SESSION II: MODELS FOR ASSISTING INSTITUTIONS RELYING ON sIRB

Incorporating sIRB Procedures into an Existing Research Network

University of Rochester CTSA Supplement
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### Who we are...

<table>
<thead>
<tr>
<th>Institution</th>
<th>Scientist/Investigator</th>
<th>IRB Professional</th>
<th>Coordinator</th>
<th>IT Professional</th>
<th>CTSI Consultants</th>
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<td>(NICHD)</td>
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<td>Rochester</td>
<td>D’Angio</td>
<td>O’Donoghue Gommel Dauenhauer</td>
<td>Scorsone</td>
<td>Nguyen</td>
<td>Bennett Rubinstein</td>
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<td>Case</td>
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<td>RTI</td>
<td>Das</td>
<td>Zaterka-Baxter</td>
<td>Palberg</td>
<td>Auman</td>
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6 of 15 institutions in multicenter, NICHD-funded Neonatal Research Network (NRN)
Grant Aims

1. Establish responsibilities and relationships for the sIRB system in multi-site research network

2. Develop tools, procedures and standards for communication and data storage and handling

3. Develops standards for the cost structure of multi-site projects for a sIRB review
Grant Aims

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3. Develops standards for the cost structure of multi-site projects for a sIRB review
Discussion Points – Aim 1
Roles and Responsibilities

Themes
• Responsibilities of the single IRB and its institution
  • Minimal requirements to act as a central IRB
  • Ensuring the lead PI understands responsibilities
• Responsibilities of relying IRBs and their institutions
  • Shape and extent of local institutional review
  • Avoiding overlap of responsibility with sIRB
• Role of Data Coordinating Center
• Relationships to Data and Safety Monitoring Committee
• Contingency planning for turnover of sIRB
Roles and Responsibilities

**Central**
- "PI" duties
- IRB
- HIPAA

**Local**
- Human Research Protection Program
  - Training
  - COI
  - Local Context
  - Monitoring
  - Ancillary reviews
  - Etc.
Discussion Points – Aim 2
Communication

**Themes**

- Formal structure of communication
  - Communication is key and needs to be laid out early
  - When available, what role for a Data Coordinating Center or Coordinating Center?

- Information technology requirements and systems
  - Minimum requirements and specifications
  - Interoperability
  - Secure communication, data storage and sharing

- Relationship to other communication platforms (SMART IRB, CTSA TIN, etc.)
Communication
Technical Issues

• Multiple IRB software systems
  • Poor interoperability
  • Not all can manage external submissions/investigators

• Most sIRB interaction systems new/incomplete
  • SMART IRB – reliance only
  • iREX (Vanderbilt) – gradually adding functions
Lead PI and sIRB at the same institution

sIRB (Institution A)

Lead PI (Institution A)

B
C
D
E
F
G

Additional Sites
Lead PI and sIRB at different institutions

- PI (Institution A)
- single IRB (Institution B)
- DCC
- Additional Sites:
  - C
  - D
  - E
  - F
  - G

Network
Lead PI and sIRB at different institutions

**DCC hub for communication**

- **Lead PI (Institution A)**
- **single IRB (Institution B)**
- **Additional Sites**
  - C
  - D
  - E
  - F
  - G
- **Network**
- **DCC**
Lead PI and sIRB at different institutions

sIRB hub for communication, but DCC information center

Network

Lead PI (Institution A)

single IRB (Institution B)

DCC

Additional Sites

C
D
E
F
G
Phase II

- Originally planned as mock reviews of existing studies
  - Advantages – comparability to actual pace of review
  - Disadvantages – duplication of effort, resources for “mock” reviews
- Altered to review of two upcoming randomized, controlled trials
  - Testing DCC-centric and sIRB-centric models
  - Advantages – effort is “real”
  - Disadvantages
Different Perspectives on Relying IRB - Rochester

- Long history of use central IRB’s
- Use own IRB application platform to manage institutional portion of external sIRB applications = two (or one-and-a-half) applications
- Clear institutional guidelines
  - Sensitive investigator information doesn’t leave UR
- Considers qualities of sIRB
  - AAHRPP accreditation
- “IRB Exchange (iREX)”
  - Cloud-based, multi-institutional capability
Different Perspectives on Relying IRB – UT Southwestern Medical Center

• Separate reliance team
  • Both for IRB of record and relying IRB applications
  • Pre-reliance meeting
• Separate system (REDCap) for intent-to-rely application
• Multiple inter-institutional agreements
  • Like all other centers, encourage SMART IRB
  • Clear delineation of responsibilities
• All documents leaving institution to go to sIRB (e.g. amendments) are first reviewed by UTSW
Conclusions

- **Impact** – Developing/testing standards for sIRB review for multi-site, existing research network
- Resources and infrastructure *partly generalizable* to other institutions that might serve as or rely on a sIRB of record
  - Every system is different
- **Best practices** for information flow for facilitating sIRB review for multi-site research may emerge from Phase II
- **SMART IRB** and other platforms facilitate multicenter work, rather than vice-versa
Thank you