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

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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)

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 CTSAAs 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 supported 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

SMART IRB EXCHANGE
- Launched Feb 2017
- 27 TIN studies
- 20 Non-TIN studies
- >400 users (IRB staff, PIs, coordinating center staff, and study teams)

Current Use
- Users

CTSA Clinical & Translational Science Awards

TRIAL INNOVATION NETWORK
**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

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

**Current Use**
- Launched Feb 2017
- 112 institutions
- 47 studies

**Users**
- HRPPs/IRBs
- Study Teams
- Coordinating Centers

**CTSA Clinical & Translational Science Awards**

**TRIAL INNOVATION NETWORK**
HRPPs track all reliance relationships
## Current Tracking Tool

### Participant Status Summary

<table>
<thead>
<tr>
<th>Site</th>
<th>SMART IRB</th>
<th>SMART IRB Exchange</th>
<th>Reliance Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baylor College of Medicine</td>
<td>✓</td>
<td>✓</td>
<td>Complete</td>
</tr>
<tr>
<td>Boston Medical Center</td>
<td>✓</td>
<td>✗</td>
<td>Not registered</td>
</tr>
<tr>
<td>Clinical Eye Research of Boston</td>
<td>✗</td>
<td>✓</td>
<td>Pending acceptance</td>
</tr>
<tr>
<td>Cornea Associates of Texas</td>
<td>✓</td>
<td>✓</td>
<td>Complete</td>
</tr>
<tr>
<td>Cornea Consultants of Nashville</td>
<td>✓</td>
<td>✓</td>
<td>Complete</td>
</tr>
<tr>
<td>Dartmouth College</td>
<td>✓</td>
<td>✗</td>
<td>Not registered</td>
</tr>
<tr>
<td>Delray Eye Associates, PA</td>
<td>✓</td>
<td>✓</td>
<td>Complete</td>
</tr>
<tr>
<td>Duke University Health Systems, Inc.</td>
<td>✓</td>
<td>✓</td>
<td>Not registered</td>
</tr>
<tr>
<td>Eyecare MD of New Jersey</td>
<td>✓</td>
<td>✓</td>
<td>Complete</td>
</tr>
</tbody>
</table>

HRPPs, CCC, Lead Study Teams track site progress on specific studies.
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
## Part I: Institutional Local Context

### Section 2: LOCAL CONTEXT

<table>
<thead>
<tr>
<th>Question</th>
<th>TN</th>
</tr>
</thead>
<tbody>
<tr>
<td>In what state is your institution located?</td>
<td></td>
</tr>
<tr>
<td>Age of majority in your state?</td>
<td>18</td>
</tr>
<tr>
<td>How does a minor become emancipated in your state?</td>
<td></td>
</tr>
<tr>
<td>Please describe how a minor becomes emancipated in your state.</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>Only adults 18 year or older and emancipated minors can consent.</td>
</tr>
<tr>
<td>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?</td>
<td>No</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
</tr>
<tr>
<td>Hepatitis A</td>
<td></td>
</tr>
<tr>
<td>Hepatitis B</td>
<td></td>
</tr>
<tr>
<td>Hepatitis C</td>
<td></td>
</tr>
<tr>
<td>HIV</td>
<td></td>
</tr>
<tr>
<td>All communicable disease</td>
<td></td>
</tr>
<tr>
<td>Do you require specific language in your consent form to describe what requires mandatory reporting to authorities?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### 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
### Documents

<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
<th>Size</th>
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<tbody>
<tr>
<td>Protocol [1.1]</td>
<td>PRO VERS 1.1.pdf</td>
<td>1 MB</td>
</tr>
<tr>
<td>Determination Letter</td>
<td>IRB FAL.pdf</td>
<td>255 KB</td>
</tr>
<tr>
<td>Consent Forms - Consent Document</td>
<td>Stamped-042 Georgetown ICD.pdf</td>
<td>2 MB</td>
</tr>
<tr>
<td>Others - Other Document</td>
<td>Stamped-042 Georgetown Poster.pdf</td>
<td>370 KB</td>
</tr>
<tr>
<td>Others - Other Document</td>
<td>Stamped-042 Georgetown Brochure.pdf</td>
<td>1004 KB</td>
</tr>
<tr>
<td>Others - Other Document</td>
<td>Stamped-042 Georgetown Poster Vers 2.pdf</td>
<td>369 KB</td>
</tr>
<tr>
<td>Others - Other Document</td>
<td>Stamped-ZEDS Recruitment Referrals.docx.pdf</td>
<td>660 KB</td>
</tr>
<tr>
<td>Others - Other Document</td>
<td>Stamped-Participant Card 2017.0511.docx.pdf</td>
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</tr>
<tr>
<td>Others - Other Document</td>
<td>Stamped-Participant Instructions and Diary_AU 2017.0515.pdf</td>
<td>6 MB</td>
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<tr>
<td>Others - Other Document</td>
<td>Stamped-Patient Instructions_Quest lab.docx.pdf</td>
<td>1 MB</td>
</tr>
<tr>
<td>Others - Other Document</td>
<td>Stamped-Screening Log for CC.pdf</td>
<td>541 KB</td>
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</tbody>
</table>

**University of Pennsylvania**

- **Initial Study: Full Board**
Dear All,

Vanderbilt University Medical Center has shared IRB approval for your institution, Baylor College of Medicine, for the following study:

**Zoster Eye Disease Study (ZEDS):** A multi-center, randomized, double-masked, placebo-controlled clinical trial of suppressive therapy in participants with a history of dendriform epithelial keratitis, stromal keratitis, endothelial keratitis, and/or iritis due to herpes zoster ophthalmicus.

This was an Initial Study: Full Board approval by the Reviewing IRB. The expiration date is 05/23/2018.

Principal Investigators & Study Contacts:
Your approval documents are attached. Please refer to the submission instructions sent previously regarding how to handle future submissions and reporting of events.

Access the study at: [https://sirb.trialinnovationnetwork.org/study/index/?proj=32](https://sirb.trialinnovationnetwork.org/study/index/?proj=32)

Thank you,
The SMART IRB Exchange Team