



SMART IRB : Lessons Learned and Opportunities Ahead

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Lessons Learned



Advancing research together



A Roadmap to Single IRB Review

Funded by NCATS beginning in July 2016

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

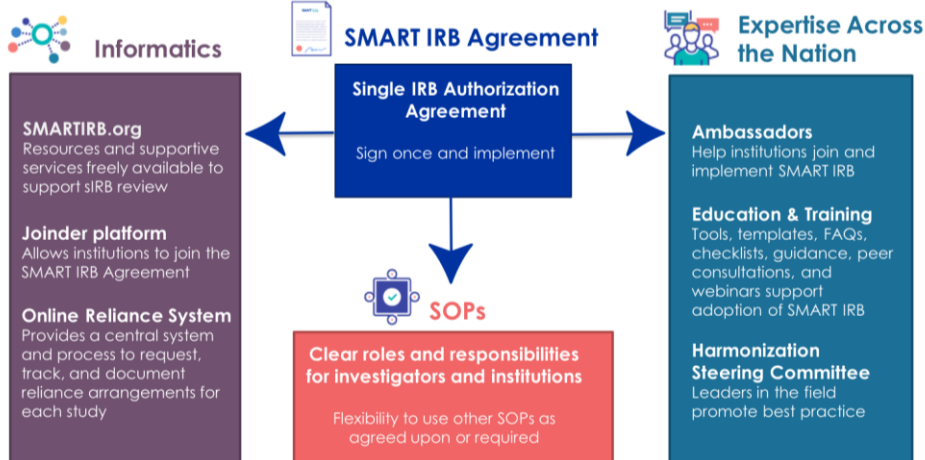
SUPPORT
Use of SMART IRB

**EDUCATE
& TRAIN**
Institutions &
Investigators

HARMONIZE
sIRB review
processes across
the nation

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Supporting single IRB review



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Master IRB Reliance Agreement

8 CTSAs came together to develop a national IRB reliance agreement

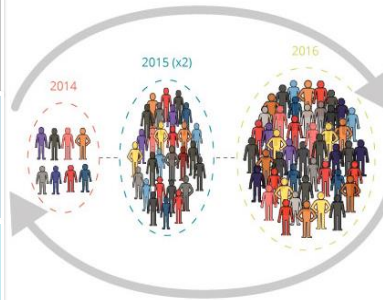
- Public & private universities
- Academic healthcare centers

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



Since 2016

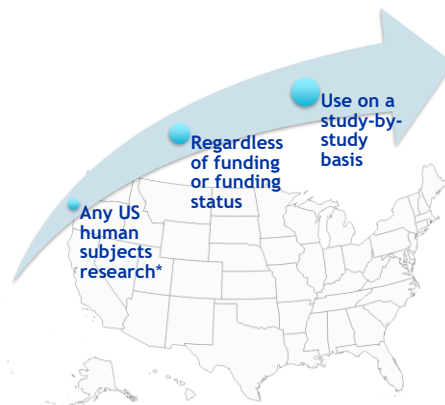
SMART IRB

More than 750 institutions have joined the SMART IRB Agreement

Broad stakeholder input ensures broad utility

smartirb.org

Supports collaboration across the nation



Inclusive & Flexible
SMART IRB is **not** just for NIH-funded studies.

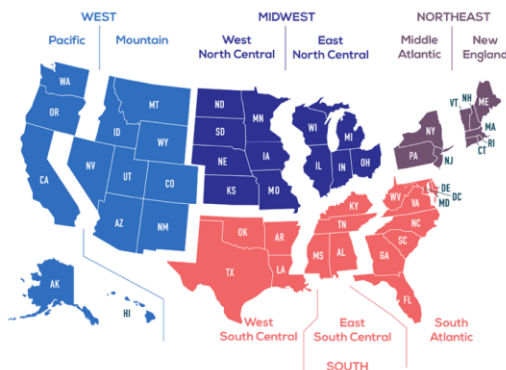
SMART IRB may be used for **any study***, regardless of funding source.

* 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

Ambassadors

- Ambassadors are HRPP professionals knowledgeable in IRB reliance.
- SMART IRB Ambassadors help institutions join and implement the SMART IRB Agreement.



Currently 789 signatories*

Find and contact your ambassador
smartirb.org/ambassadors

* 9 Sept 2020

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Lessons Learned

- Flexible terms allow the agreement to cover many different types of research
- IRB/HRPP Experts in Single IRB serve as Ambassadors
- Defined points of contact have improved communication between institutions
- Standardization has helped to streamline the reliance process by removing negotiation of individual reliance agreements
- Education, coordination, communication, and trust are key

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Building Community

A monthly email newsletter

- Announcements, news
- Resources, education
- 2700+ subscribers

SMART Talk - Monthly virtual forums

- Best practices
- Emerging issues
- Ask the experts

The latest is always @SMARTIRB.



SMART IRB

SMART IRB: The Essentials

The "Fall, Leaves, Fall" Edition.

All things being equinox.

Balancing apples with single IRB review.
Who's on first? Who's doing what? Reporting to federal agencies? Ensuring personnel training? Identifying COI? We've got it all mapped out in our Institution v. IRB Responsibilities guide for reviewing IRBs and relying institutions (thanks to the Harmonization Steering Committee for navigating the corn maze!).

Take a hint.

Helpful tips for study teams, at your service.
Looking to get investigators and study staff up to speed on what it really means to rely on an external IRB? Send them our FAQs for Research Teams. Or, use our template to customize the FAQs to reflect your institution's extra special particularities. But wait, there's more to fall for at smartirb.org/resources - one-stop shopping for tools, templates, and checklists to help with single IRB review at prices you can't beat.

Immediate gratification.

Data at your finger tips.
When your institution uses SMART IRB's Online Reliance System to document reliance arrangements, you can pull on-demand reports with information about all reliance requests involving your institution. Just log in and click on the "Reports" tab. Note: this feature is only available to an institution's Reliance POC and POC Backups. On-demand
reliance data reports are available to POCs and POC Backups only.

Class picture perfect.

(Awkwardly) smile if you're one of our Participating Institutions. Take a look at our big, beautiful, and ever-expanding reliance network! Be a pal and let us know if we have any apple crisp between our teeth.

Fall fashion trend.

Voted Vogue's #1 accessory for '18.
Once you've joined, sport a SMART IRB badge on your website.



Rolling admissions.

The time has never been better to join SMART IRB. Lend your affiliates a helping hand by sharing this guidance...and forward them the signature element of our press kit, the SMART IRB newsletter.

Study hall.

Education & Training

SMART Talk



Webinars

- A Follow-Up Conversation: Getting Ready for the 2020 Single IRB Requirements
- Managing Reliance with the SMART IRB Online Reliance System
- Operationalizing an HRPP under Single IRB
- Getting Ready for the 2020 Single IRB requirements
- Harmonization - Reportable Events

- Getting Started with SMART IRB & the Online Reliance System
- Implementing the SMART IRB Agreement
- Responsibilities of Relying Institutions
- Serving as a Reviewing IRB
- SMART IRB Resources for IRB/HRPP Personnel

Start-Up Packages & Resources for IRB & HRPP Professionals

SMART IRB AGREEMENT ONLINE RELIANCE SYSTEM HARMONIZATION **LEARNING CENTER** RESOURCES ABOUT US SUPPORT

Learning Center for IRB and HRPP Administrators

The videos and companion resources below are designed to help IRB and HRPP administrators and staff successfully manage single IRB arrangements

- Start-Up Packages
- Implementing the SMART IRB Agreement
- Serving as a Reviewing IRB
- Responsibilities of Relying Institutions
- Getting Started with SMART IRB and the Online Reliance System
- Online Reliance System Walkthrough
- SMART IRB Resources for IRB and HRPP Personnel
- SMART Talk Monthly Community Forum
- Training for Investigators and Study Teams

SMART IRB Start-Up Packages

These packages contain a suite of resources to help you understand and fulfill your roles and responsibilities in a single IRB arrangement. Each package provides a guide describing how and when to use the included resource as well as links to online tools and further information. See also: [Start-Up Packages for Study Teams](#).

[Download Reviewing IRB Package](#) [Download Relying Institution Package](#)

Start-Up Packages & Resources for Investigators & Study Teams

SMART IRB AGREEMENT ONLINE RELIANCE SYSTEM HARMONIZATION **LEARNING CENTER** RESOURCES ABOUT US SUPPORT

Learning Center for Investigators and Study Teams

The videos and companion resources below are designed to help investigators and study teams successfully plan for and navigate single IRB review arrangements for their studies. Questions about local processes and policies are best addressed by your institution's SMART IRB Point of Contact.

- Start-Up Packages
- Introduction to Single IRB Review and SMART IRB
- Overview of the NIH Single IRB Policy
- Selecting a Single IRB
- Developing a Single IRB Plan
- Potential Effects of NIH Single IRB Policy on Research Costs
- Study Team Roles Related to Single IRB
- Using the SMART IRB Online Reliance System

SMART IRB Start-Up Packages

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.

[Download Study Team Package](#) [Download NIH Grant Preparation Package](#)

Opportunities Ahead

Harmonization

Harmonization Steering Committee (HSC)

- To promote a more strategic, effective, efficient and cooperative approach to policies, processes and procedures related to single IRB review of multisite studies

Co-chairs:

Barbara E. Bierer, MD
Director of Regulatory Policy, SMART IRB

Valery Gordon, PhD, MPH
Division of Clinical Innovation, National Center for Advancing Translational Sciences (NCATS),
National Institutes of Health

The HSC and its working groups follow an iterative development cycle guided by content experts, and responsive to public review and comment.

HSC: Iterative development cycle

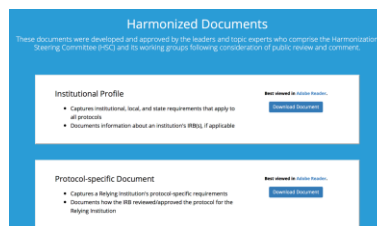


Finalized:

- Institutional Profile
- Protocol-specific Document
- Fees & Costing Models Guidance
- Institution v. IRB Responsibilities Guidance
- Reportable Events
- Single IRB Review: Responsibilities Associated with the Review of Study Personnel

Coming Soon:

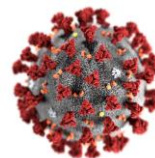
- Continuing Review Considerations
- Post-Approval Auditing
- Ancillary Reviews
- Conflicts of Interest



<https://smartirb.org/harmonization/>

smartirb.org

SMART IRB Support of COVID-19 Research



- The SMART IRB Online Reliance System has been utilized for reliance arrangements in over 100 studies COVID-19 studies
 - The median time to achieve reliance has been 3 days with the minimum time being 16 minutes!
- SMART IRB gathered a group of IRB/HRPP leaders to discuss issues facing Single IRB review during the COVID-19 pandemic
- SMART IRB is a community

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SMART IRB Master Reliance Agreement v2

- The Agreement has been revised to enable the NIH Intramural Research Program to sign on
 - NIH proposed revisions to the SMART IRB Agreement in four areas:
 - Insurance
 - Conflicts of Interest
 - Congruence of Grant Applications/Contract Proposals
 - No Violation of Law

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Coming Soon...Agreement v3

	Agreement 2.0	Agreement 3.0
Revisions proposed by	NIH	NIH, VA, DoD, HSC, Ambassadors and Current SMART IRB Participating Institutions
Summary of Revisions included	<ul style="list-style-type: none"> • Insurance Coverage • Conflicts of interest • Grant Congruency • No violation of law statement added 	<ul style="list-style-type: none"> • Insurance Coverage • Conflicts of interest • Grant Congruency • No violation of law statement added • Revised Common Rule - Updates throughout document to avoid confusion with regulatory changes. • Indemnification • HIPAA • Digital Signatures - Allows the use of digital signatures to the joinder agreement. • Statement added to prohibit modification of the agreement by participating institutions • Choice-of-law and venue provision to the Agreement added. • Updates definitions • Other

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Opportunities Ahead: Advance together

- Providing continued education and training
- Development of resources for:
 - IRB/HRPP Professionals
 - Investigators/Study teams
- Harmonization of policies, processes and procedures
- Revision of SMART IRB Agreement only as necessary
- SMART IRB support of COVID-19 research and complex challenges
- Deploying the community to optimize processes and decrease administrative burden while maintaining participant protections

Thank you
Discussion & Questions