SMART IRB

Your Roadmap to Single IRB Review

Implementing the SMART IRB Agreement

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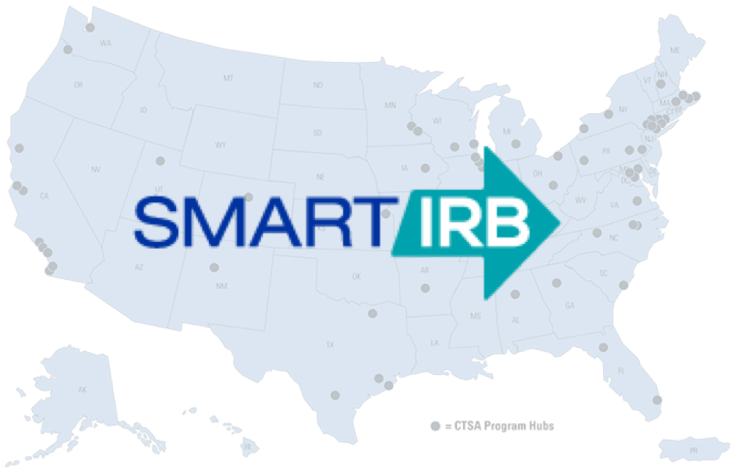
Advancing research together



A Roadmap to Single IRB Review

Funded by NCATS beginning in July 2016

As of July 2018, led by Harvard University and University of Wisconsin-Madison, along with a team of Ambassadors from across the U.S.

GROW
A national IRB reliance network

SUPPORT
Use of SMART IRB

EDUCATE & TRAIN
Institutions & Investigators

HARMONIZE
sIRB review processes across the nation

Supporting single IRB review

Informatics

SMARTIRB.org
Resources and supportive services freely available to support sIRB review

Joinder platform
Allows institutions to join the SMART IRB Agreement

Online Reliance System
Provides a central system and process to request, track, and document reliance arrangements for each study

SMART IRB Agreement

Single IRB Authorization Agreement

Sign once and implement

SOPs

Clear roles and responsibilities for investigators and institutions

Flexibility to use other SOPs as agreed upon or required

Expertise Across the Nation

Ambassadors
Help institutions join and implement SMART IRB

Education & Training
Tools, templates, FAQs, checklists, guidance, peer consultations, and webinars support adoption of SMART IRB

Harmonization Steering Committee
Leaders in the field promote best practice

Using the Agreement

Nature of the SMART IRB Agreement

The Agreement is a “master” agreement which means:	
No additional IRB authorization agreements required to enable reliance among institutions that have joined SMART IRB	Reliance arrangements, however, need to be documented for each study

Initiating & Documenting Reliance with the SMART IRB Online Reliance System

The SMART IRB Online Reliance System

Request, track, and document reliance arrangements

For Investigators and Participating Institutions

Facilitates reliance arrangements on a study-by-study basis

Key Roles in the Reliance Process

Overall PI

Home Institution Point of Contact (POC)

Reviewing IRB POC

Relying Institution POC

Need for a Reliance Arrangement

A researcher plans on conducting a multisite research project

Single IRB review is required by a funding agency

OR

Overall PI wants to streamline the regulatory process by using a single IRB

Requesting Single IRB Review: Step 1

Overall PI (or designee)

Contact Overall PI's Home Institution POC to discuss a reliance arrangement, including a proposed Reviewing IRB and mechanism to request single IRB review.

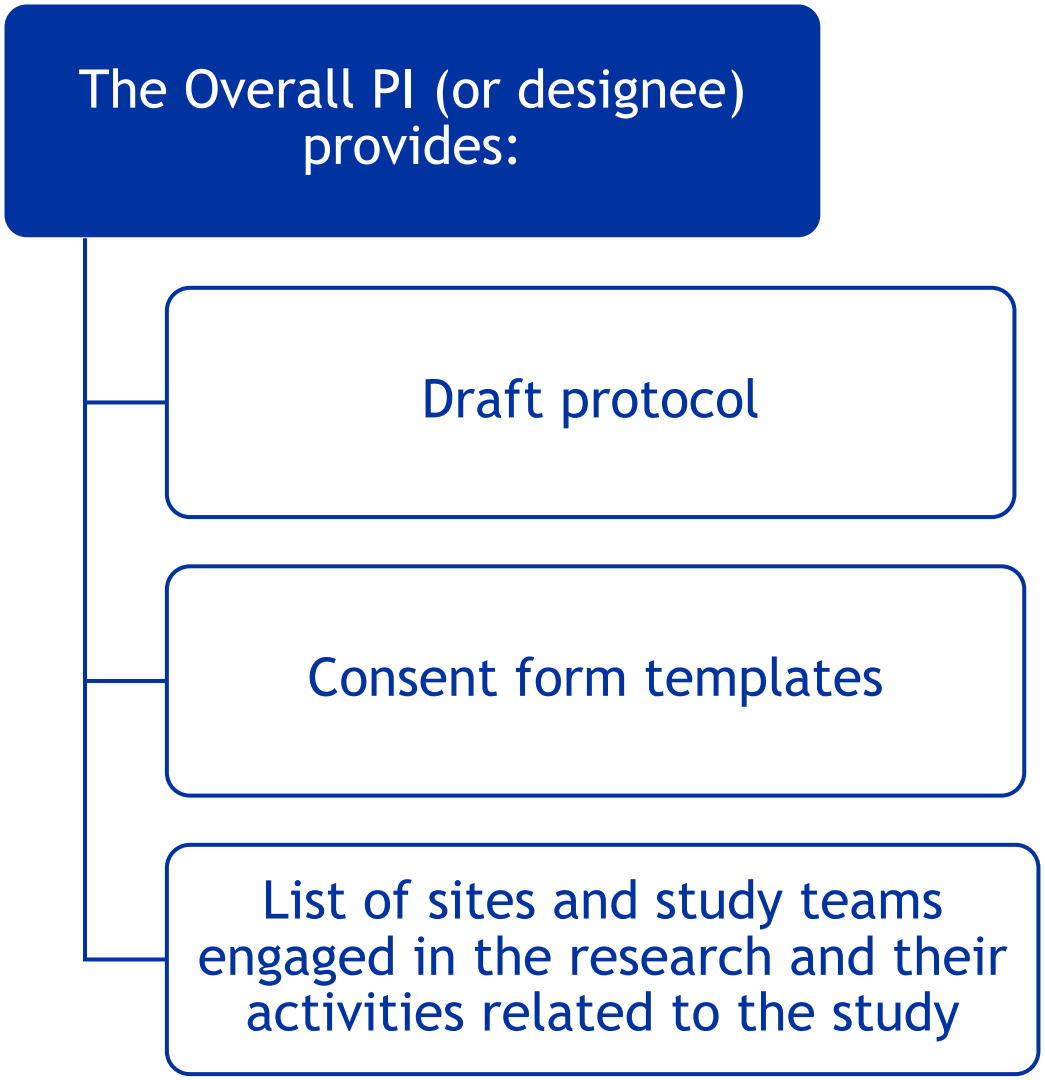
Requesting Single IRB Review: Step 2

Overall PI (or designee)

Submits a request for reliance via the SMART IRB Online Reliance System* and proposes a Reviewing IRB

*** Or via other mechanism, as required.**

Reliance Request Requirements



NOTE: If the Overall PI will use the SMART IRB Standard Operating Procedures (SOPs), a Lead Study Team must be identified.

Requesting Single IRB Review: Step 3

Home Institution Point of Contact (POC)

Determines if the study is eligible for single IRB review and, if so, either confirms the proposed Reviewing IRB or proposes a new Reviewing IRB

Requesting Single IRB Review: Step 4

Proposed Reviewing IRB POC

If PI's Home Institution will serve as Reviewing IRB, this will be the same as the Home Institution POC.

Proposed Reviewing IRB POC reviews materials and communicates to proposed Relying Institution POCs whether his/her institution will serve as the Reviewing IRB for the study.

Proposed Relying Institution POCs notified by Online Reliance System or via other mechanism

Requesting Single IRB Review: Step 5

Proposed Relying Institution POCs

Review materials related to the request and communicate decision whether to rely on the proposed Reviewing IRB.

If agree to rely, also communicate key local context information.

Proposed Relying Institution POCs can record determination and include local context information in the Online Reliance System

Information Provided by Relying Institutions

If ceding review, Relying Institutions provide the Reviewing IRB POC with information about:

- State laws and/or institutional requirements that could affect the IRB's review
- Confirmation of the training and qualifications of their study team throughout the life of the study
- Any conflicts of interest relevant to study and applicable management plans throughout the life of the study
- Locally required consent form language in 3 areas
  1. availability of treatment and compensation for research-related injury
  2. payment or reimbursement of research costs incurred by subjects
  3. local contact information

Requesting Single IRB Review: Step 6

After receiving decisions/information from other institutions, Proposed Reviewing IRB POC:

- Reviews provided local context information
- Confirms for which institutions the IRB will oversee the research
- Documents the reliance determination
- Communicates which SOPs it will follow

Note: If the Reviewing IRB is not using the SMART IRB SOPs, it must provide the applicable SOPs to Relying Institutions.

SMART IRB Online Reliance System Documentation: Determination Letter Information

Reliance Determination:

Overall Principal Investigator: Stacy Miller

The Reviewing IRB is: Belledale Institute
Federal Wide Assurance (FWA): FWA0000001
Point of Contact: Thomas Werner, institution_poc@belledale.org
Site Investigator: John Dorean

Reviewing IRB accepts review for:

Adams University
Federal Wide Assurance (FWA): FWA0000014
Site Investigator: Christopher Turk, example@test.com

Belledale Institute
Federal Wide Assurance (FWA): FWA0000001
Site Investigator: John Dorean, example@test.com

Golden Gate Eye Research Institute
Federal Wide Assurance (FWA): FWA0000002
Site Investigator: John Doe, jdoe@gmail.com

Ridgeview Research Facility
Federal Wide Assurance (FWA): FWA0000005
Site Investigator: Stacy Miller, applicant@ridgeview.net

The following institutions will NOT rely upon the Reviewing IRB:
Approval for each must be obtained from the IRB for that site (or through other arrangement, as applica[illegible]e) prior to initiating study activity at that site. Please consult the institution's Point of Contact for further instructions:

Salk University for Medical Sciences, Point of Contact: Sarah Alonzo, institution_poc@salk.edu

Identifies the Reviewing IRB

Identifies the institutions the IRB will oversee

Identifies the institutions the IRB will NOT oversee

If institutions are not using the Online Reliance System, suggested templates and other materials are available on the Resources page at smartirb.org.

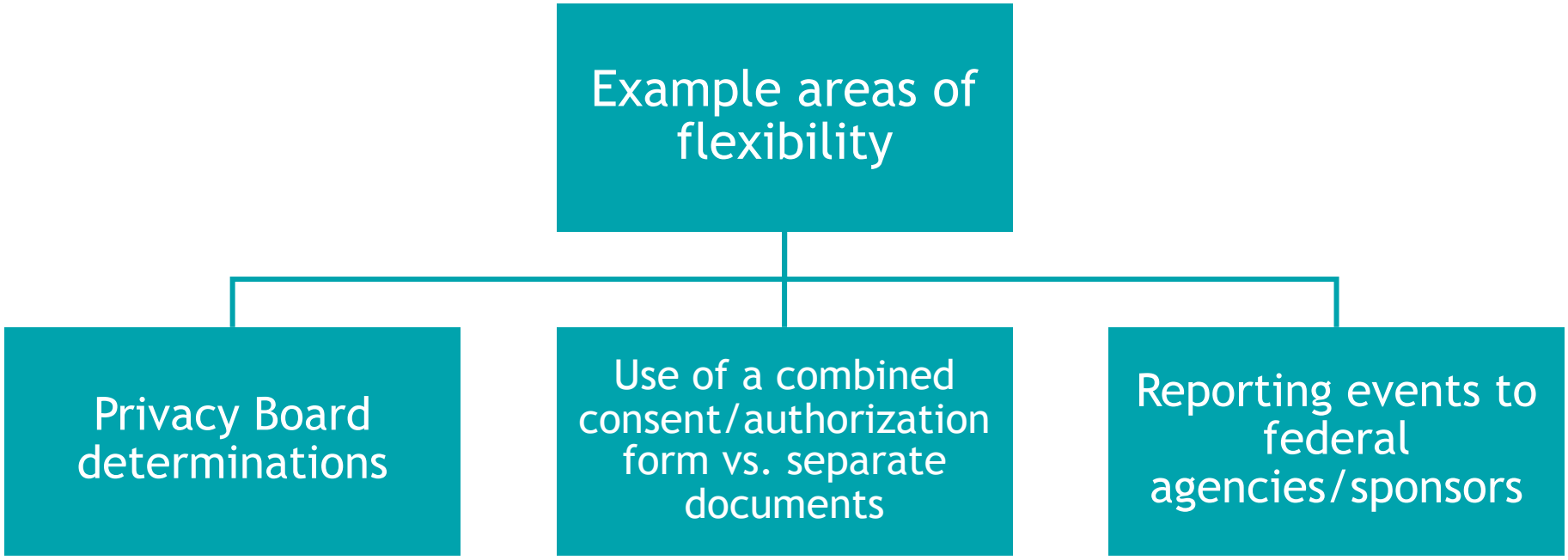
Summary of Reliance Steps

STEP	ROLE	ACTION
1	**Overall PI**	Contacts Home Institution POC to discuss a reliance arrangement, including a proposed Reviewing IRB and mechanism to request single IRB review.
2	**Overall PI**	Initiates a request for reliance via the SMART IRB Online Reliance System (or alternative approach agreed upon) and proposes a Reviewing IRB.
3	**Home Institution POC**	Reviews and determines if study eligible for reliance and, if so, either confirms the proposed Reviewing IRB or proposes a new Reviewing IRB
4	**Proposed Reviewing IRB POC**	Reviews materials and communicates to proposed Relying Institution POCs whether his/her institution will serve as the Reviewing IRB for the study.
5	**Proposed Relying Institution POCs**	Review materials related to the request and communicate decision whether to rely on the proposed Reviewing IRB. If agree to rely, also communicate key local context information.
6	**Proposed Reviewing IRB POC**	After receiving decisions/information from other institutions: 1. Reviews provided local context information 2. Confirms for which institutions the IRB will oversee the research 3. Documents the reliance determination 4. Communicates which SOPs the Reviewing IRB will follow

Other Implementation Issues

Addressing the SMART Agreement Flexibility

The Reviewing IRB should explain to Relying Institutions how it will implement flexibility allowed by the Agreement



Resource: SMART IRB Implementation Checklist at smartirb.org/resources

Communicating with the Overall PI (or designee, such as the Lead Study Team)

The Reviewing IRB POC should reach out to the Overall PI (or designee) to:

- Communicate when the IRB application should be submitted for review
- Explain how to request approval for relying institutions (e.g., by creating separate applications vs. adding each new site as an amendment)
- Develop a communication plan

Elements of a Communication Plan

Clarify and document who will:

- Provide confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research
- Communicate local context information to the Reviewing IRB regarding state laws and institutional requirements that pertain to the review of the ceded study
- Submit studywide initial application and amendments to the Reviewing IRB
- Prepare site-specific applications and site-specific amendments to the Reviewing IRB
- Distribute IRB determinations and IRB-approved study materials to relying site study teams

Template *Communication Plan* at smartirb.org/resources

Disseminating IRB documents & policies

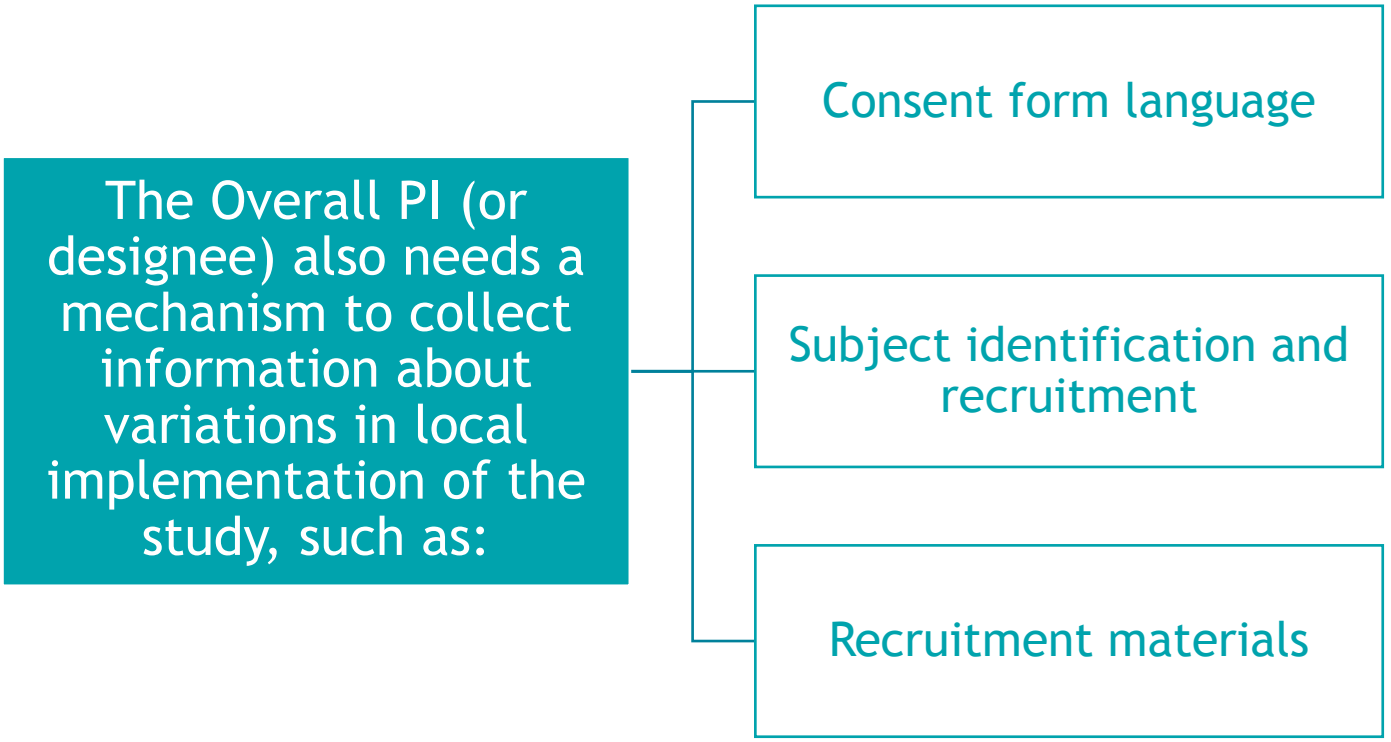
A key consideration is how IRB approvals and other determinations will be distributed to study teams (e.g., by providing access to the review system or posting documents on a shared secure platform)

The Reviewing IRB also must ensure the Overall PI (or designee) and Relying Site Study Team are aware of their relevant policies, such as:

- Reportable events: what needs to be reported, when, and to whom
- Personnel changes

Collecting Local Context Information

The SMART IRB Online Reliance System provides a mechanism to collect key local context information. If this system will not be used, the Reviewing IRB needs to identify how it will obtain this information.



Template Local Context Surveys available at smartirb.org/resources

Educating Study Teams about their Responsibilities

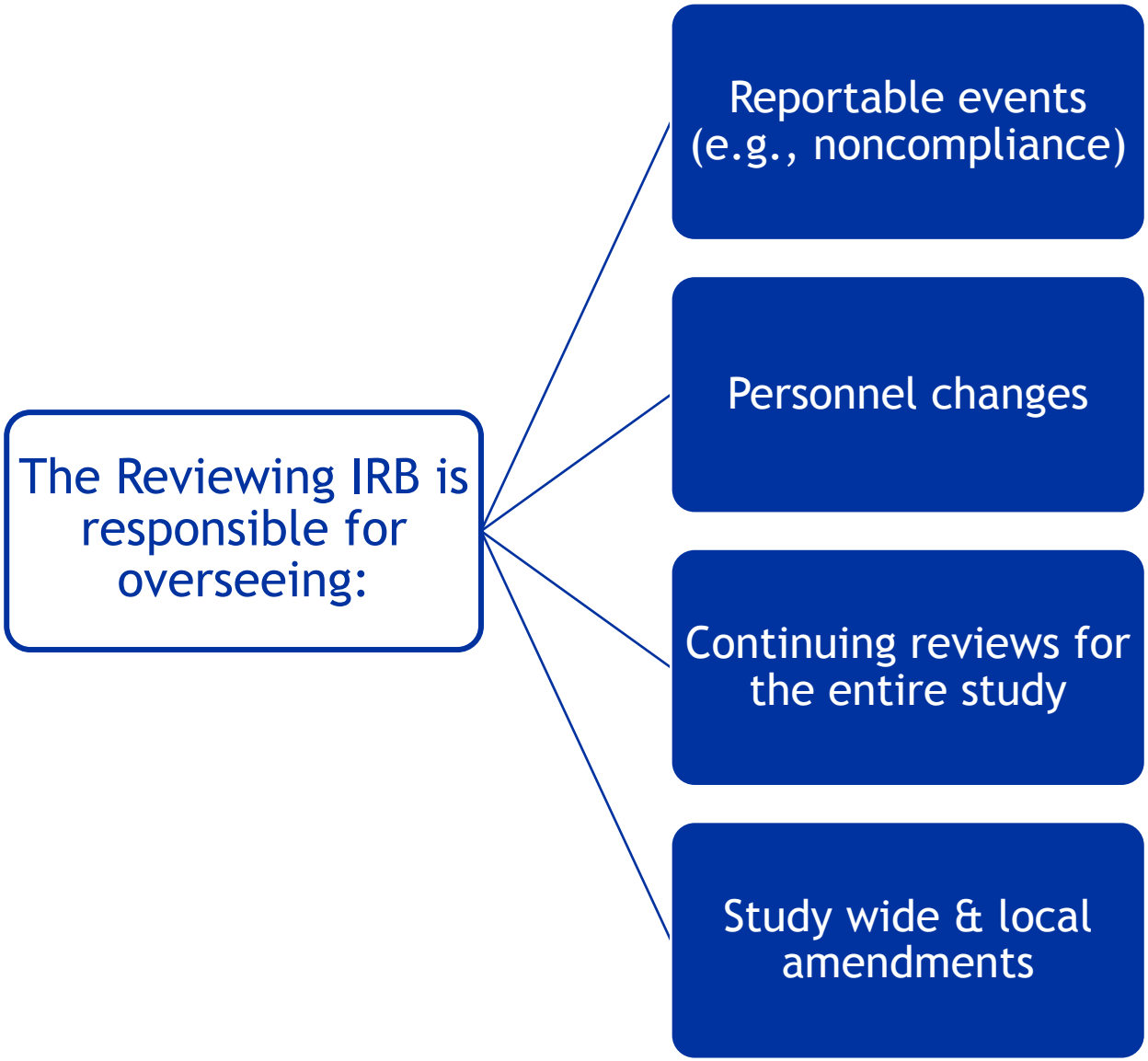
Under the SMART IRB Agreement, institutions are responsible for ensuring their study teams are aware of and comply with the terms of the Agreement.

Investigators will need assistance in understanding their roles and responsibilities related to single IRB and how they differ when they are the Overall PI (or Lead Study Team) vs. a Relying Site Study Team, especially when the SMART IRB SOPs are followed.

Overall PI and Study Team Checklists are available at smartirb.org/resources

Post Reliance Processes

After Initial Review: Reviewing IRB



After Initial Review: Relying Institution

Relying Institutions must have processes in place to provide information to the Reviewing IRB after their site is approved, including mechanisms for:

- **Ensuring personnel added to the study after initial approval are qualified and have completed required training**
- **Providing the Reviewing IRB with information regarding**
  - **New or updated management plans for their personnel related to the ceded study**
  - **Audits of ceded research**
  - **Information/events that could affect the ceded research (e.g., serious noncompliance finding for the research team on another study)**

Reliance Scenarios

Scenario One

Belledale Clinic

Ridgeview Research Institute

Adams University

Collaborate on a research project

Belledale & **Ridgeview** have joined the SMART IRB Agreement

Belledale is willing to serve as Reviewing IRB

Ridgeview agrees to cede review to Belledale

Adams also agrees to cede review to Belledale

Belledale and Ridgeview use the SMART IRB agreement.
A separate IRB authorization agreement between Belledale and Adams will be required (or Adams may join SMART IRB).

Scenario Two

Belledale Clinic

Ridgeview Research Institute

Adams University

Collaborate on a research project

All have joined the SMART IRB Agreement

Belledale is willing to serve as Reviewing IRB

Ridgeview agrees to cede review to Belledale

Due to study population, Adams retains local IRB review

Belledale and Ridgeview can still use the SMART IRB Agreement to cover their reliance arrangement.

Scenario Three

Belledale Clinic

Ridgeview Research Institute

Adams University

Collaborate on a research project

All have joined the SMART IRB Agreement

Overall PI proposes her Home Institution, Belledale, as Reviewing IRB

Ridgeview has more expertise & agrees to be Reviewing IRB at Belledale's request

Adams University agrees to cede review to Ridgeview

SMART IRB Online Reliance System allows Home Institution (Belledale) POC to suggest a different Reviewing IRB.

We're here to help

help@smartirb.org

SMART IRB

Access SMART IRB Resources at smartirb.org

Expertise and Guidance

Connect with an ambassador or request a peer consultation

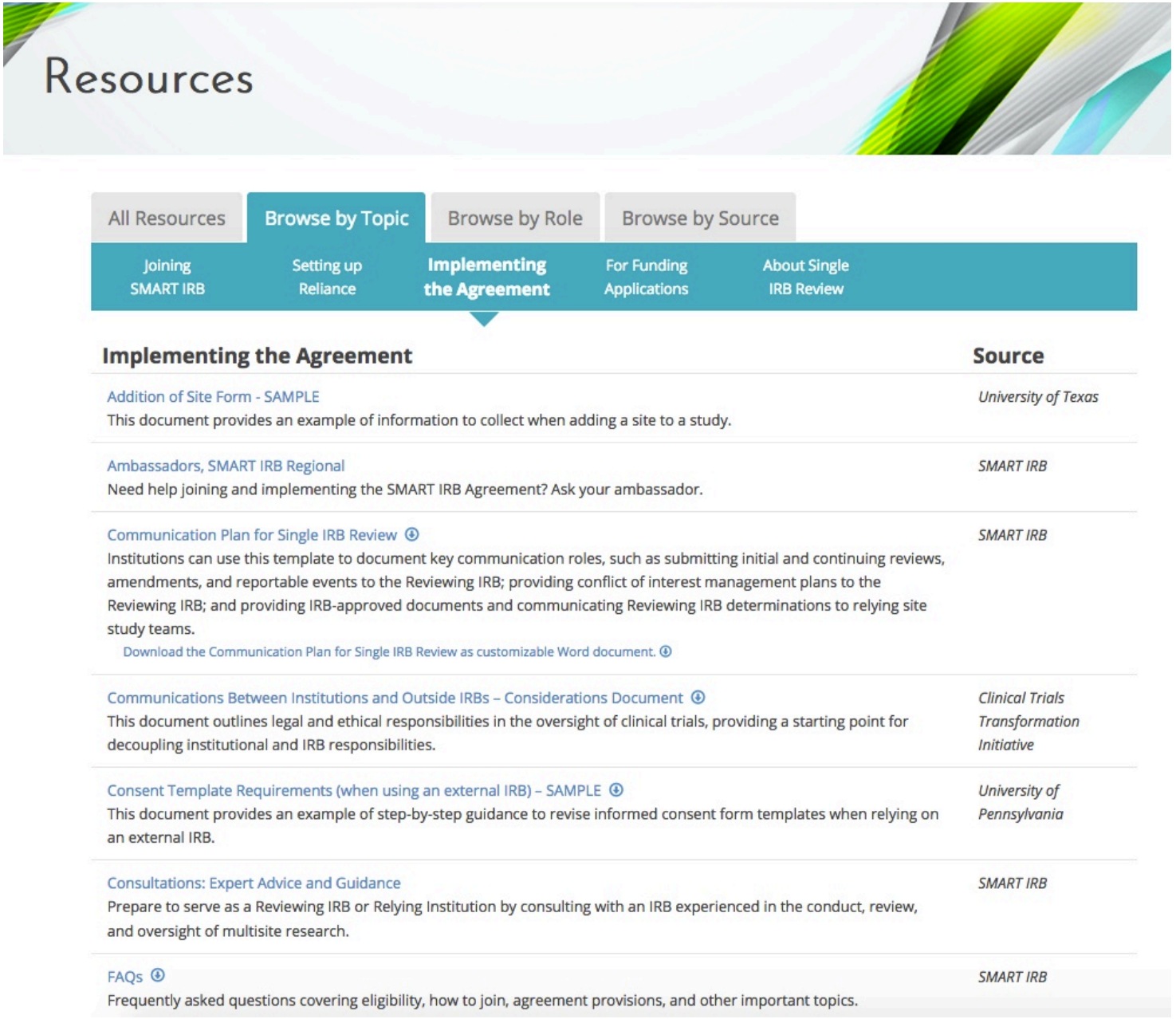
Support for Single IRB Review

Access a growing library of FAQs, SOPs, templates, checklists, and guidance

Online Reliance System

Request, track, and document reliance arrangements on a study-by-study basis

SMART IRB Resources Page: smartirb.org/resources



Questions and Discussion