The Trial Innovation Network and SMART IRB Exchange: Promoting Innovation and Standardization around sIRB Review

Emily Serdoz, MPA
Manager of Translational Research
SMART IRB Exchange Project Manager
Vanderbilt University Medical Center
Trial Innovation Network
Objectives

• Provide an Overview of the Trial Innovation Network
• Provide an overview of the SMART IRB Exchange
• Describe current efforts to innovate and standardize processes
Trial Innovation Network
Trial Innovation Network Components

CTSA Hubs

- Trial Innovation Network Hub Liaison Teams
- Collaborative Strategic Management

Trial Innovation Centers (TICs)
- Trial Innovation Centers (TICs)

Reruitment Innovation Centers (RIC)
- Recruitment Innovation Centers (RIC)

Partners
- NIH ICs
- Federal
- Non-federal

Partners
- Participants
- Providers
- Public
Trial Innovation Network

- Initiative launched by NCATS to leverage the resources of the CTSA and help accelerate clinical trials

- **Three Trial Innovation Centers [TICs] each with their own central IRB [CIRB]:**
  - University of Utah
  - Duke University/Vanderbilt University
  - Johns Hopkins University School of Medicine/Tufts University

- **Recruitment Innovation Center [RIC]: Vanderbilt University**

- **Trial Assignment through the Proposal Assessment Team [PAT]**

CIRB Working Group Goals

- Develop systems and tools to support the activities of the CIRB
- Develop plans to monitor the IRB approval process and develop metrics to evaluate CIRB success
- Work with other TICs to develop innovative strategies for operationalizing CIRB review

Activity of the TIC CIRBs is support by a platform hosted by Vanderbilt:

SMART IRB EXCHANGE
**Trial Innovation Network**

*Key Federally-Funded Resources that Support Single IRB Review and TIN CIRBs*

- **Sponsor**
  - NCATS
    - (National Center for Advancing Translational Science)

- **Initiative**
  - Trial Innovation Network
  - SMART IRB

- **sIRB Tools and Resources**
  - SMART IRB Exchange
  - CIRB Letter of Indemnification
  - SMART IRB Reliance Agreement
  - Ambassadors & Working Groups
  - Online Reliance System

*Tools used by TIN CIRBs*
Trial Innovation Network
TIN CIRB Infrastructure

SMART IRB
>300 sites

SMART IRB Exchange
112 sites

CIRB LOI
72 sites

Current Use
- Launched Feb 2017
- 27 TIN studies
- 20 Non-TIN studies

Users
- >400 users (IRB staff, PIs, coordinating center staff, and study teams)

>300 sites

112 sites

72 sites
Trial Innovation Network

TIN CIRB Studies

27 TIN Studies with CIRB Services

- Supporting more than 319 reliances across all studies
- 12 studies in pipeline pending NIH funding

Diverse Study Demographics

- **Vary in Size**: # of participating sites ranges from 2 to ~60
- **Include Diverse Types of Institutions**: sites include academic medical centers, VA hospitals, small clinics, and adult day centers
- **Cover the Lifespan**: study participants range from neonates to adults with limited decision making capacity
SMART IRB Exchange

A web-based platform to support single IRB workflow and implementation
SMART IRB Exchange

- SMART IRB Exchange Supports sIRB Implementation
  - IRBs document and track IRB reliance relationships
  - IRBs and study teams manage all IRB approval documents for Participating Sites
  - IRBs and/or Coordinating Centers streamline and automate study-related notifications to Participating Sites
  - Lead Study Teams or Coordinating centers monitor study start up and manage approvals
  - Coming Soon: IRBs and study teams centralize and standardize the capture of local considerations

Users
- HRPPs/IRBs
- Study Teams
- Coordinating Centers

Use Cases
- All TIN studies
- Non-TIN studies
- Non-SMART IRB agreements

Current Use
- Launched Feb 2017
- 112 institutions
- 47 studies
HRPPs track all reliance relationships
**Current Tracking Tool**

### Participant Status Summary

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HRPPs, CCC, Lead Study Teams track site progress on specific studies.
COMING SOON: Capture & Track Local Context

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Part I: Institutional Local Context

Section 2: LOCAL CONTEXT

In what state is your institution located? TN

Age of majority in your state? 18

How does a minor become emancipated in your state?
- By judicial petition with age limitations
- By judicial petition
- By marriage
- By joining the armed forces
- Temporarily while in policy custody to consent to medical treatment
- After giving birth
- Other

Please describe how a minor becomes emancipated in your state: See attached Department of Health definition of emancipated minor

What circumstances affect age of consent in your state? For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment

Only adults 18 year or older and emancipated minors can consent.

Do you have any state or local laws or institutional policies that require record keeping for longer than federal law requires under the Privacy Rule or Common Rule?

No

Please indicate the diseases below that require mandatory reporting to health authorities in your state. Please do not include all diseases, only list those diseases for which there would likely be a reason for testing in a research setting.
- Cancer
- Hepatitis A
- Hepatitis B
- Hepatitis C
- HIV
- All communicable disease
- Other (please describe below)

Do you require specific language in your consent form to describe what requires mandatory reporting to authorities? Yes

Institutional Profiles:

General overview of the organization:
FWA number & legal components
Is the organization a HIPAA covered entity?
Is the organization accredited?

Over-arching state laws or institutional policies that affect all research at the organization?

Organizational Noncompliance:
Have there been any recent findings [OHRP/FDA] about your site?

How your site works
Is your organization willing to serve as the privacy board?
Does your site permit the use of short forms?
Part 2: Study-Specific Local Context Questionnaire

**Process**

- Completed by the Relying Organization on a study-specific basis
- Allows the Relying Organization to provide site-specific information with consideration for the specific study
  - What are the institutional policies that are relevant for THIS study?
    - What ancillary reviews are required for THIS study?
- Completion can be concurrent with the process to ensure all other responsibilities have been addressed [training, COI, etc.]

**Content**

- Whether any FCOIs been identified specific to this study & provision of management plans
- Verification of appropriate training/credentials for site study personnel
- Study-specific consent requirements [general consent requirements may be collected up front]
- Identification of ancillary reviews that may impact the review of the sIRB
- Site specific requirements based on state law/institutional policy relevant to the study [data security, recruitment, community considerations]
COMING SOON: Capture & Track Local Context

- Track site’s progress towards reliance
- Track submission of local considerations:
  - Site-specific
  - Study-specific
  - PI/Study Team
- Send reminders to or notify sites about questions or clarifications
- Export completed information

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Capture site-specific approval documents

Sites can download all docs in single file
Automatically notify relevant Study Teams + HRPP contacts of approval

Include IRB approval documents