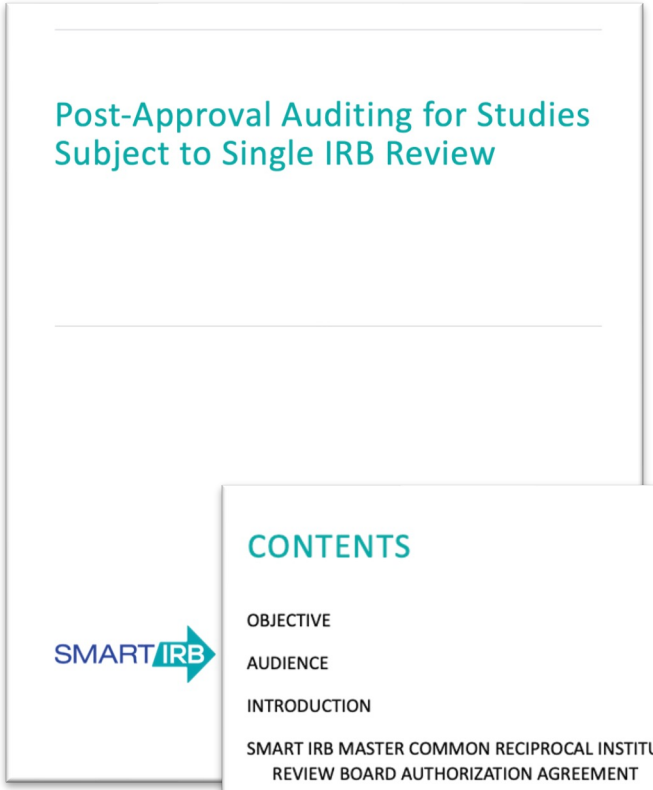
https://smartirb.org/harmonization/

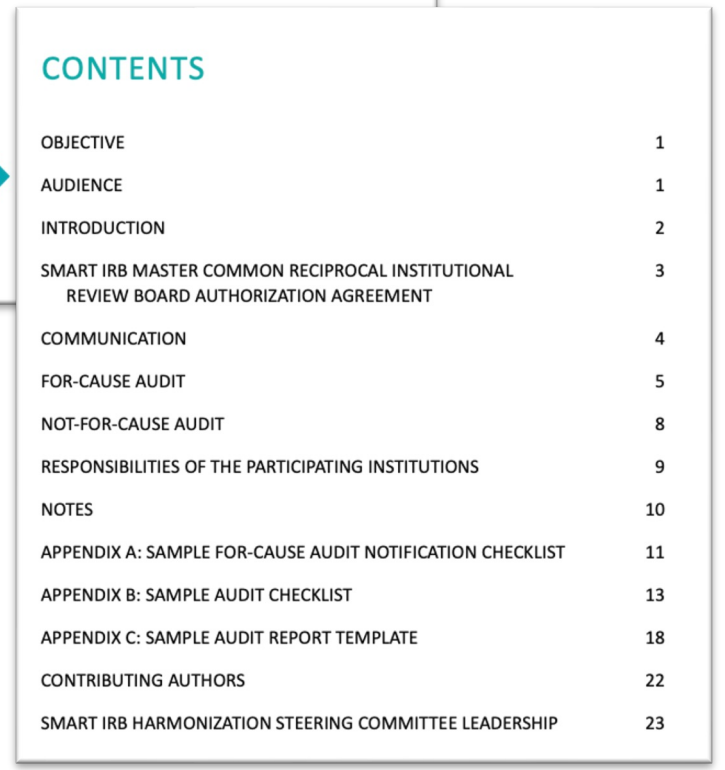
Harmonization Guidance: https://smartirb.org/harmonization/

- Delineates Relying Institution and Reviewing IRB responsibilities for sIRB research
- Provides templates, checklists and forms to be edited and implemented locally

Harmonization Guidance: Post-Approval Auditing







https://smartirb.org/harmonization/

Checklists and Templates

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

SMART IRB

SAMPLE FOR-CAUSE AUDIT NOTIFICATION CHECKL

FOR USE BY THE REVIEWING IRB REQUESTING THE AUDIT

STUDY TITLE: _____

PRINCIPAL INVESTIGATOR: _____

PARTICIPATING SITE FOR AUDIT: _____

SITE INVESTIGATOR: _____

RELYING INSTITUTION POINT OF CONTACT: _____

SPONSOR: _____

Funding Sources *(check all that apply)*: ☐ Industry Sponsor ☐ Foundation ☐ Government/NIH ☐

Type of Study: ☐ Drug/Biologic ☐ Device ☐ Tissue/Sample Repository ☐ Genetics ☐
☐ Questionnaire ☐ Chart Review/Database ☐ Other: _____

WHAT CONCERNS PROMPTED THE REQUEST FOR AN AUDIT?

☐ Reviewing IRB has reason to suspect serious or continuing noncompliance or unanticipated problem involving r
others based on information received in a submission or upon report of an investigator or other member of the

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

☐ Reason to need verification that the Research is being conducted in accordance with the IRB-approved pr
[including known/suspected issues with study conduct, data integrity, etc].

Comments and additional information:

**DOCUMENTS AND INFORMATION THAT THE REVIEWING IRB REQUESTS TO BE REVIEWED IN ORDER TO M
REGARDING NON-COMPLIANCE?** (include relevant subject selection and/or percent of records to be reviewed wh

☐ Current Protocol in use by site

☐ Current Consent Documents in use by site

☐ Investigator/Study Team Training Documentation

☐ Source Documentation *(Specify)*: _____

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

☐ Additional information *(Specify)*:

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

SMART IRB

SAMPLE AUDIT CHECKLIST

FOR USE BY INDIVIDUAL(S) CONDUCTING THE AUD

A. REGULATORY DOCUMENTATION

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

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

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

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

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

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

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

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

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

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

SMART IRB

SAMPLE AUDIT REPORT TEMPLATE[1]

PROTOCOL TITLE: _____

PRINCIPAL INVESTIGATOR: _____
Name

_____
Department, School

FUNDING SOURCE: _____

DATE OF REVIEW: _____

AUDITORS: _____

_____

_____

DATE OF REPORT: _____

DISTRIBUTION: _____
PI Name

CONFIDENTIAL

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

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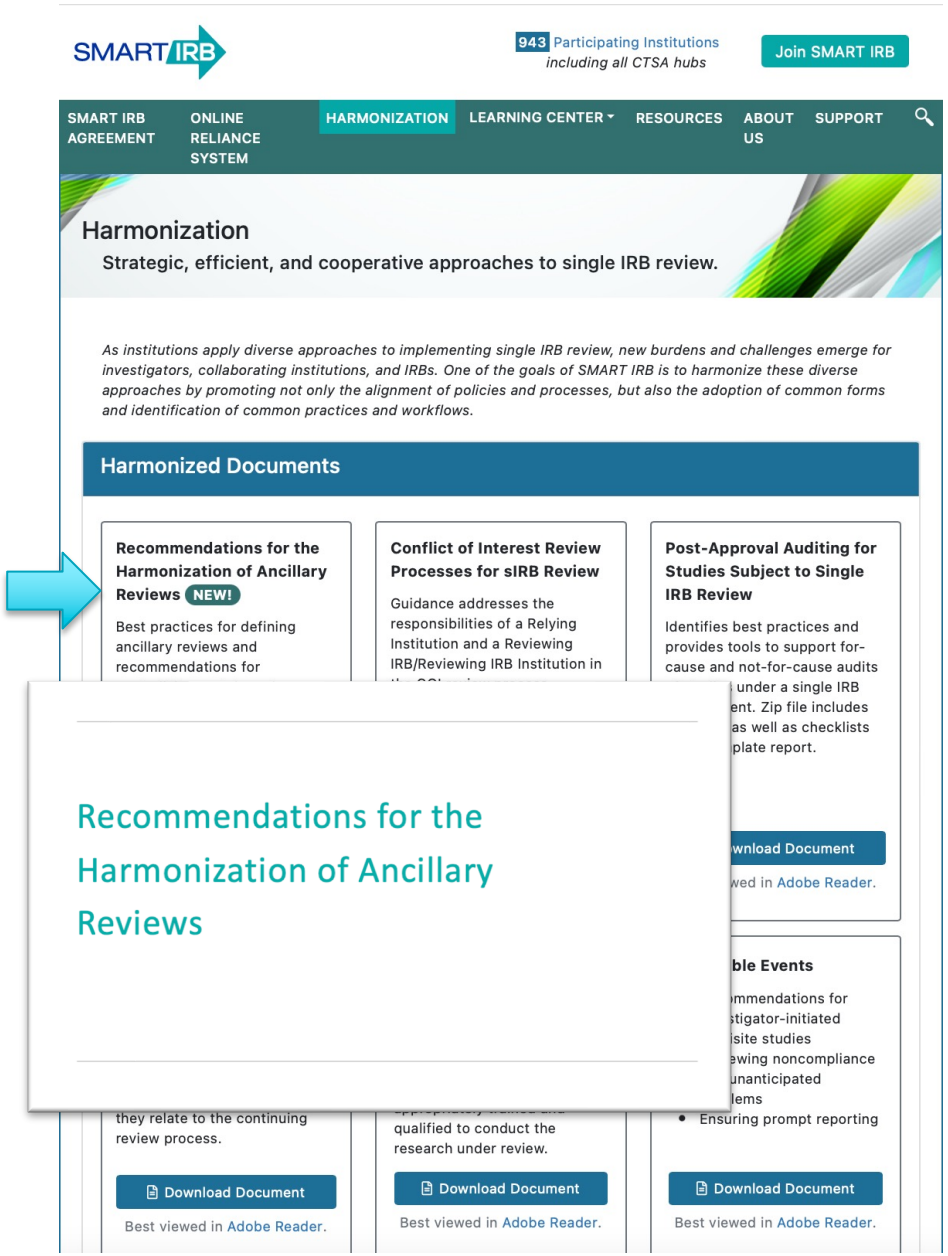
1

https://smartirb.org/harmonization/

Recommendations for the Harmonization of Ancillary Reviews



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

https://smartirb.org/harmonization/

Harmonization

- Significant work accomplished by leaders, operations, and compliance professionals
- Use whatever resources you find
- “If you see something, say something”
  - Polly Goodman at Polly_Goodman@hms.harvard.edu ☺
- Any challenges or ideas, please let us know

Implementing Harmonization

Implement SMART IRB Harmonized Guidance

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

Discussion/Questions

SMART IRB Resources Recap

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

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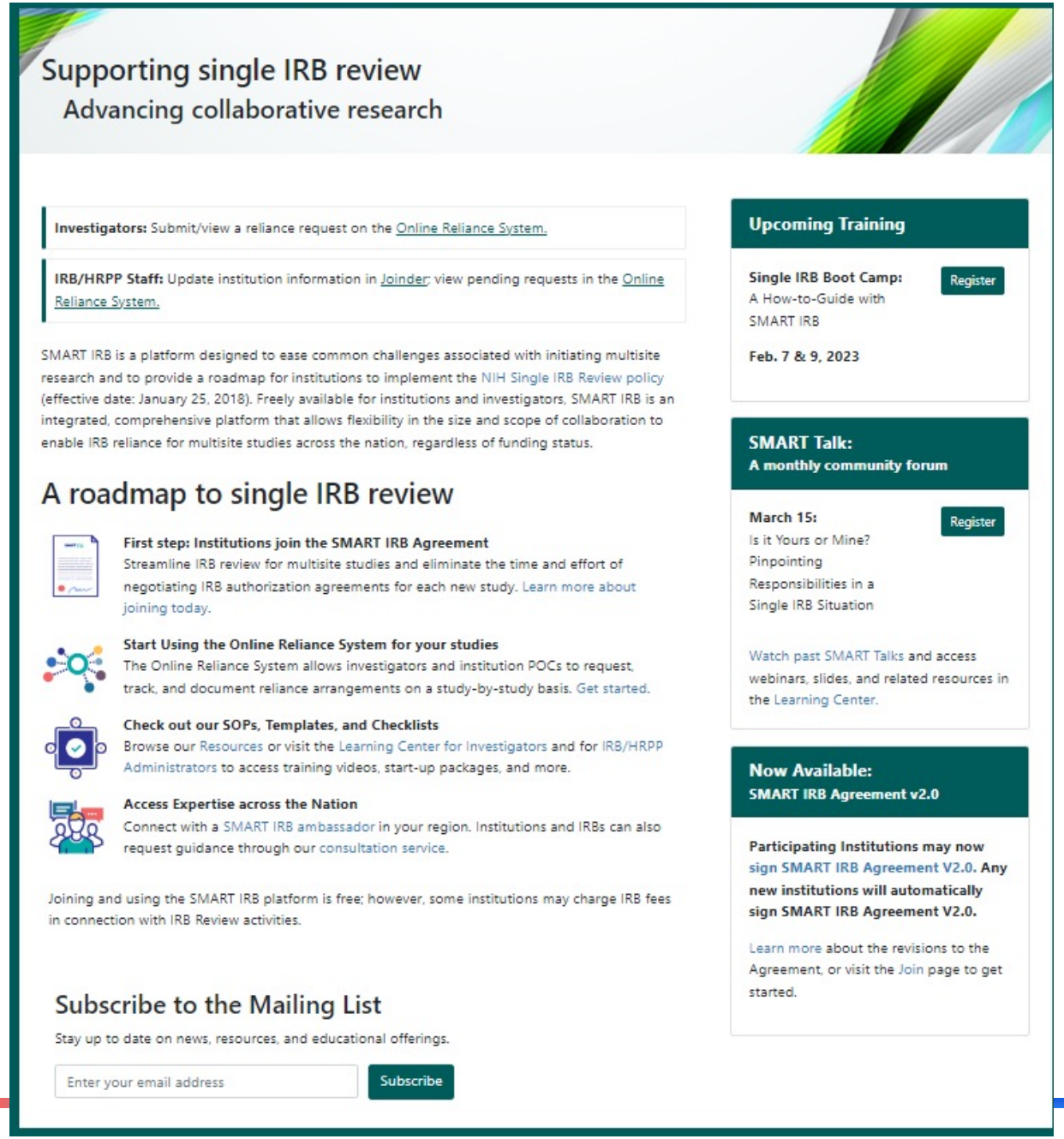


Supporting single IRB review

Advancing collaborative research

Investigators: Submit/view a reliance request on the Online Reliance System.

IRB/HRPP Staff: Update institution information in Joinder; view pending requests in the Online Reliance System.

SMART IRB is a platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH Single IRB Review policy (effective date: January 25, 2018). Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation, regardless of funding status.

A roadmap to single IRB review

First step: Institutions join the SMART IRB Agreement
Streamline IRB review for multisite studies and eliminate the time and effort of negotiating IRB authorization agreements for each new study. Learn more about joining today.

Start Using the Online Reliance System for your studies
The Online Reliance System allows investigators and institution POCs to request, track, and document reliance arrangements on a study-by-study basis. Get started.

Check out our SOPs, Templates, and Checklists
Browse our Resources or visit the Learning Center for Investigators and for IRB/HRPP Administrators to access training videos, start-up packages, and more.

Access Expertise across the Nation
Connect with a SMART IRB ambassador in your region. Institutions and IRBs can also request guidance through our consultation service.

Joining and using the SMART IRB platform is free; however, some institutions may charge IRB fees in connection with IRB Review activities.

Subscribe to the Mailing List

Stay up to date on news, resources, and educational offerings.

Enter your email address | Subscribe

Upcoming Training

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

Feb. 7 & 9, 2023

SMART Talk:
A monthly community forum

March 15: Is it Yours or Mine? Pinpointing Responsibilities in a Single IRB Situation — Register

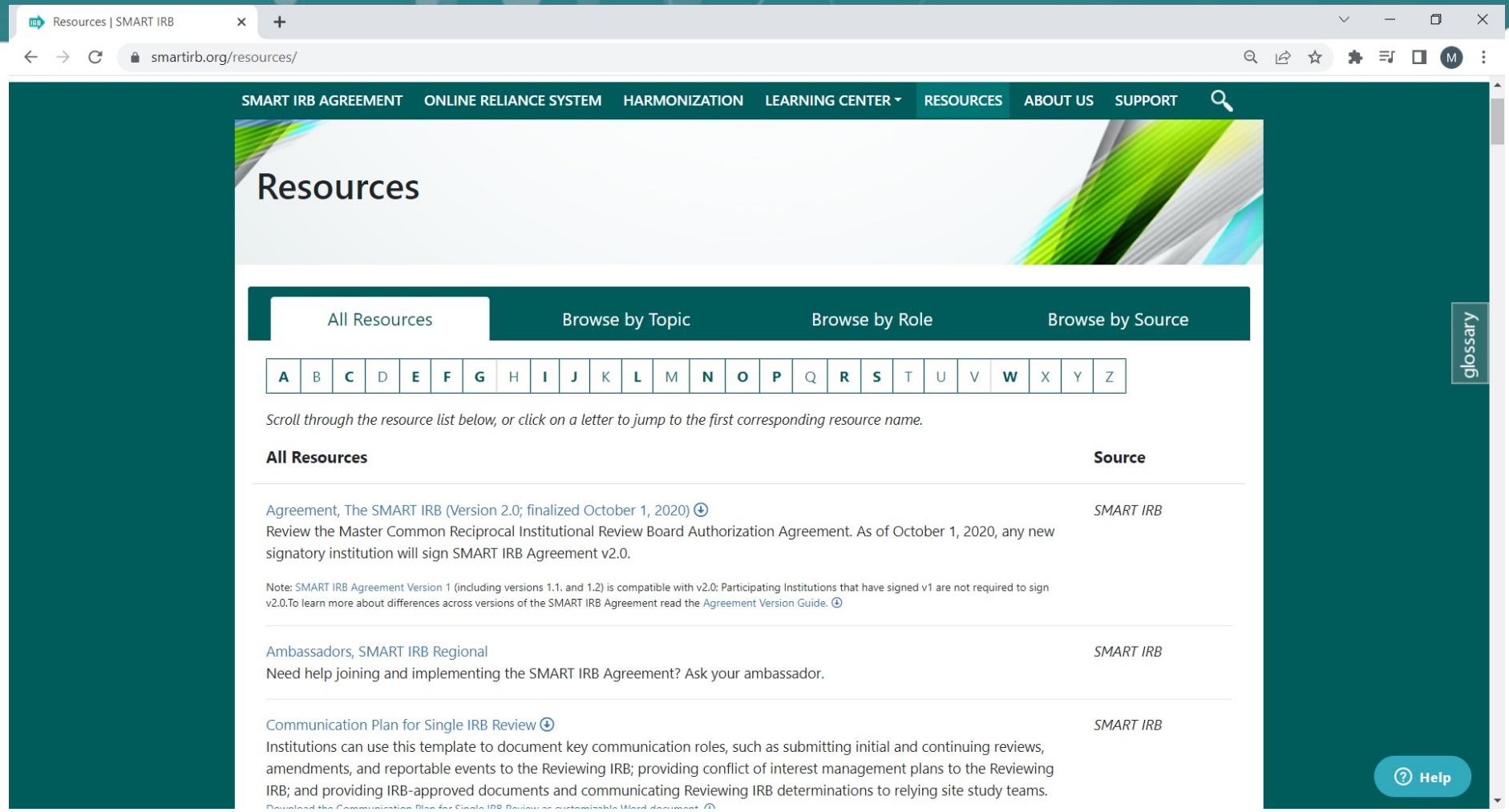
Watch past SMART Talks and access webinars, slides, and related resources in the Learning Center.

Now Available:
SMART IRB Agreement v2.0

Participating Institutions may now sign SMART IRB Agreement V2.0. Any new institutions will automatically sign SMART IRB Agreement V2.0.

Learn more about the revisions to the Agreement, or visit the Join page to get started.

smartirb.org/resources/



Learning Center for Investigators and Study Teams

Learning Center for Investigators and Study Teams

The videos and companion resources below are designed to help investigators and study teams successfully plan for and navigate single IRB review arrangements for their studies. Questions about local processes and policies are best addressed by your institution's SMART IRB Point of Contact.

Start-Up Packages	Introduction to sIRB Review	NIH sIRB Policy	Selecting an sIRB
Developing an sIRB Plan	Effects on Research Costs	Study Team Roles	Online Reliance System

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

Learning Center for IRB and HRPP Administrators

Learning Center for IRB and HRPP Administrators

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

Start-Up Packages	Implementing the Agreement	Reviewing IRBs	Relying Institutions	Getting Started
Online Reliance System	Resources for IRB/HRPPs	SMART Talk Forum	Training Study Teams	

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

SMART Talks:
A monthly community forum

2023 Smart Talks

Everything You Wanted to Know about Single IRB but Were Afraid to Ask...Part Deux

Download Slides

2022 Smart Talks

2021 Smart Talks

2020 Smart Talks

2019 Smart Talks

2022 Smart Talks

A Conversation with the FDA and OHRP about Single IRB

Download Slides

Single IRB and Noncompliance - A Case Study

Download Slides

Everything You Wanted to Know about Single IRB but Were Afraid to Ask

Download Slides

A Conversation with the Department of Defense (DOD), Department of Energy (DOE), and Department of Veterans Affairs (VA) about Single IRB

Download Slides

Serving as a Reviewing IRB for a Large Multisite Study

Download Slides

Where We've Been and Where We're Heading

Download Slides

Single IRB from the Perspective of Research Teams

Download Slides

A Conversation with NIH and OHRP about Single IRB

Download Slides

New Resources

- **Single IRB Readiness Checklist for Lead Study Teams & Coordinating Centers: Reliance Arrangements**
- This checklist will assist you to identify the processes and resources you may need to facilitate a single IRB reliance arrangement for your multi-site research study:

New Resources

- **Model Template for Reviewing IRB to Identify Policies for Relying Institutions, Site Investigators, and Lead Study Teams**
- A Reviewing IRB may use this template to identify the key policies that Relying Institutions, Site Investigators, and Lead Study Teams must follow when the single IRB review model is used.

SMART Study Team Engagement and Advisory Meeting (STEAM)

Goals

1. Improve dissemination and utilization of current research team resources
2. Determine if additional resources are needed
3. Promoting/raising awareness of the available resources through these sessions
4. Identifying avenues through which we might reach more research team members

https://smartirb.org/resources/

Logistics: Survey and Materials

Please provide feedback by completing the survey – a link will be emailed.

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

Questions & Discussion

Additional questions, please email: Help@SMARTIRB.org