Roadmap to Single IRB Review

Overview of the SMART IRB Agreement

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Advancing research together

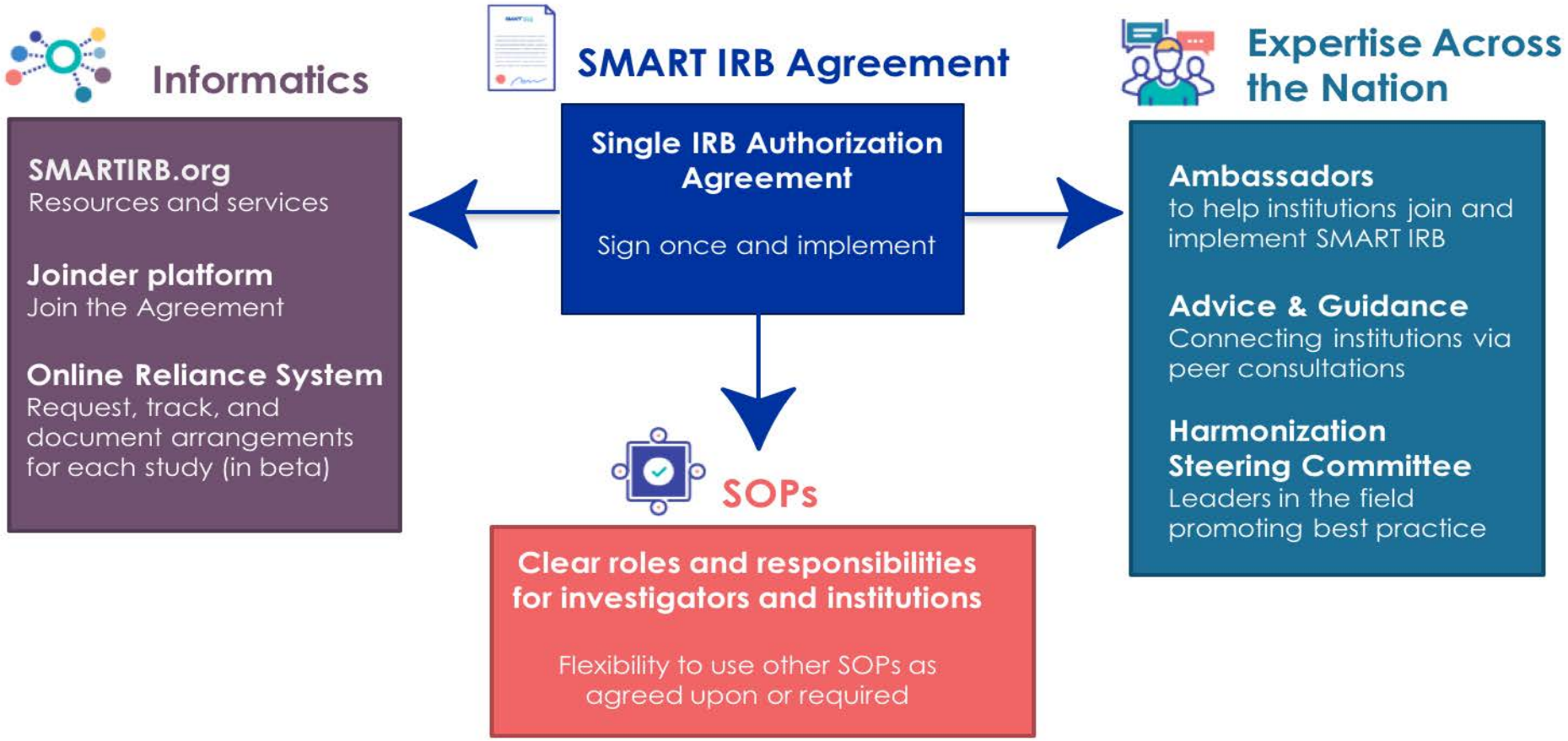
A roadmap to implement the NIH Single IRB Policy

JOIN
SMART IRB

ENABLE
multi-site research

HARMONIZE
across the nation

Supporting single IRB review



Streamlining collaborative research, ensuring robust protections for participants

Master IRB reliance agreement and SOPs developed with broad stakeholder input

8 Clinical & Translational Science Award Hubs came together to develop a national IRB reliance agreement

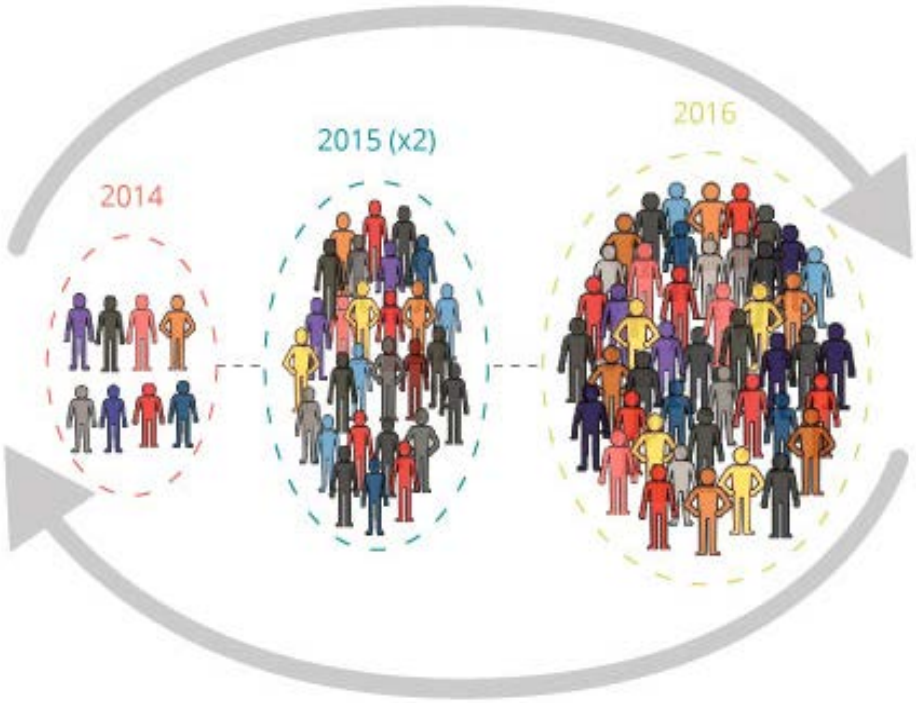
- Public & private universities
- Academic healthcare centers

Shared with 72 Institutions

+ 25 CTSAs in 19 states
+ Community hospitals
+ Independent/commercial IRBs

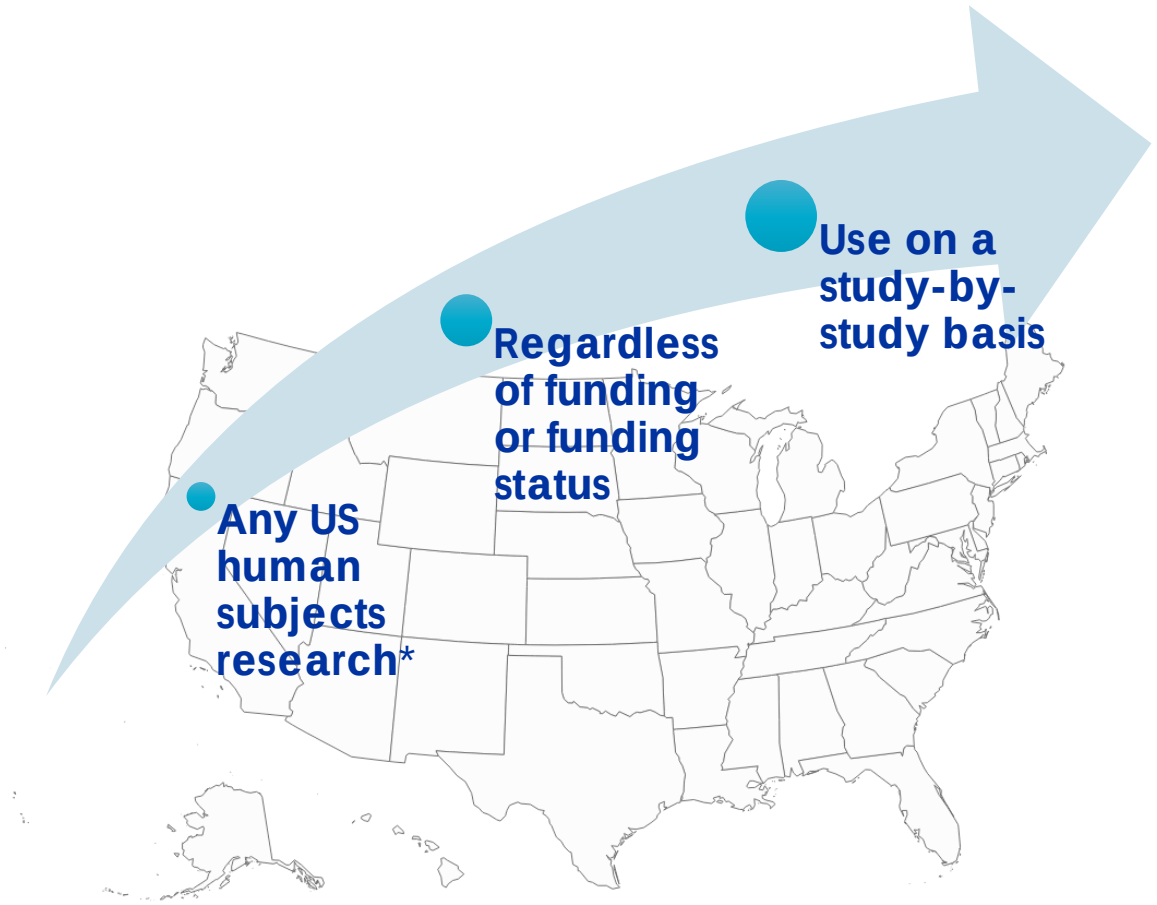
Shared with 115+ Institutions

+ 64 CTSAs in 33 states
+ NIH agencies



Over 300 institutions have joined the SMART IRB Agreement.

SMART IRB supports collaboration across the nation



* Research for which local IRB review is required by law or otherwise is not eligible

No need to negotiate agreements for each study

No obligation to enter into reliance or serve as reviewing IRB

Nature of the SMART IRB Model

The Reviewing IRB is responsible for overseeing:

- Initial Reviews
- Reportable events (e.g., noncompliance)
- Personnel changes
- Continuing reviews for the entire study
- Study wide & local amendments

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

Eligibility to Join SMART IRB

Institution has a Federalwide Assurance (FWA)

Institution provides oversight of all research, including exempt and not federally funded

If the institution is or has an IRB, must have a way of evaluating the quality assurance of its human research protection program (HRPP) within past 5 years of joining the agreement (initiated or completed)

Institution must assign a Point of Contact (POC)

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

Launched in beta May 4th

We're here to help

help@smartirb.org

SMART IRB

Access SMART IRB Resources at smartirb.org

Expertise and Guidance

1. Connect with an ambassador in your region who is knowledgeable in the practicalities of IRB reliance, or
2. Request guidance through our consultation service

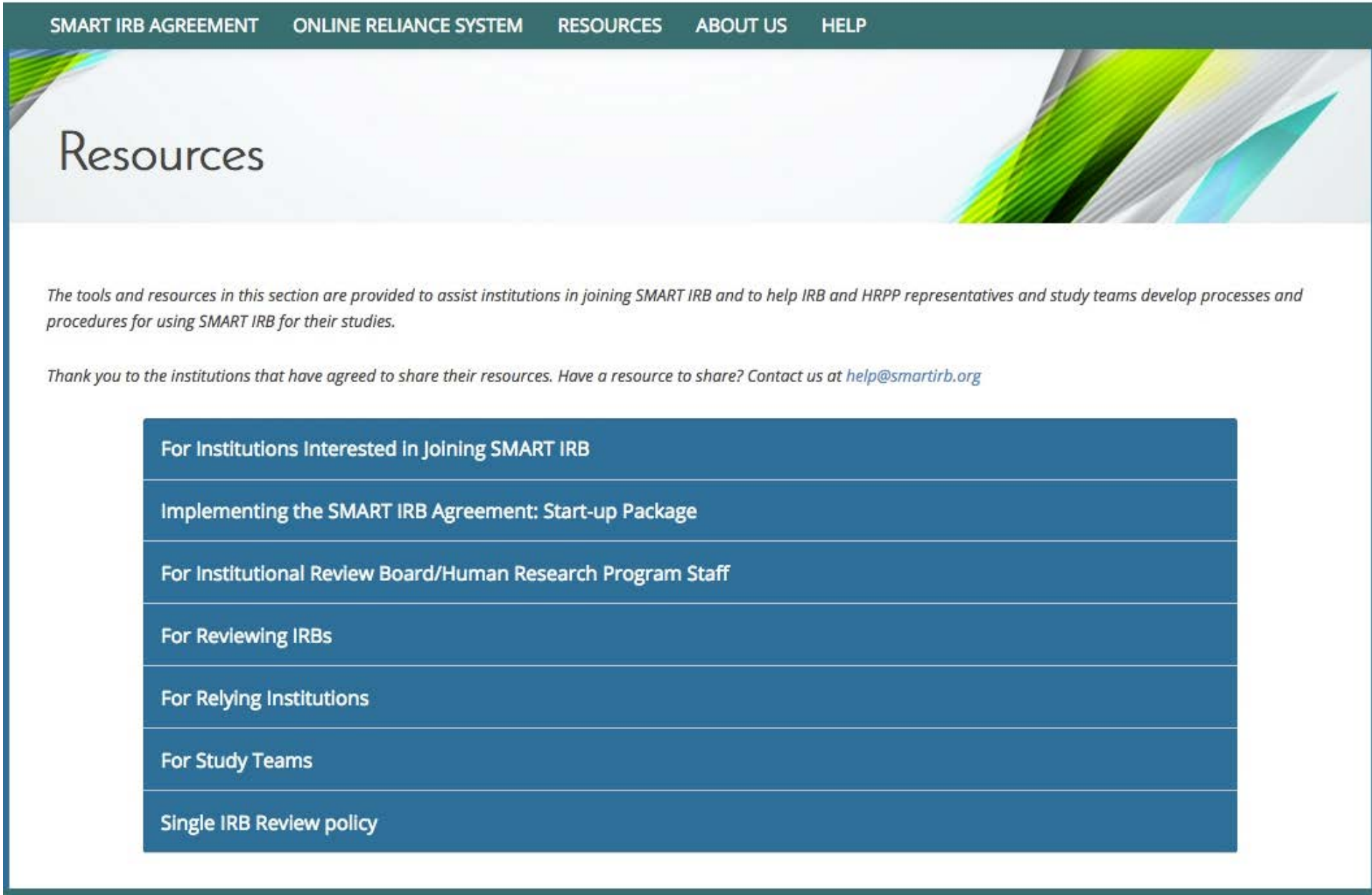
Support for Single IRB Review

Access our growing collection of resources, including SMART IRB's FAQs and SOPs, as well as a Single IRB Review Start-up Package

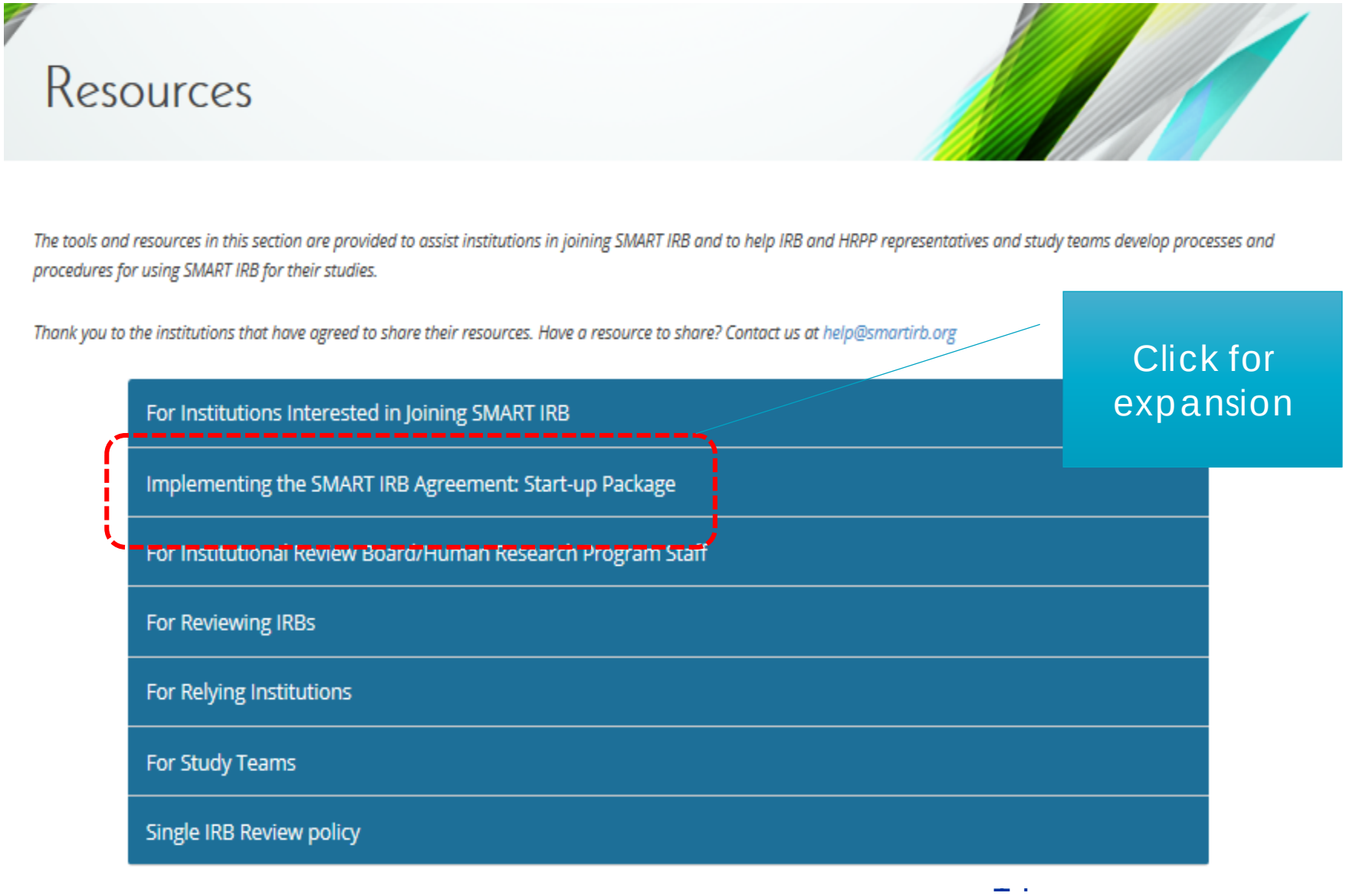
Online Reliance System (beta)

Use our web-based system to request, track, and document reliance arrangements on a study-by-study basis; freely available to investigators and institutions

SMART IRB Resources Page: smartirb.org



At SMARTIRB.ORG



SMART IRB Resources Page: Start-up Package

Implementing the SMART IRB Agreement: Start-up Package

Document Name	Source
Template Letter of Acknowledgement *If not using the SMART IRB Online Reliance System to coordinate and document study-specific reliance arrangements, institutions may use this template to document the Reviewing IRB and Relying Institutions for a specific study.*	SMART IRB
Local Context Survey *A Reviewing IRB POC may use this survey to obtain key local context information from Relying Institutions.* Download the Local Context Survey as a customizable Word document.	SMART IRB
Survey for Relying Site Study Teams *The Overall Principal Investigator and/or Lead Study Team may use this survey to obtain key information from a relying site study team to determine whether particular regulatory or institutional requirements should be communicated to the Reviewing IRB.* Download the Survey for Relying Site Study Teams as a customizable Word documemnt.	SMART IRB
Communication Plan for Single IRB Review *Institutions can use this template to document key communication roles, such as submitting initial and continuing reviews, amendments, and reportable events to the Reviewing IRB; providing conflict of interest management plans to the Reviewing IRB; and providing IRB-approved documents and communicating Reviewing IRB determinations to relying site study teams.* Download the Communication Plan for Single IRB Review as customizable Word document.	SMART IRB
Overall PI (and Lead Study Team) Checklist *This checklist helps an Overall PI (and Lead Study Team, where applicable) understand and fulfill his/her responsibilities, particularly for studies using the SMART IRB SOPs, which require identification of a Lead Study Team.* Download the Overall PI (and Lead Study Team) Checklist as customizable Word document.	SMART IRB
Relying Institution PI Checklist *This checklist helps site investigators and study teams understand and fulfill their responsibilities when a study has been ceded to an external institution.* Download the Relying Institution PI Checklist as customizable Word document.	SMART IRB

Questions and Discussion