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
November 14, 2017
Silver Spring MD
CTSA Program IRB Agreement Networks

UC BRAID
U Texas
IRB SHARE
Wisconsin/MARCH/GPC
Ohio Collaborative
U New Mexico
IRB Rely

New England

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

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Principal Investigator
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Co-Investigator
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Principal Investigator
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Chief Informatics Officer
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Chief Informatics Officer
Harvard Catalyst

• 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