Navigating the Single IRB Process

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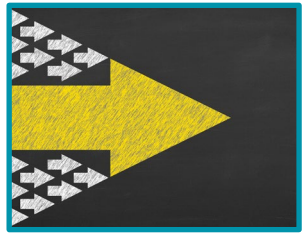
What This Talk Is About

- Brief overview of single IRB requirements
- Effect of single IRB on study teams
- Single IRB navigation strategies
- Resources for study teams

What Is Single IRB Review?

Single IRB review refers to the use of one IRB to review and approve all or most sites participating in a multisite research study, rather than each site obtaining approval for their activities from a different IRB.



Other terms for a single IRB include:

Central IRB

Reviewing IRB

IRB of record

What Single IRB changed

When study teams need to talk to IRBs about a research study

Information flow

Monitoring for institutional requirements

Shift or increase in responsibilities

What has not changed…

Relying institutions are still responsible for the protection of human participants and ensuring their study teams comply with IRB determinations

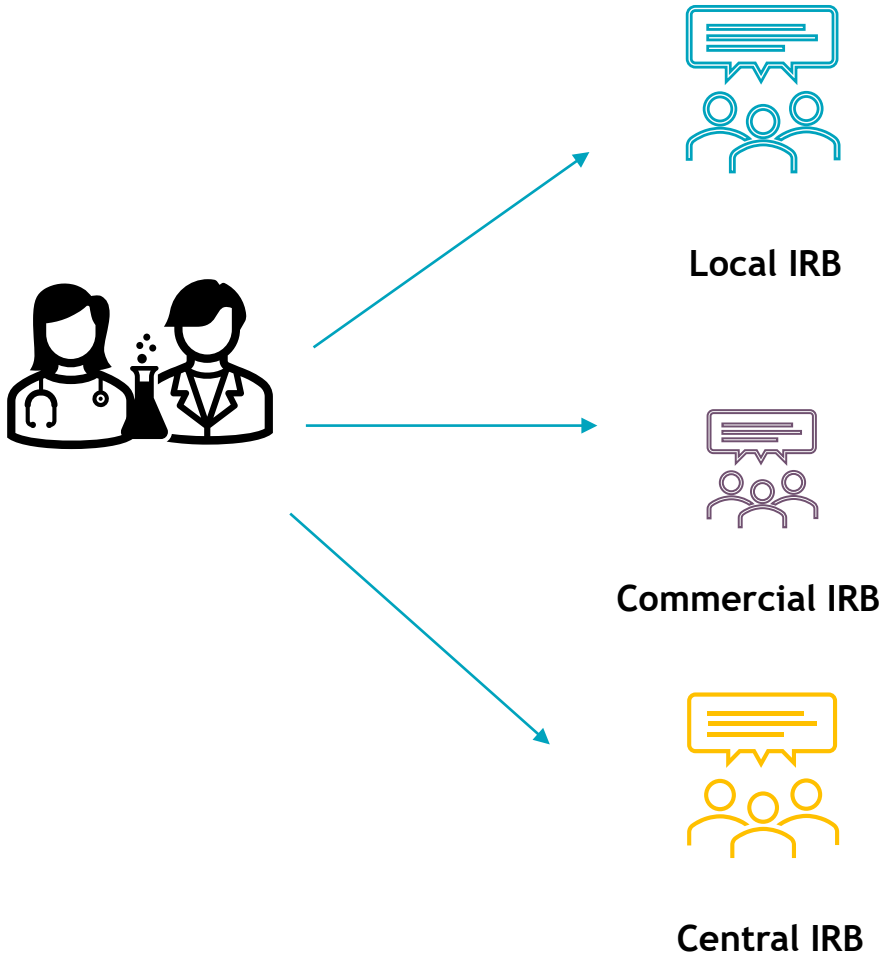
Which is why

Relying Institutions:

- Request a local application for review as part of the reliance request process
- Conduct post-approving monitoring of studies reviewed by an external IRB

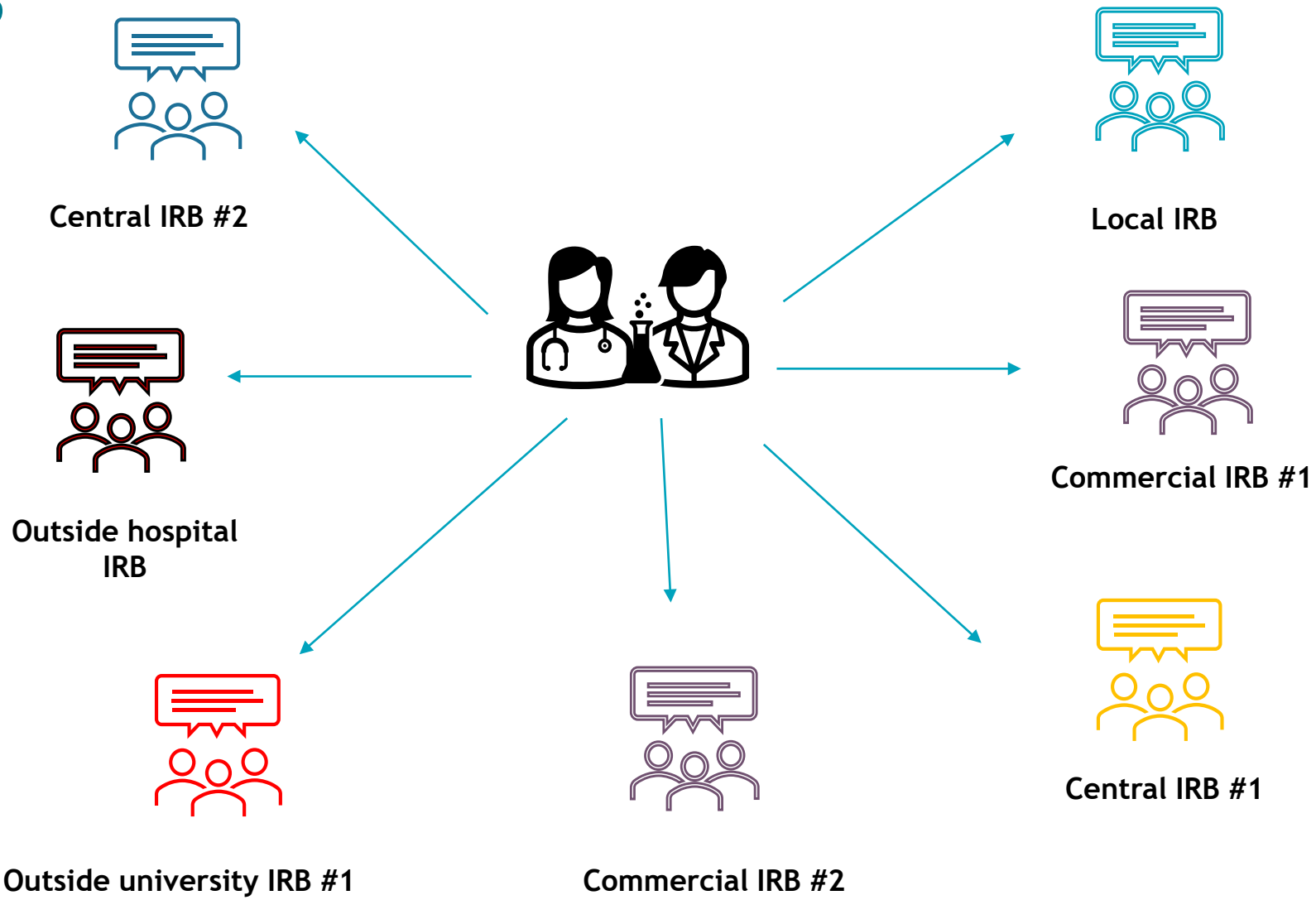
Before Single IRB

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



Navigation Strategy #1: Know when your research study might require single IRB review

Brief History of Federal Single IRB Review Mandates

The concept of using a single IRB has been with us for a while, such as the National Cancer Institute (NCI) Central IRB or use of independent IRBs for industry-sponsored research. What's different is the scale and types of studies requiring single IRB review.

Prior to 2018

Using one IRB to oversee multisite (aka cooperative) research occurred on a limited basis

January 25, 2018

Most multisite research supported by the National Institutes of Health (NIH) requires single IRB review

January 20, 2020

Most multisite research subject to the Common Rule requires single IRB review

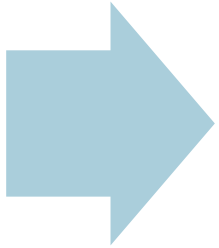
September 2022

The FDA issues a Notice of Proposed Rulemaking that outlines it proposed single IRB requirements.

Regulations and Policies That Might Trigger Single IRB Review

Sponsor Requires Single IRB Review at Your Site

Your site is part of a multi-site study mandated to use a single IRB



Industry sponsor requires sites to rely on the study's single IRB

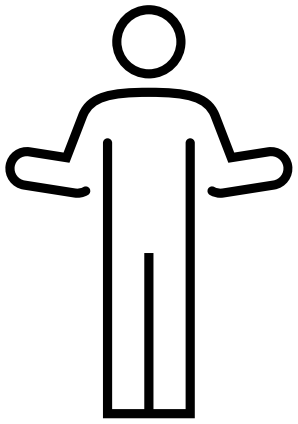
Navigation Strategy #2: Know how to address single IRB if you are applying for a federal grant to support a multisite study

Federal Grants that include Multisite Human Participants Research

What IRBs said to research teams:

Before Single IRB Review

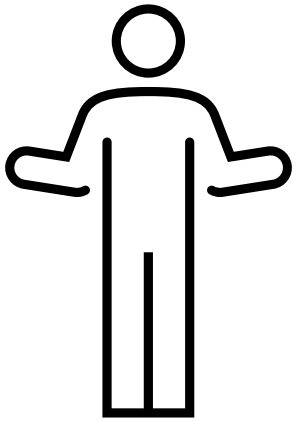
Come back to us when you get your funding!



The IRB

After Single IRB Review

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



The IRB

Your local IRB might not agree to serve as the single IRB for the study.

What study teams might need to budget for:

IRB fees

- Some independent IRBs have special rates for federally supported research
- Many academic institutions now charge fees for IRB review of external sites

If you are the Lead Study Team:

- Someone who can coordinate the single IRB review process across sites
- A platform to collect information from sites and share documents across sites

Navigation Strategy #3: Be aware of the reliance agreement process

Use of a Single IRB Must Be Documented

Reliance agreements spell out the responsibilities of the Reviewing IRB and Relying Institutions

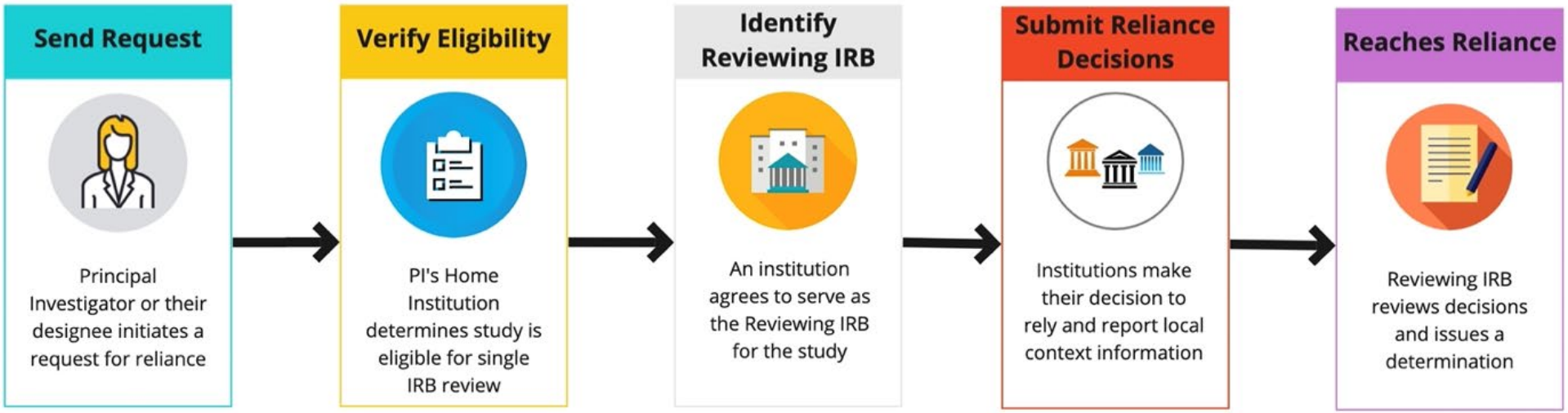
Reliance agreements are commonly called IRB Authorization Agreements (IAAs)

A frequently used reliance agreement is SMART IRB

Although study teams are not usually responsible for putting such agreements in place, they sometimes need to help sites work with their local IRBs and HRPPs to execute a reliance agreement

The SMART IRB Online Reliance System

Request, track and document reliance arrangements

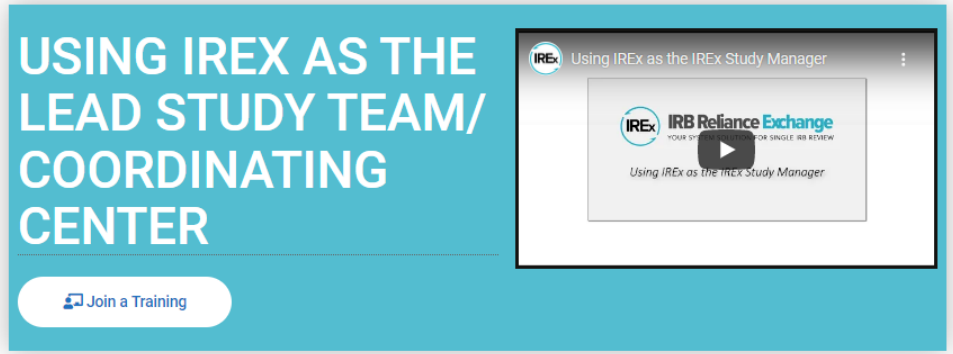


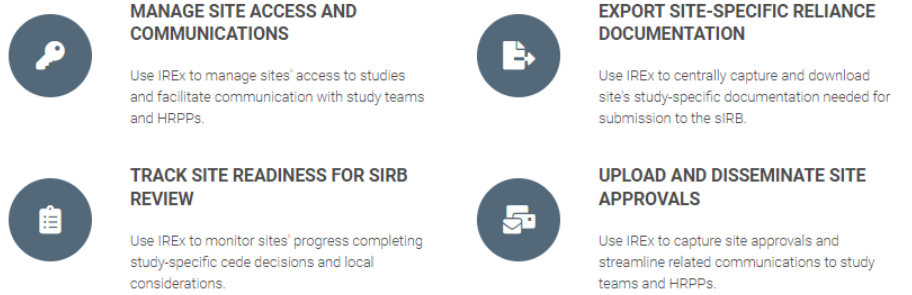
IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

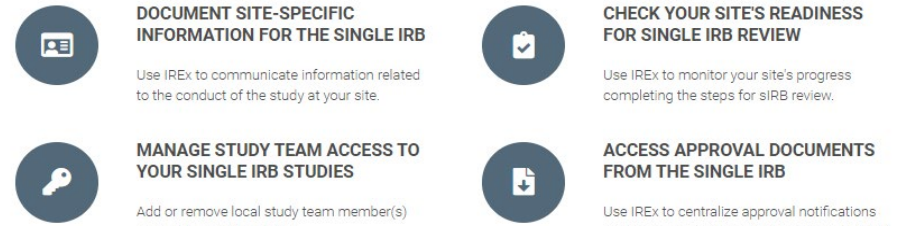
IRB Reliance Exchange

- A freely available, web-based portal supporting single IRB review documentation and coordination for multi-center clinical trials.
- The IRB Reliance Exchange provides a document sharing platform that allows dissemination of IRB determinations and approved documents

https://www.irbexchange.org/







Navigation Strategy #4: Know your roles and responsibilities, particularly for communication

Key Study Team Roles

Overall Principal Investigator (PI)

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

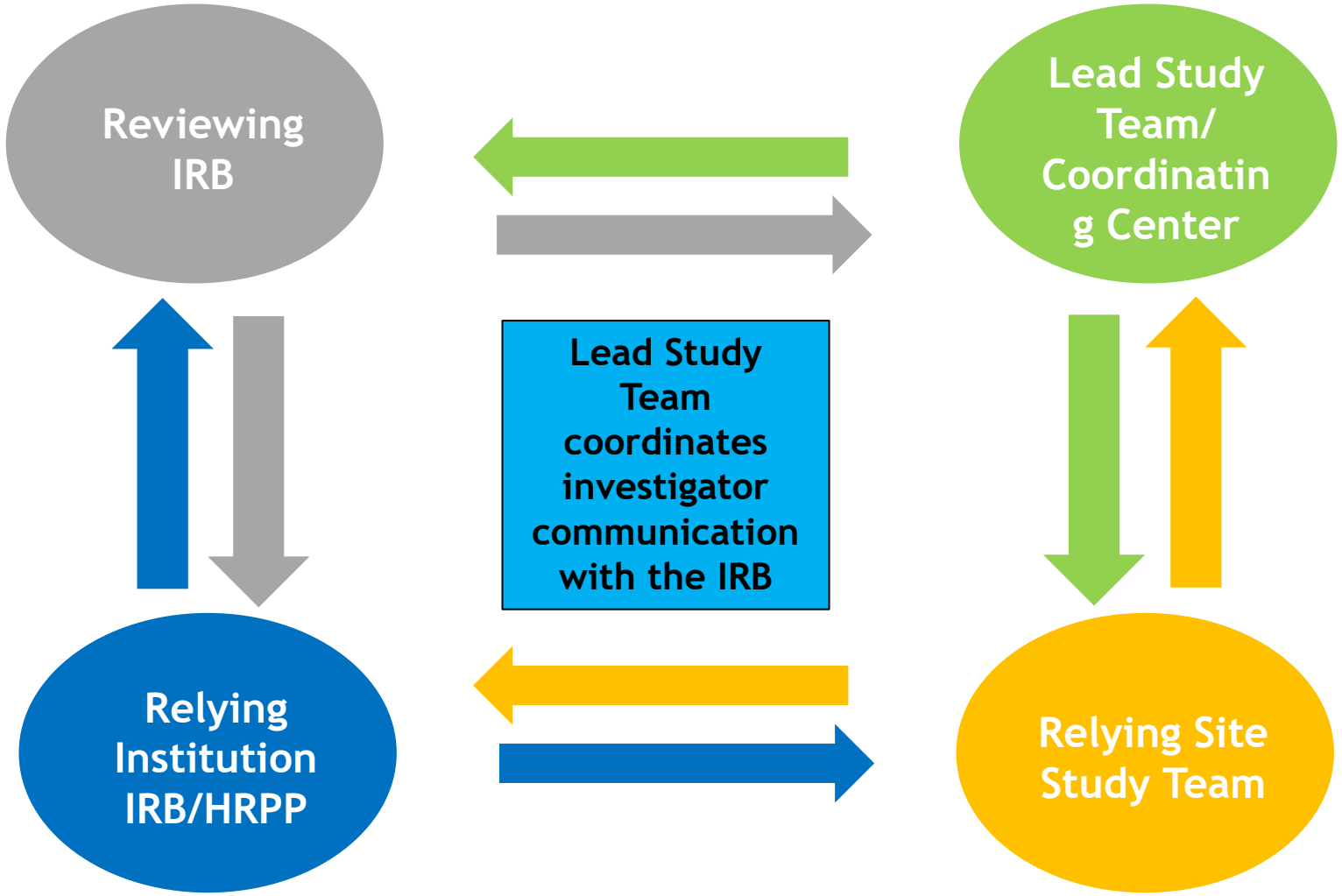
Provides key administrative and communication support for the study. May be a coordinating center.

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 Single IRB Communication Model



Common Key Responsibilities: Lead Study Team

Educating relying site study teams about Reviewing IRB processes, requirements and policies (e.g., regarding reportable events)

Providing draft study materials to all site study teams, including any proposed consent form template

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

Distributing IRB-approved materials and determination letters to all site study teams

Common Key Responsibilities: Site PIs & Relying Site Study Teams

Following the policies and procedures of the Reviewing IRB (e.g., for reportable events, personnel updates)

Providing the 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

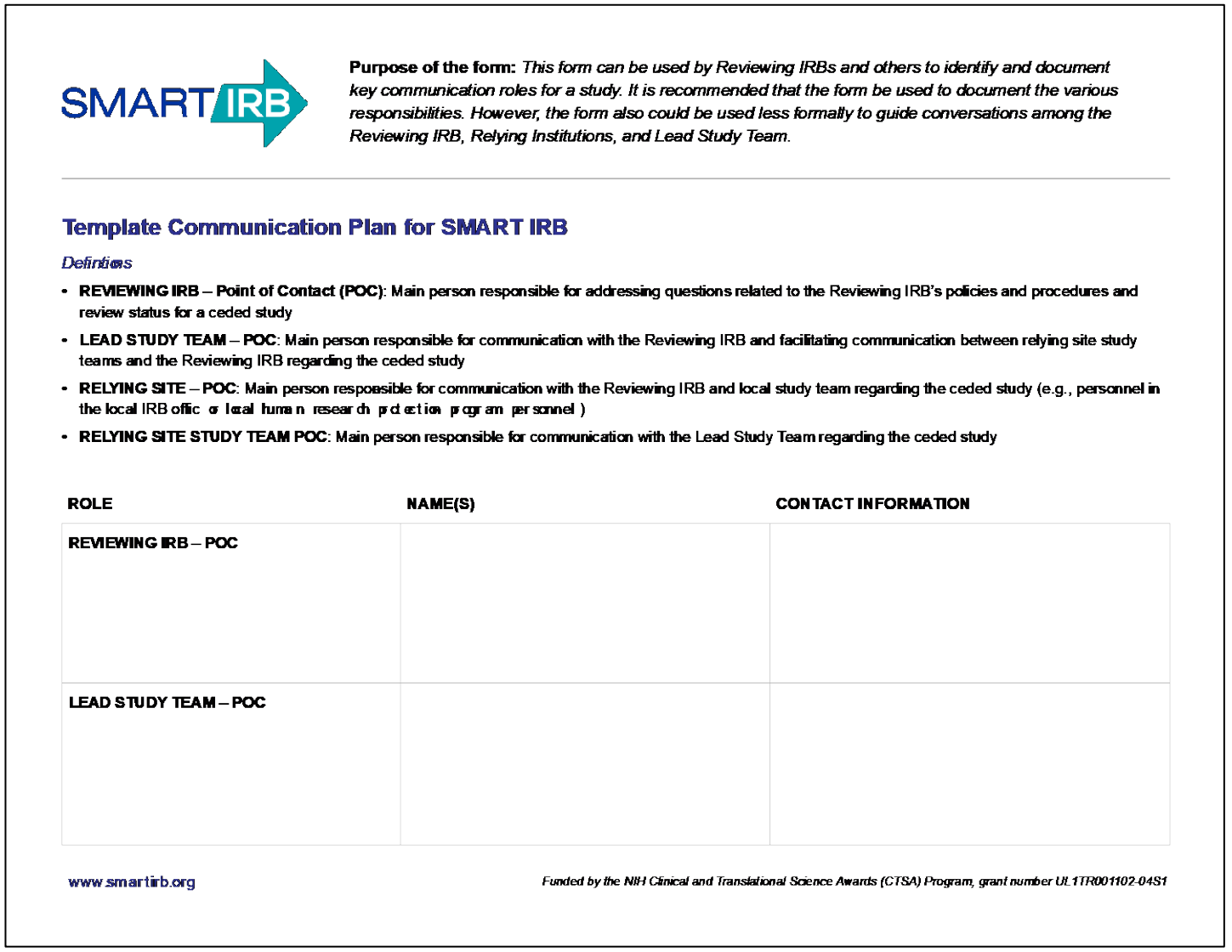
Providing information to include in the informed consent document (e.g., study team contact information and unique study costs) and using the Reviewing IRB's consent form template

Obtaining authorization from their local institutions, such as reliance Point of Contacts (POCs), in the case of personnel changes, conflict of interest updates, and/or changes that may be affected by State law or institutional requirements

Communication plan for single IRB review

Use to document key communication roles, such as responsibilities for:

- submitting initial and continuing reviews, amendments, and reportable events
- providing conflict of interest management plans
- distributing IRB-approved documents and communicating Reviewing IRB determinations



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

ROLE	NAME(S)	CONTACT INFORMATION
REVIEWING IRB – POC		
LEAD STUDY TEAM – POC		

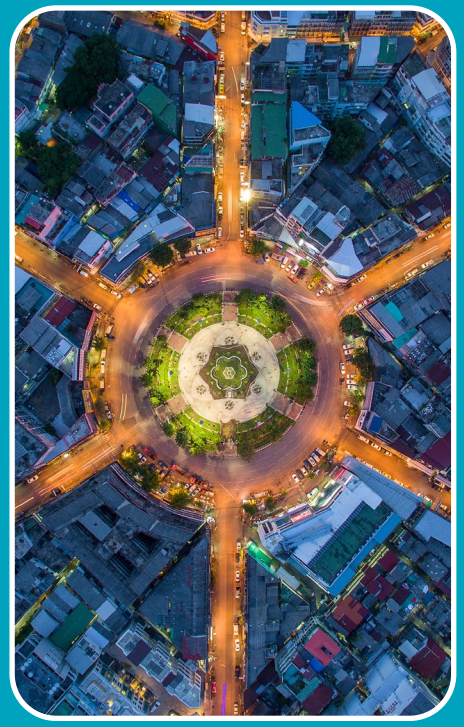
www.smartirb.org

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

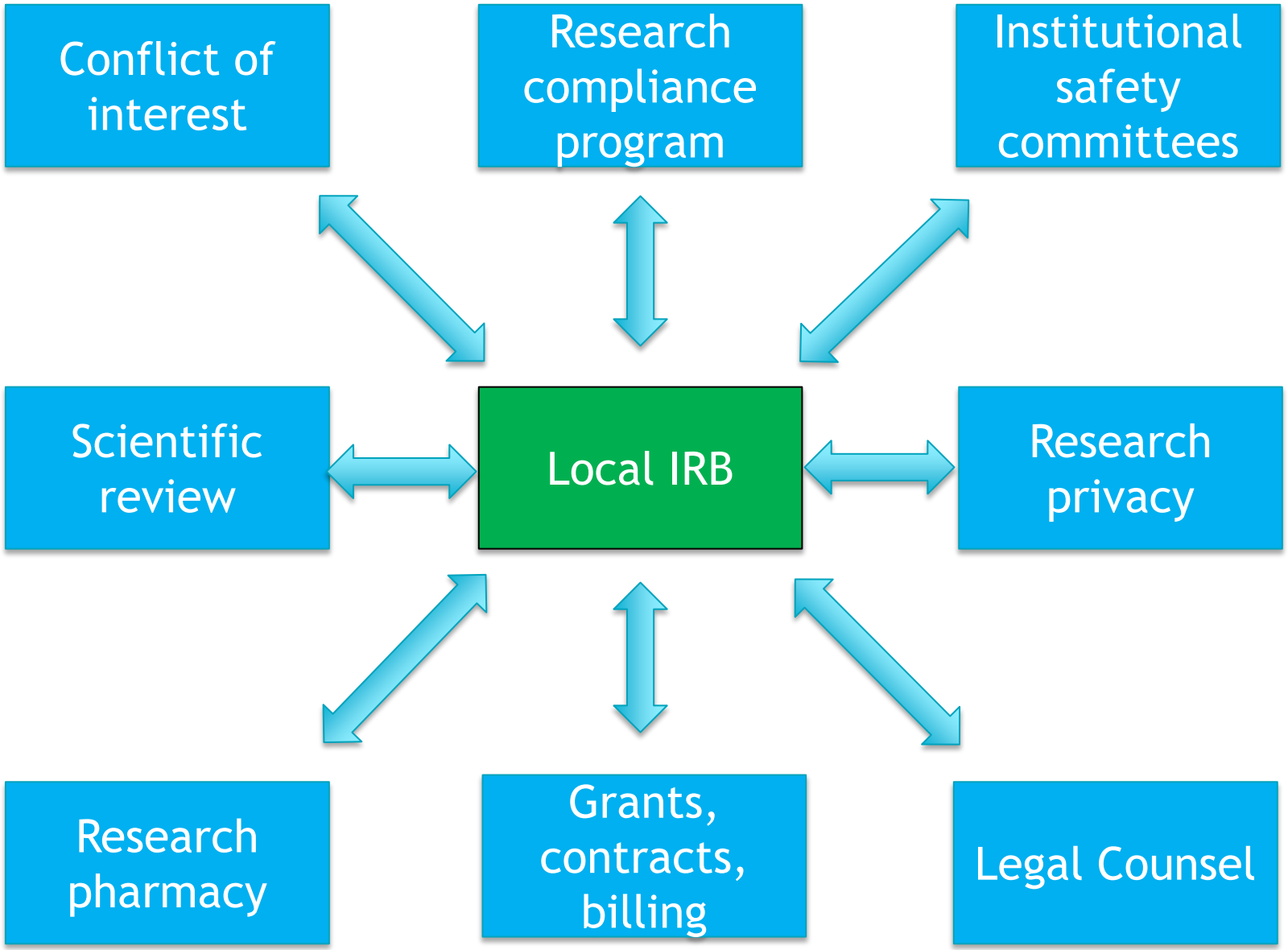
Communication Plan available at https://smartirb.org/sites/default/files/Communications_Plan_Form.pdf

Helpful Hints

- Communicate early and often!
- Be clear on expectations and communication flow
- Be flexible
- Use Smart IRB Resources to assist in developing communication plan



Navigation Strategy #5: Don’t forget about your institutional requirements

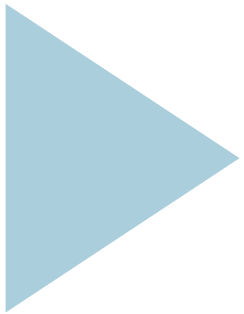


Monitoring for Institutional Requirements BEFORE Single IRB

Monitoring & Communicating Institutional Requirements AFTER Single IRB

With a Single IRB Arrangement

Study teams need to take more responsibility for identifying other institutional requirements, such as ancillary committee reviews, that may need to be met in addition to obtaining IRB approval



IRB approval ≠ ready to activate the study

Navigation Strategy #6: Know what your responsibilities are after IRB approval

After Initial IRB Approval

Common Events

- Personnel updates
- Changes of protocol
- Continuing review
- Reportable events (noncompliance, unanticipated problems)

Keep in Mind

What the single IRB requires you to report to them and when → their policies may differ from your those at your institution

What your institution requires to be reported locally and when

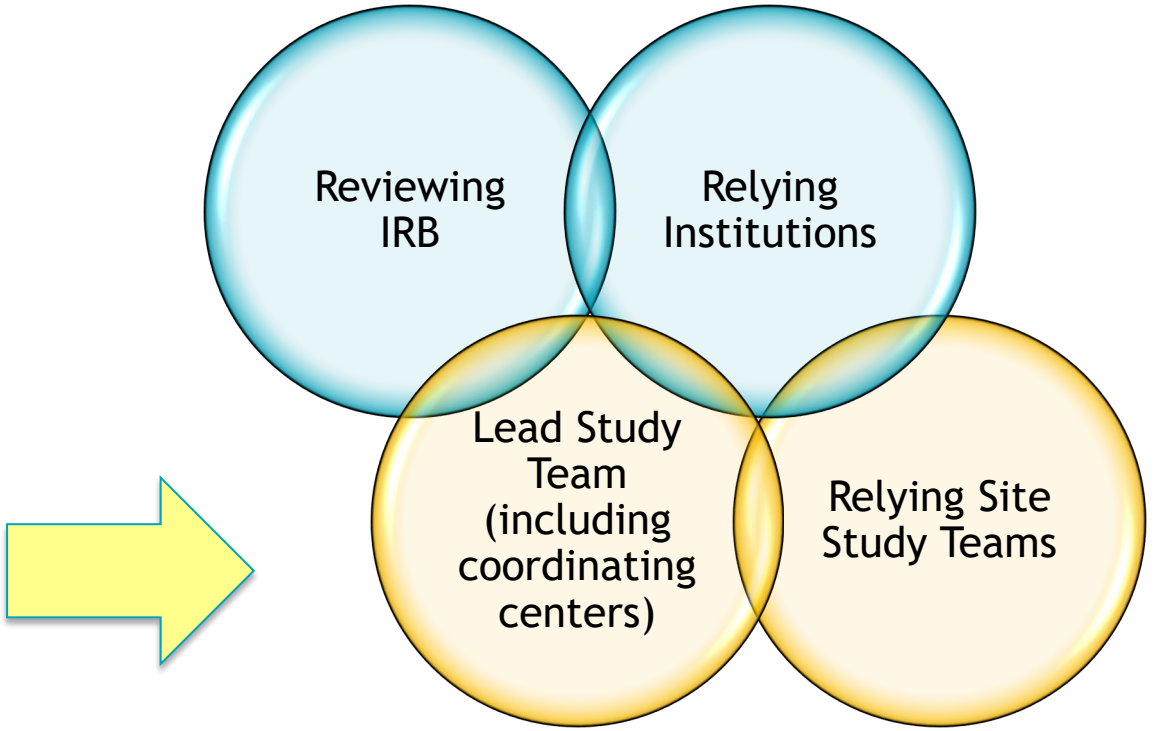
When updates or events can trigger local institutional reviews (e.g., Conflict of Interest Committee, billing compliance, HIPAA compliance)

Navigation Strategy #7: Get to know your point of contacts (POCs)

Communication Points of Contact (POCs)

Extremely important to keep communications organized and consistent

Lead Study Teams should have a designated POC, who can help Relying Site Study Teams with single IRB processes



A Point of Contact (POC) should be identified for each group

Reliance POCs

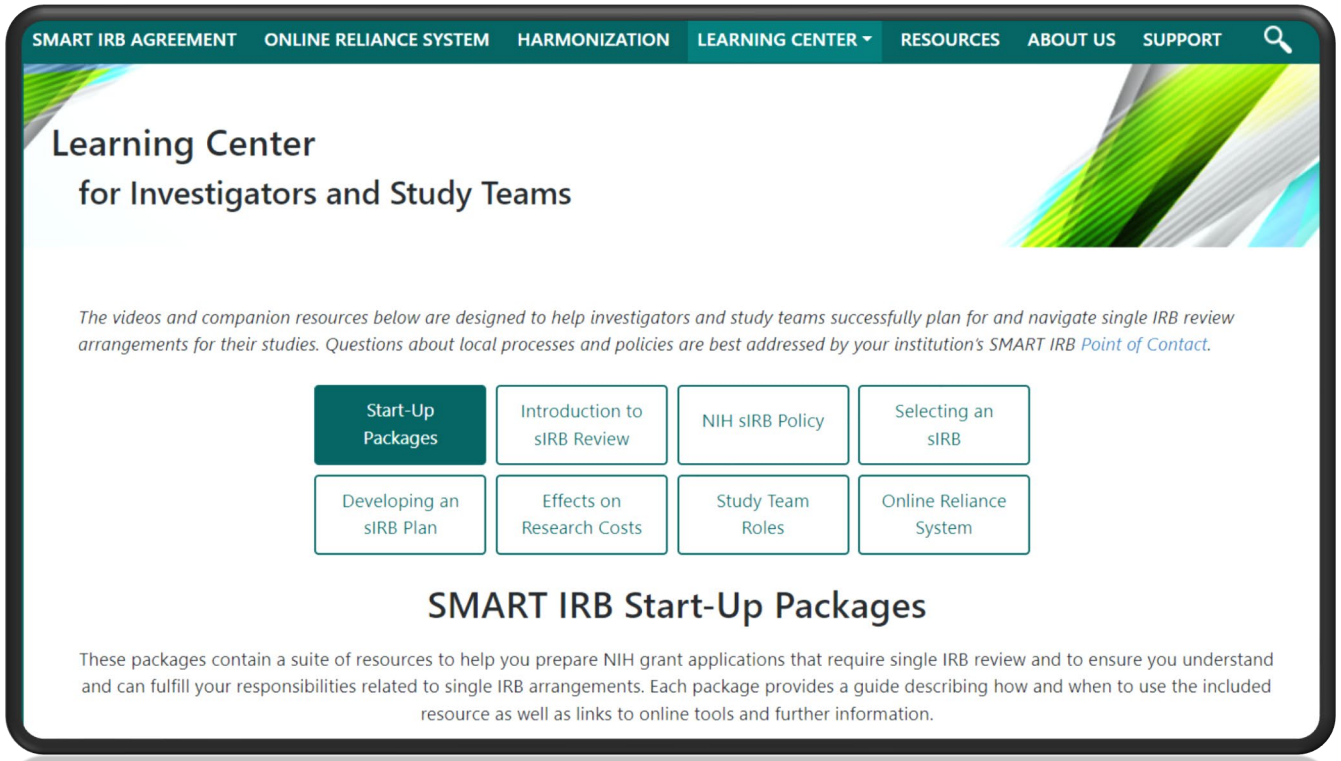
- Know when a study requires single IRB review
- Assist study teams in navigating single IRB processes
- Can help identify an appropriate Reviewing IRB for a study
- Facilitate reliance arrangements
- Are available for questions about single IRB or when problems arise

Resources for Study Teams

Start Up Packages

For investigators

These packages contain a suite of resources to help you prepare NIH grant applications that require single IRB review and to ensure you understand and can fulfill your responsibilities related to single IRB arrangements. Each package provides a guide describing how and when to use the included resource as well as links to online tools and further information.



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

Researcher Team Training Presentations

On-demand videos on key topics less than 10 minutes in length.

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

- Topics:
- 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

Summary of Effects of Single IRB on Responsibilities

Shift in responsibilities for academic IRBs & institutions

- Reviewing IRBs: consideration of local context issues for each site, including informed consent documents
- Relying Institutions: new processes compliance monitoring for compliance (institutional requirements, federal regulations, & with IRB determinations) & communication

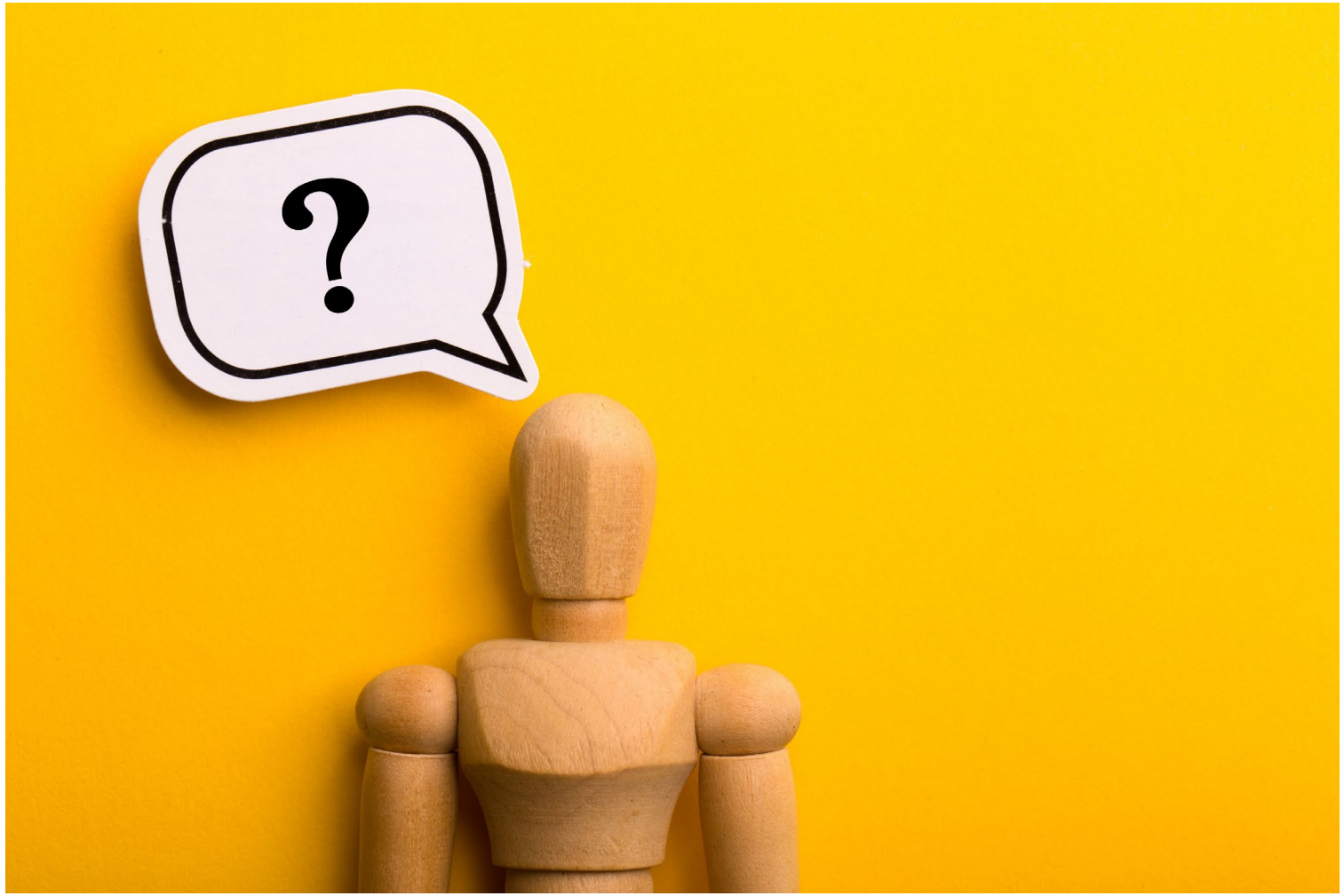
Increase in responsibility for Overall PIs/Lead Study Teams

- Managing regulatory submissions for and additional communication responsibilities with relying sites throughout the life of a study

Decrease in regulatory responsibility for Relying Site Study Teams?

- Eliminates the need to prepare IRB submissions; however, must provide information to the Lead Study Team and ensure compliance with both Reviewing IRB and relying institution requirements

THANK YOU AND QUESTIONS



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