



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



Informatics

SMARTIRB.org

Resources and services

Joinder platform

Join the Agreement

Online Reliance System

Request, track, and document arrangements for each study (in beta)



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

to help institutions join and implement SMART IRB

Advice & Guidance

Connecting institutions via peer consultations

Harmonization

Steering Committee

Leaders in the field promoting best practice

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

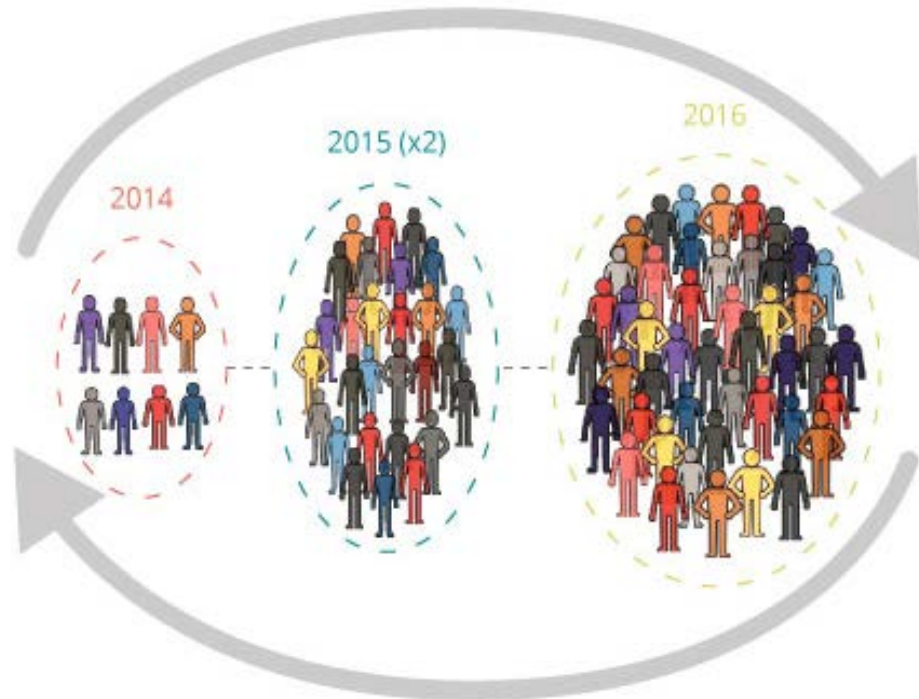
- Public & private universities
- Academic healthcare centers

Shared with 72 Institutions

- + 25 CTSA's in 19 states
- + Community hospitals
- + Independent/commercial IRBs

Shared with 115+ Institutions

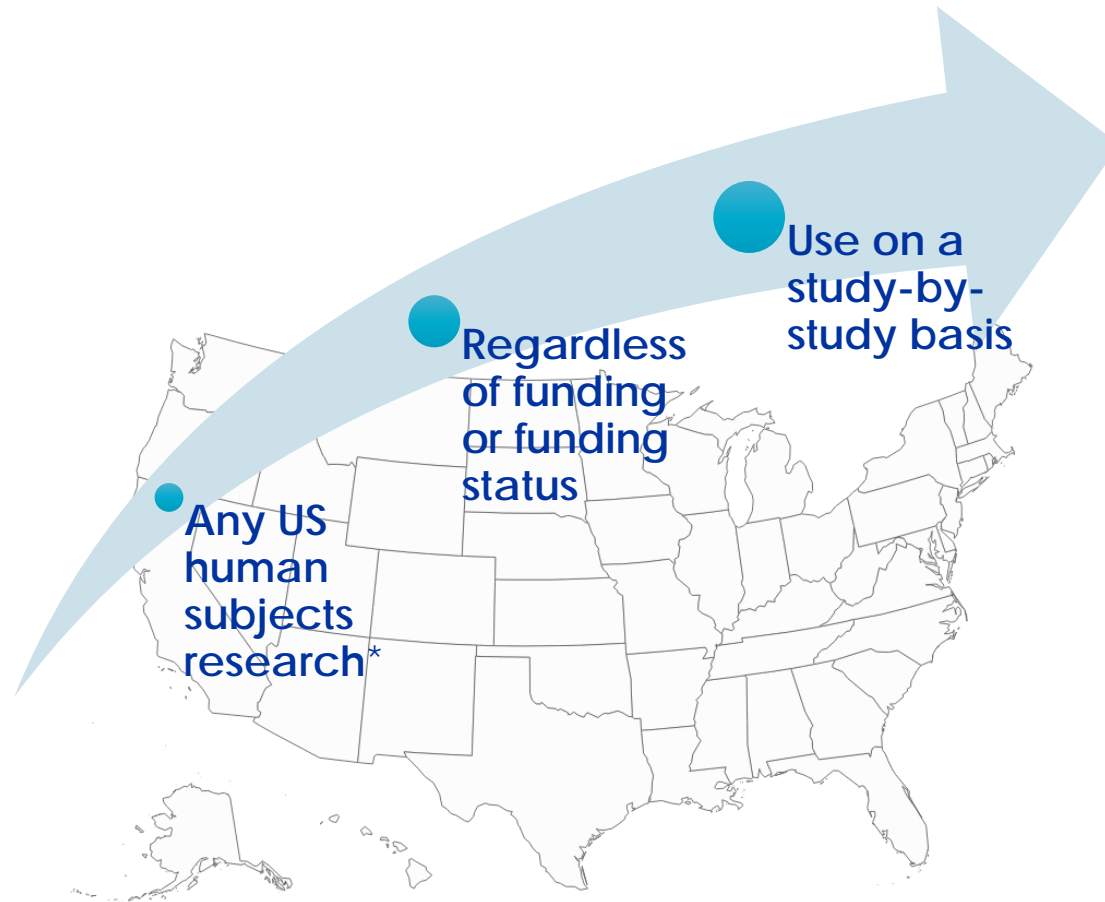
- + 64 CTSA's in 33 states
- + NIH agencies



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

Provides a single point of entry to standardize reliance processes

Serves as communication portal to eliminate tracking requests via email or other methods

Guides investigators and institutions through the workflow, making clear when action is required

Facilitates reliance arrangements on a study-by-study basis

Launched in beta May 4th



We're here to help
help@smartirb.org





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

[SMART IRB AGREEMENT](#)

[ONLINE RELIANCE SYSTEM](#)

[RESOURCES](#)

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Resources

The tools and resources in this section are provided to assist institutions in joining SMART IRB and to help IRB and HRPP representatives and study teams develop processes and procedures for using SMART IRB for their studies.

Thank you to the institutions that have agreed to share their resources. Have a resource to share? Contact us at help@smartirb.org

[For Institutions Interested In Joining SMART IRB](#)

[Implementing the SMART IRB Agreement: Start-up Package](#)

[For Institutional Review Board/Human Research Program Staff](#)

[For Reviewing IRBs](#)

[For Relying Institutions](#)

[For Study Teams](#)

[Single IRB Review policy](#)

At SMARTIRB.ORG

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expansion

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Single IRB Review policy

SMART IRB Resources Page: Start-up Package

Implementing the SMART IRB Agreement: Start-up Package	
Document Name	Source
<p>Template Letter of Acknowledgement ⓘ</p> <p><i>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.</i></p>	SMART IRB
<p>Local Context Survey ⓘ</p> <p><i>A Reviewing IRB POC may use this survey to obtain key local context information from Relying Institutions.</i></p> <p>Download the Local Context Survey as a customizable Word document. ⓘ</p>	SMART IRB
<p>Survey for Relying Site Study Teams ⓘ</p> <p><i>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.</i></p> <p>Download the Survey for Relying Site Study Teams as a customizable Word document. ⓘ</p>	SMART IRB
<p>Communication Plan for Single IRB Review ⓘ</p> <p><i>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.</i></p> <p>Download the Communication Plan for Single IRB Review as customizable Word document. ⓘ</p>	SMART IRB
<p>Overall PI (and Lead Study Team) Checklist ⓘ</p> <p><i>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.</i></p> <p>Download the Overall PI (and Lead Study Team) Checklist as customizable Word document. ⓘ</p>	SMART IRB
<p>Relying Institution PI Checklist ⓘ</p> <p><i>This checklist helps site investigators and study teams understand and fulfill their responsibilities when a study has been ceded to an external institution.</i></p> <p>Download the Relying Institution PI Checklist as customizable Word document. ⓘ</p>	SMART IRB

Questions and Discussion