

NCATS SMART IRB Platform

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

Petra Kaufmann MD MSc FAAN

*Director, Office of Rare Diseases Research
National Center for Advancing Translational Science, National Institutes of Health*

CTTI Single IRB Review Workshop
November 14, 2017
Silver Spring MD



CTSA Program IRB Agreement

Networks

UC BRAID

U Texas

IRB SHARE

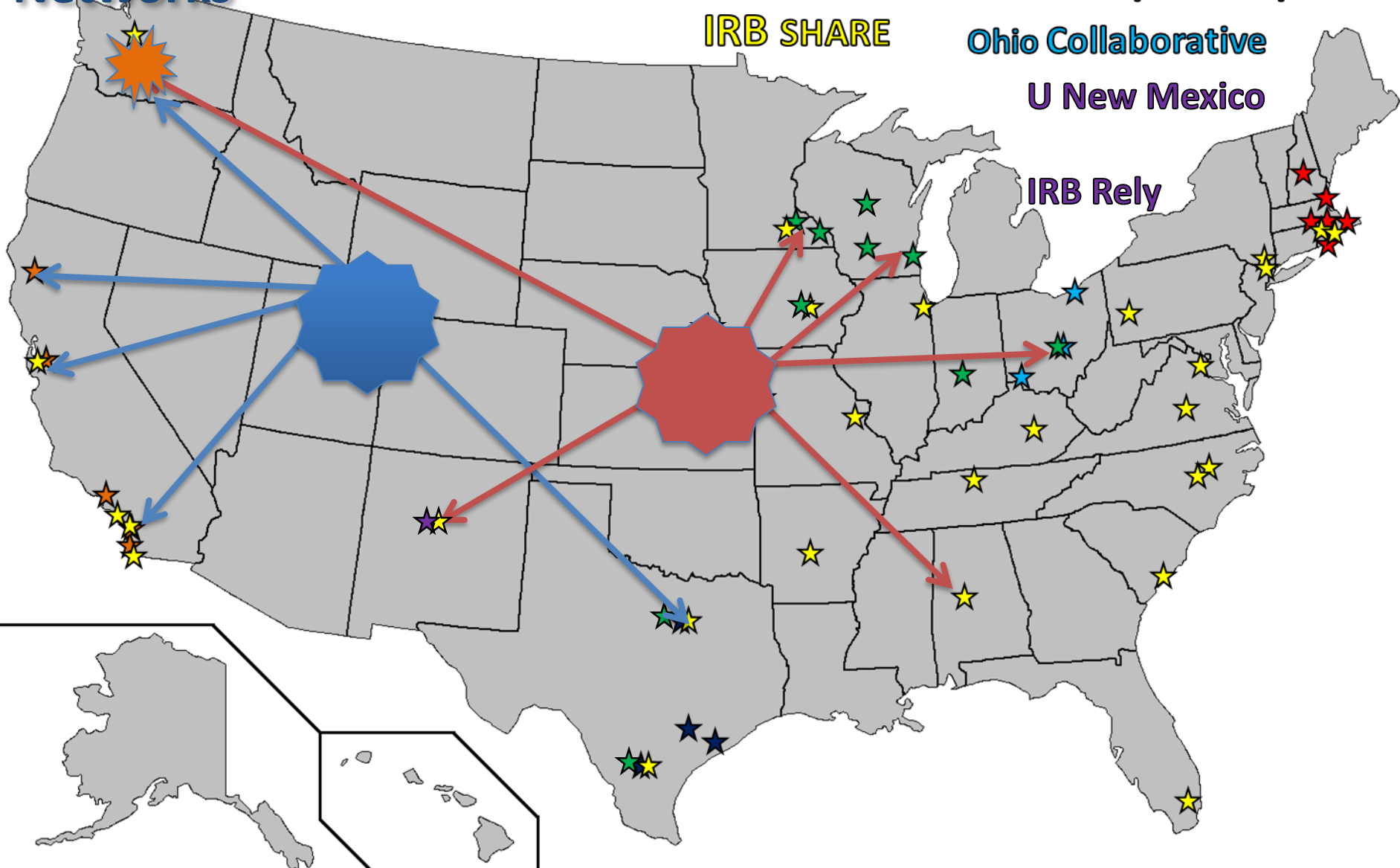
New England

Wisconsin/MARCH/GPC

Ohio Collaborative

U New Mexico

IRB Rely



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

Sstreamlined, 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 CTSA came together to develop a national IRB reliance agreement

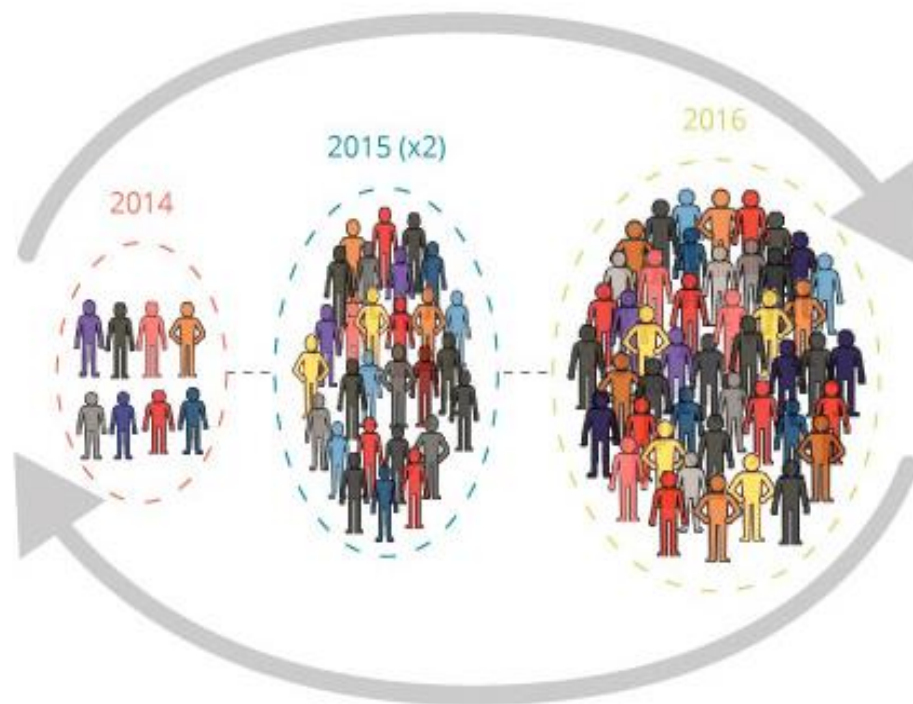
- Public & private universities
- Academic healthcare centers

Shared with 72 Institutions

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

Shared with 115+ Institutions

- + 64 CTSA 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

Principal Investigator

Lee Nadler, MD

Principal Investigator
Harvard Catalyst | The Harvard Clinical and Translational Science Center

Co-Investigator

Alan Green, MD

Principal Investigator
Dartmouth Synergy Clinical and Translational Science Institute

Co-Investigator

Marc Drezner, MD

Principal Investigator
UW Institute for Clinical and Translational Research
University of Wisconsin-Madison

Executive Director

Laura Weisel, MBA

Executive Director
Harvard Catalyst

Director of Regulatory Policy

Barbara Bierer, MD

Program Leader
Regulatory Foundations, Ethics, and Law Program
Harvard Catalyst

Chief Regulatory Operations Officer for Implementation

Nichelle Cobb, PhD

Director
Health Sciences IRB Office
University of Wisconsin-Madison

Chief Informatics Officer

Douglas MacFadden, MS

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

