CIRB in your future? Flexibility Tips!

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Agenda Overview:

PART I: Who we are/Our role as Trial Innovation Center CIRBs

PART II: Areas of Challenge in Operationalizing sIRB Review & Tools we are Using to Inspire Flexibility

- The Process for Ceding Review
- Consent Forms
- Local Context

Part III: Stretching our Flexibility

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PART I: Who are we/Our role as Trial Innovation Center (TIC) CIRBs

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What is the Trial Innovation Network?

The Trial Innovation Network is a new collaborative initiative within the CTSA Program and is composed of three key organizational partners – the CTSA Program Hubs, the Trial Innovation Centers (TICs), and the Recruitment Innovation Center (RIC). The goal is to improve the clinical trials process and introduce operational innovations in trial planning & execution.

Three Trial Innovation Centers [TICs] each with their own central IRB [CIRB]:

- University of Utah
- Duke University/Vanderbilt University
- Johns Hopkins University /Tufts University

Recruitment Innovation Center [RIC]: Vanderbilt University

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What is the charge of the Trial Innovation Center CIRBs?

- ❖Work together to develop harmonized SOPs, tools and approaches to streamline the operationalization of CIRB review
- ❖Develop systems to support the activities of the CIRB
- ❖Develop plans to monitor the IRB review process and metrics to evaluate CIRB success
- ❖Test innovative strategies for CIRB review through the provision of CIRB services

Important Facts

- Trials are “Assigned” to each TIC CIRB
- Each TIC CIRB processes studies per its normal review pathway [Common review strategies/tools are used across the three TIC CIRBs]
- TIC CIRBs may support studies for which there is no local investigator engaged
- Studies approved for CIRB services are diverse in type and scope:
  - Wide range in the number of sites
  - Varied experience in sites supported
  - Challenging regulatory areas [EFIC, research with vulnerable populations]

How do we work together?

- Weekly phone calls
- Three face-to-face meetings annually to share lessons learned, prioritize tasks and harmonize efforts
- Activity of the TIC CIRBs supported by a platform hosted by Vanderbilt University

smart irb exchange

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What do **WE** see as our mission?

- Force our own flexibility
- Foster a dialogue to understand the barriers to sIRB review:
  - Resources? Uncertainty? Institutional Rigidity?
- Provide good data about what works/doesn't work
- Continuously incorporate feedback from our research partners

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PART II: Areas of Challenge in Operationalizing sIRB review and Tools we are Using to Inspire Flexibility

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Challenge Area: The Process for Ceding Review

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CHALLENGE: The Reliance Agreement

OUR SOLUTION: SMART IRB Master Common Reciprocal Reliance Agreement

- Standardization is implementing flexibility

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CHALLENGE: The Reliance Agreement

OUR SOLUTION: SMART IRB + Exchange's "SSRP"

- SMART IRB reliance agreement *offers* flexibility
  - Auditing
  - HIPAA
  - External Reporting
- Exchange documents what flexibility looks like for a study

Exchange: Study-specific Reliance Plan (SSRP)

HIPAA: Will the Reviewing IRB review HIPAA authorizations and requests for waivers for Relying Institutions? (Note: All entities are responsible for local accounting of disclosures):	Yes
The Reviewing IRB's process for **external reporting** (e.g., unanticipated problem, serious or continuing non-compliance, suspensions or terminations) to OHRP/FDA is to:	○ File first without comment from the relying IRB ● Work jointly with the Relying Institution on the report ○ File once letter has been reviewed by the relying IRB ○ Allow relying IRB to independently file report after review and comment
Will the Reviewing IRB provide an opportunity for Relying Institutions to comment on **unanticipated problem or serious or continuing non-compliance reports** to OHRP/FDA?	Yes
The Reviewing IRB will allow the following amount of time for the Relying Institution to comment on **unanticipated problem or serious or continuing non-compliance reports**:	5 calendar days
Will the Reviewing IRB provide an opportunity for the Relying Institution to comment on **suspension/termination for cause reports** to OHRP/FDA?	Yes
The Reviewing IRB will you allow the following amount of time for the relying Institution to comment on **suspension/termination for cause reports**:	72 hours
The following person at the Reviewing IRB/Institution should be contacted if a Relying Institution learns of an unanticipated problem or serious or continuing non-compliance, or to report suspensions or terminations:	Rebecca Abel singlerb@vanderbilt.edu 615-875-8960
In the event that a **for cause audit** needs to be conducted at a Relying Institutions, the following applies:	○ The Relying site would conduct the audit ○ The Reviewing IRB would conduct the audit ● The Reviewing IRB would work with the Relying site to share audit responsibilities ○ The Reviewing IRB would hire an independent entity to conduct the audit ○ Other
For **routine audits** at a Relying Institution, the following applies:	○ The Relying site would conduct the audit ○ The Reviewing IRB would conduct the audit ● The Reviewing IRB would work with the Relying site to share audit responsibilities ○ The Reviewing IRB would hire an independent entity to conduct the audit ○ Other

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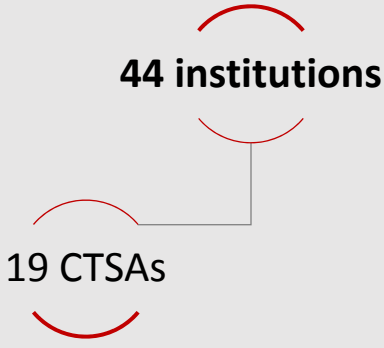
CHALLENGE: Indemnification

OUR SOLUTION: Common Letter of Indemnification (LOI)

- TIN CIRBs utilize the same LOI
- State + Non-state requirements and limitations
- LOI as a template for other, non-TIN studies
- Define "Covered Research" for your institution (e.g., types of studies that require indemnification)



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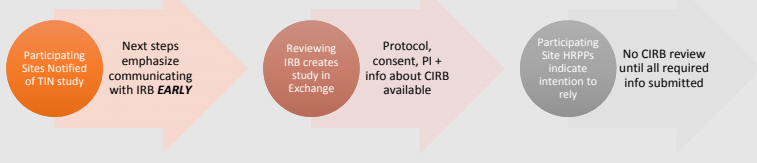
CHALLENGE: Institutional Requirements to Cede Review

- **Our Solution: Separate the intention to rely from the local context review**
  - Varying processes confuse investigators (e.g., some of us require submissions before indicate plan to rely)
  - Don't confirm local context until you have (1) completed the necessary reviews and (2) any locally required submission
  - CIRB does not grant approval without local context



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Challenge Area: Consent Forms

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Consent Forms- Challenges

- Everyone wants their own template, layout, and language
- Investigators may not provide most accurate template language
- Allowing access to editable document may result in multiple versions of consent making document management challenging and cumbersome

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Consent Forms– Ideas/Solutions?

Development and use of general HIPAA language

- Network specific HIPAA authorization language for all consent documents
- All regulatory elements fulfilled by language

Consent Forms– Ideas/Solutions?

Use of network wide short form for non-English speakers

- Minimize multitude of varied documents for different sites
- Ensure standardization of information approved by IRB for participants
- Streamline document management at both IRB and coordinating center level

Consent Forms– Ideas/Solutions?

Site-specific components

- Sites will provide local language for a site-specific page to be included with each template consent form
- Streamlines consent form creation
- Committee reviews consent template once, but can more easily review local context information with individual site specific forms that are included with the template

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Challenge Area: Local Context

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Local Context - Challenges

Gathering information from each site:

- Does it include everything (adequate to review on another's behalf)
- Burdensome to provide information
- Redundant information for each study

Local Context – Ideas/Solutions?

Institutional Profiles:

- Information that does not change per study
- Filled out once (potential check in annually)
- Includes local laws, policies, information about the institution (site) and populations served
- Build a "library or repository" of institutional profiles usable to anyone wishing to review for another site

Local Context – Ideas/Solutions?

Study specific information:

- Collected from Investigators, potentially in RedCap
- Specific to the study that might vary study to study (e.g., recruitment methods)
- Questions the PI's IRB might ask on their applications

PART III: Stretching our Flexibility

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Part III – Stretching Our Flexibility

How do we push through our discomfort?

- HIPAA language and determinations
- Local standards of care differences
- Conflicts of Interest
- Assessing and reporting non-compliance

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HIPAA Language & Determinations

- Are we okay using HIPAA authorization language written by another institution?
  - Lay language preferences
  - Organization preferences
  - Formatting preferences
- Are we okay letting another institution determine when sharing our data is okay using a waiver of authorization?
  - Agreeing with justification for the waiver
  - Institutional data sharing policy considerations
  - Oversight of data use, sharing, and transfer agreements

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Local Standard of Care Differences

- Are we okay with more general statements about costs in the consent document?
- Are we okay with risk determinations based on different standards of care?

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Conflicts of Interest

- Are we okay with the management plans from other institutions?
- Are we okay with a CIRB adding restrictions on top of our management plans?
- Are we okay allowing COI language in a consent form written by another institution?

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Assessing and Reporting Non-Compliance

- Are we okay with non-compliance definitions and interpretations used at other institutions?
- Are we okay with the corrective and preventive actions that may be issued by another institution?
- Are we okay with the external reporting 'style' used by another institution?
- Are we okay letting our 'troublesome' investigators be overseen by a CIRB?

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Questions/Discussion?

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