NCATS SMART IRB Platform

Accelerating the path from discovery to health benefit: Single IRB for multi-site studies

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CTTI Single IRB Review Workshop
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Silver Spring MD
CTSA Program IRB Agreement

 Networks

UC BRAID

U Texas

IRB SHARE

New England

Wisconsin/MARCH/GPC

Ohio Collaborative

U New Mexico

IRB Rely

NIH National Center for Advancing Translational Sciences
Components of a National CTSA Program IRB Initiative

**Governance**
- Provide leadership for effort and support to sites
- Identify resources needed to support
- Help to ensure sustainability

**Workflows**
- Application process
- Communicating determinations

**IT solutions**
- To facilitate workflow and documentation
- Harmonized across CTSA Program hubs if possible

**Communication and Web-based access**
- Information about initiative and joining the agreement
- SOPs and other supporting documents

**Best practices and harmonization**
- Requirements for IRBs of record, particularly for larger studies
- Universal consent form template
- Reportable event requirements
NCATS SMART IRB Reliance Platform

Streamlined, Multisite, Accelerated Resources for Trials

• A single national Authorization (reliance) Agreement that is pre-negotiated and signed by institutions once
• Flexible for large and small studies, networks and non-networks
• Harmonized and streamlined approach
• Electronic systems for communicating Reliance documentation
NCATS SMART IRB Platform

- Master Authorization Agreement
- Standard Operating Procedures
- Informatics
- Harmonization

SMART IRB Platform
Master IRB reliance agreement and SOPs developed with broad stakeholder input

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
One SMART IRB Reliance agreement – One workflow
Sign once and implement

- Use SMART IRB on a study-by-study basis
- Default allocation of responsibilities

Flexibility
- Who serves as privacy board
- Who reports reportable events
- Need for insurance (or waive)
- Etc.
Using SMART IRB to streamline IRB review for multi-site research

**IRBs or INSTITUTIONs**

Use the SMART IRB Agreement to facilitate single IRB review

**PRINCIPAL INVESTIGATORS**

Work with their institution’s SMART IRB Points of Contacts (POCs) to determine an appropriate reliance arrangement, discuss their responsibilities related to single IRB review, and identify a mechanism for setting up a reliance arrangement, such as the SMART IRB Online Reliance System

**The Reviewing IRB**

takes on all IRB oversight responsibilities

**Relying Institutions**

provide Reviewing IRB with local context regarding state law, study team member training / qualifications, and any applicable conflicts of interest
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 |
The SMART IRB Online Reliance System

Introduced as a tool to help institutions 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

SMARTIRB.org
Value of NCATS SMART IRB Reliance Platform

✓ National platform that will support all types of multi-site clinical research studies regardless of the size of the study or from where the research study originates

✓ Leverages expertise from CTSA Program hubs and the Trial Innovation Network support an developing IRB reliance network

✓ Opportunity to implement single and central IRB process across the CTSA Program
Building capacity and community across the nation

By joining SMART IRB, institutions:

• Reduce negotiations - sign once and implement
• Determine reliance on a study-by-study basis
• Enable all types of research regardless of funding or type
• Maximize flexibility while respecting autonomy
• Have access to expertise across the nation
• Work together to inform, enable, and harmonize single IRB practices
SMART IRB Team

- NCATS DCI Team
- CTSA Investigators and their teams
- Partners at PCORNET, RDCRN, VA and others

THANK YOU
Resources

SMART IRB Authorization Agreement
https://smartirb.org/  or email: help@smartirb.org
SMART IRB Exchange
admin@SMARTIRBExchange.org

NIH SIRB Implementation FAQs:
http://osp.od.nih.gov/sites/default/files/sIRB_Extramural_FAQs_0.pdf

Mailboxes
SingleIRBpolicy@mail.nih.gov
GrantsCompliance@nih.gov