SMART IRB

Your Roadmap to Single IRB Review

Responsibilities of Relying Institutions

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Presentation Goals

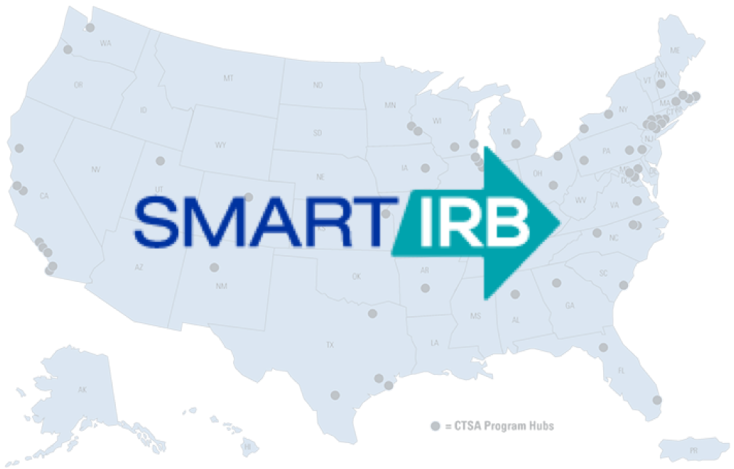
Provide a brief overview of the SMART IRB Program

Describe the responsibilities under the SMART IRB Master Agreement of Relying Institutions

Discuss the impact of single IRB review on institutional policies & processes

SMART IRB OVERVIEW

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

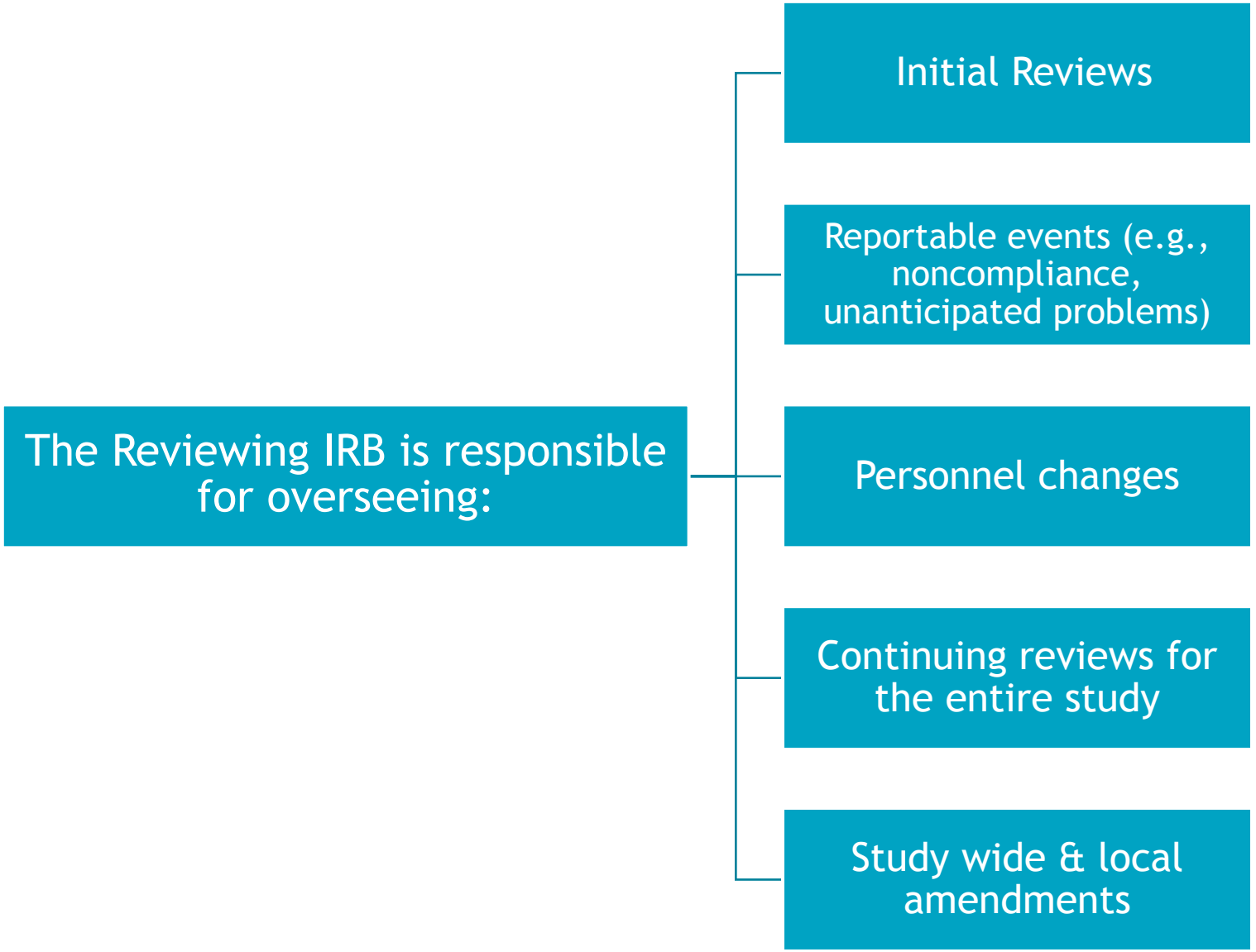
Education & Training
Tools, templates, FAQs, checklists, guidance, peer consultations, and webinars support adoption of SMART IRB

Harmonization Steering Committee
Leaders in the field promote best practice

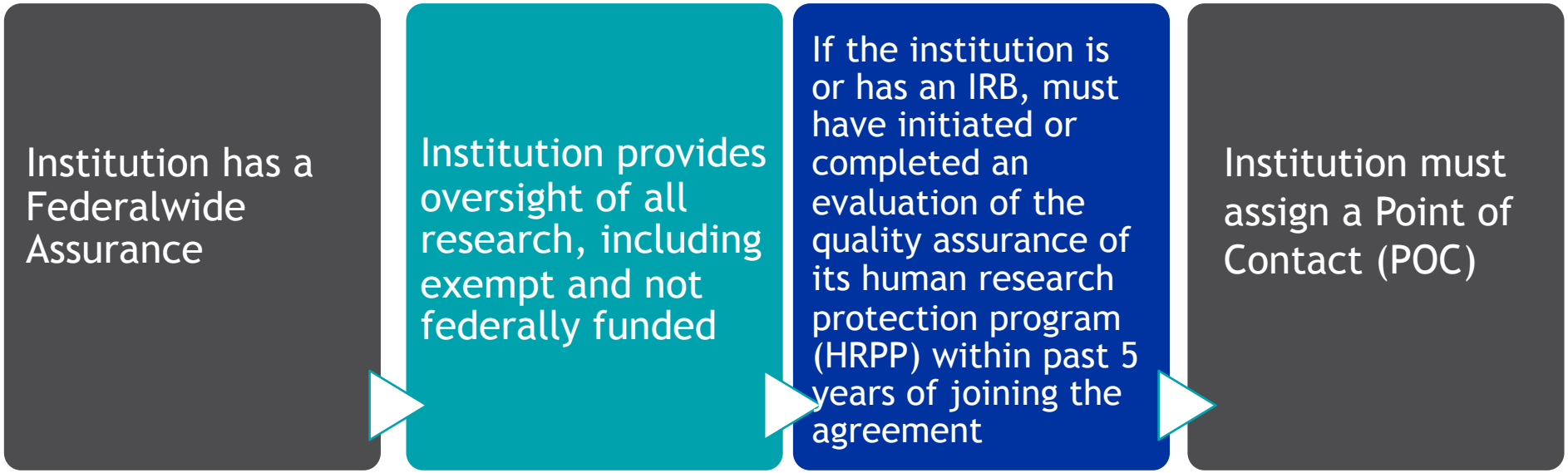
Nature of the SMART IRB Agreement

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

Nature of the SMART IRB Model



Eligibility to Join SMART IRB



Responsibilities of All Institutions that Join

Maintain, implement, or have access to a human subjects research QA/QI process/function/program/ service that can conduct and report to the Participating Institution the results of for-cause and not-for-cause audits

UNLESS the Reviewing IRB waives this requirement

Maintain sufficient insurance coverage (includes self-funded liability coverage in the case of state institutions) to cover their activities related to the reliance arrangement

UNLESS the Reviewing IRB waives this requirement

SMART IRB MASTER AGREEMENT: RELYING INSTITUTION RESPONSIBILITIES

Ensuring Study Teams:

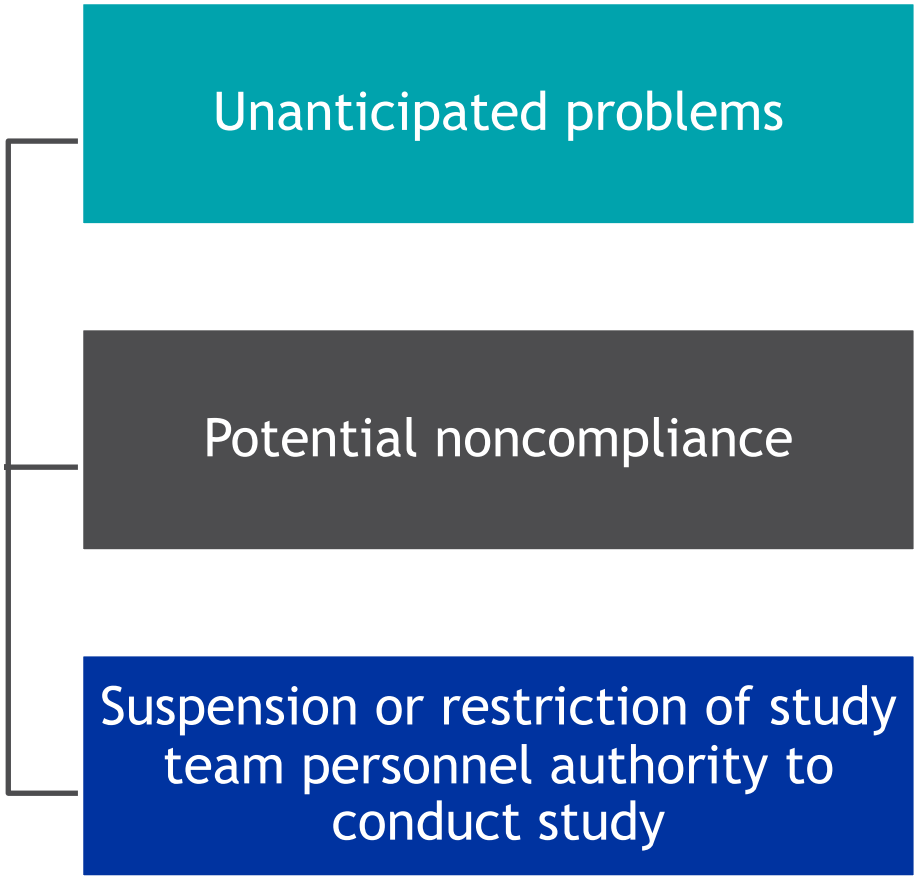
- Do not initiate any study or changes of protocol* without approval from the Reviewing IRB

  (*except those to eliminate an apparent immediate hazard)

- Provide the Reviewing IRB with information about local study conduct for continuing review

- Maintain research records (e.g., consent forms, HIPAA authorization)

Ensuring Study Teams Notify the Reviewing IRB of:

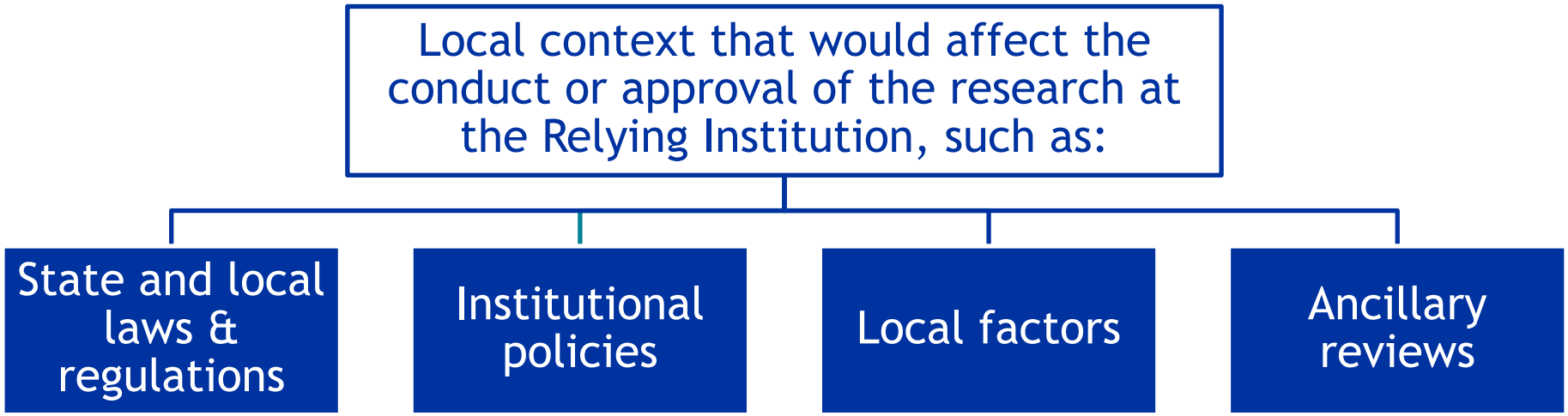


Research Personnel

Provide information or documentation to a Reviewing IRB regarding:

its research personnel's education, training, and qualifications as requested

Institutional Communication with the Reviewing IRB



Consent Documents

Providing site-specific information in the customizable sections of the Reviewing IRB's consent form, such as:

- Compensation for injury language
- Variations in costs
- Local contact information

Conflicts of Interest (COI)

Maintain & share COI policies

Perform COI analysis (unless alternate arrangement agreed upon with Reviewing IRB)

Communicate COI determinations (e.g., management plans, restrictions) to the Reviewing IRB

Abide by Reviewing IRB COI determinations

HIPAA Privacy Rule

Work with Reviewing IRB to establish whether a separate HIPAA authorization form or combined consent/authorization will be used for the research

Provide any language specific to the Relying Institution to the Reviewing IRB

Notify the Reviewing IRB of any specific local requirements and restrictions on use and disclosure of protected health information (PHI) that could prevent the Reviewing IRB from approving a request for waiver of HIPAA authorization for the Relying Institution

If a separate HIPAA authorization form will be used, the Relying Institution will ensure:

The accuracy of the information within the form

Compliance of the form with the HIPAA Privacy Rule

That the form permits PHI to be used by and disclosed to the Reviewing IRB, the Reviewing IRB Institution, and all Relying Institutions as necessary for conducting, reviewing and overseeing the Research (including investigation and evaluation of events)

Injury Coverage

Ensuring the provisions of any applicable grant or contract that address financial coverage for research-related injuries in connection with research:

- Are consistent with the approved research protocol and consent form

OR

- That the approved research protocol and consent form, if more protective of human subjects, will control

Complaints

The Relying Institution must have

an institutional mechanism by which complaints about the research can be made by local research participants or others to a local contact

Cooperates When the Reviewing IRB or Reviewing Institution Requests an Audit

- Provide research records and related information
- Meet with representatives from the Reviewing IRB/ Reviewing IRB institution
- Help to carry out corrective action(s), as applicable
- Report its findings to the Reviewing IRB/ Reviewing IRB Institution within a reasonable timeframe in the case of its own or a joint investigation
- Comply with all corrective actions required by the Reviewing IRB/ Reviewing IRB Institution

Reporting to Regulatory Agencies

Promptly providing any comments on any draft report from the Reviewing IRB/Reviewing Institution

If the Reviewing IRB/Reviewing IRB Institution requests the Relying Institution make the report, promptly prepare the draft report and provide the Reviewing IRB/Reviewing IRB Institution with the opportunity to review and comment on the draft report

If the Relying Institution elects to make its own additional report, provides a copy to the Reviewing IRB/Reviewing IRB Institution

Promptly notify the Reviewing IRB/Reviewing IRB Institution of communications received from FDA, OHRP, and/or other regulatory agencies related to any reporting

IMPACT OF SINGLE IRB REVIEW ON RELYING INSTITUTIONS

Impact on Reliance Policy

Institutional policy for ceding review or serving as reviewing IRB should identify:

WHO	WHAT
can make reliance determinations	research qualifies for reliant review

Impact on Reliance Process

Institutional process should include:

- Identification of information needed to make reliance decision and how to collect it
- A mechanism for study teams to request reliance arrangements
- A process for handling reliance requests
- A means for ensuring all institutions relying on the IRB are aware of and support reliance agreements (e.g., affiliated hospitals)

One Solution:
The SMART IRB Online Reliance System

- Provides investigators and institutions a centralized workflow to initiate, document, and track reliance arrangements
- Standardizes the information collected to assess whether a study is eligible for a reliance arrangement
- Connects institutions with the appropriate point of contact (POC) for each institution involved in the reliance request
- Built-in Flexibilities: Add sites by amendment; customize institution contact information; designate multiple POCs within institution; send reminders; pull reports on-demand

Local HRPP Infrastructure Needs Related to Reliance

A means for ensuring compliance with the terms of the IRB authorization agreement

A mechanism to ensure non-IRB institutional requirements are met, such as ancillary reviews, clinicaltrials.gov registration and updates, congruency of contract/consent injury language, coverage analysis

Training for study teams to understand the implications of single IRB review, including responsibilities when research ceded to an external IRB

Ability to track ceded research to allow the institution to appropriately oversee its research portfolio

Addressing IRB fees, if the external IRB charges or if serving as a Reviewing IRB under the NIH Single IRB Policy

Communicating reliance arrangements to grants/contracts and post-approval monitoring personnel

Addressing situations when the Reviewing IRB will not serve as a Privacy Board or a separate authorization form required

If you need help:
email
help@smartirb.org

SMART IRB

Access SMART IRB Resources at smartirb.org

Expertise and Guidance

Connect with an ambassador or request a peer consultation

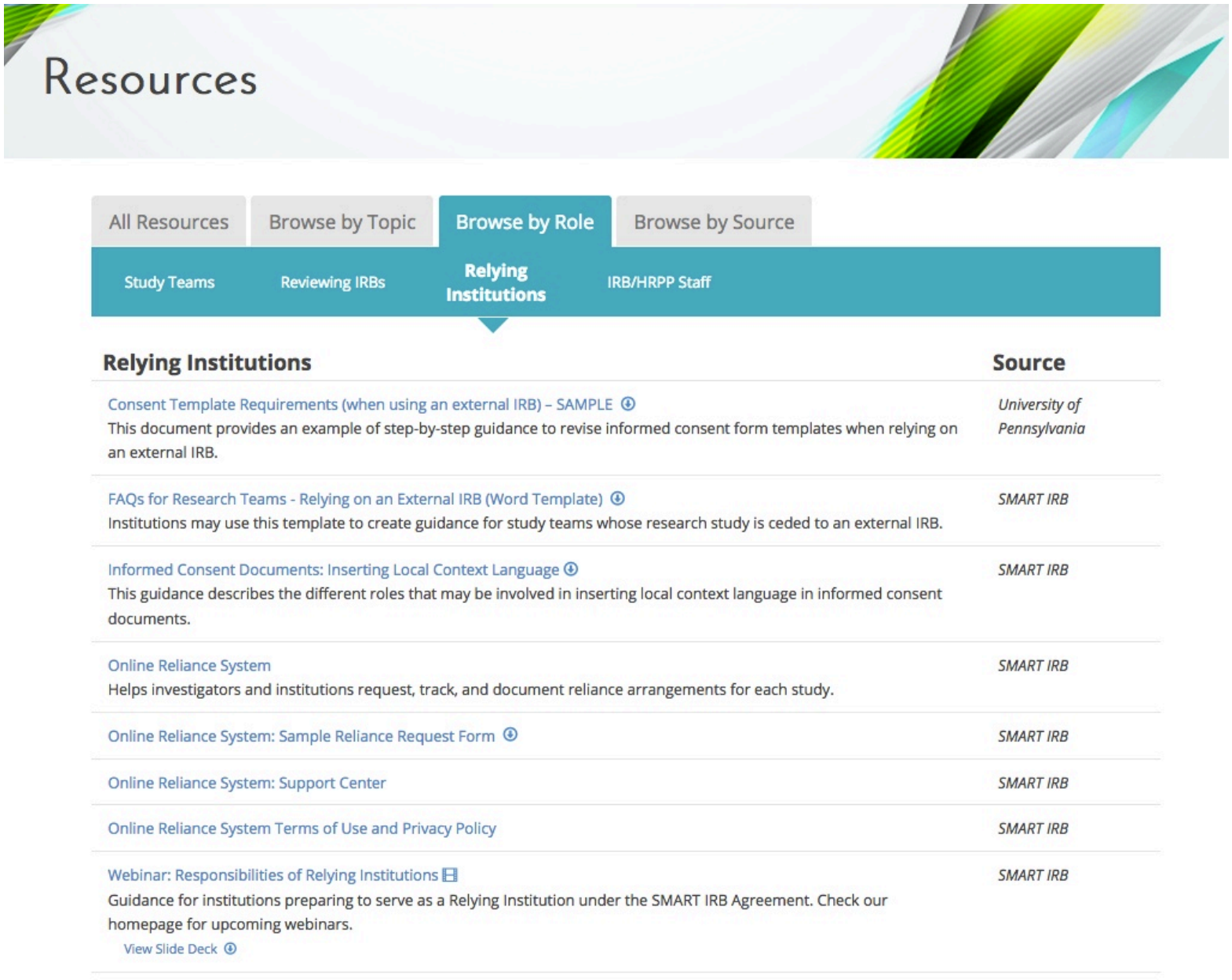
Support for Single IRB Review

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