IRBrely

Where we started, where we are, where we’re heading...

Sabune J. Winkler, JD
Co-Regulatory Lead for IRBrely
Director, Regulatory Affairs Operations Operations
Harvard Catalyst | the Harvard Clinical and Translational Science Center

Nichelle Cobb, Ph.D.
Co-Regulatory Lead for IRBrely
Director, Health Sciences Institutional Review Boards Office
University of Wisconsin Madison, Wisconsin

Flexibility Coalition
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Today’s IRBrely Conversation

• Quick Review: Origins and Aims
• Current Status
• Next Steps
What are we talking about?
Toward a National IRB Reliance System

October 2014 – August 2015

Develop a standard IRB reliance agreement with supporting SOPs and informatics that:

– is not specific to a research area or region
– can be used for small and large-scale studies
– can be applied to a range of research areas
– can be expanded beyond CTSA sites
– can allow FWA only institutions and IRB organizations to participate
Major IRB networks working together to develop a standard IRB reliance agreement with supporting SOPs.
The National IRB System
IRB *Reliance* Project is a standard reciprocal IRB reliance agreement with supporting SOPs

The IRB reliance agreement and supporting SOPs are **NOT:**

– A template – this is an executable master agreement
– A Central IRB model, but can be used to support central IRBs
– Limited to CTSA sites – open to all who meet the requirements
– Limited to AAHRPP accredited sites – other ways to demonstrate quality
– Set in stone – iterative learning and development
# Components and Activities of IRBRely

<table>
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<th><strong>IRB Master Reliance Agreement</strong></th>
<th><strong>Standard Operating Procedures (SOPs)</strong></th>
<th><strong>Informatics Support</strong></th>
<th><strong>Pilot</strong></th>
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<td><strong>OCT-DEC 2014</strong></td>
<td><strong>JAN-APR 2015</strong></td>
<td><strong>MAY-AUG 2015</strong></td>
<td><strong>Demonstrate feasibility of proposed national IRB reliance model by piloting with a low-risk multi-center clinical trial</strong></td>
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| - A Single IRB authorization form that all sites can use to cede review | - Spell out roles and responsibilities:  
  - Reviewing IRB  
  - Relying Site(s)  
  - Lead PI & Lead Study Team  
  - Relying Study Team(s)  
  - Lead Regulatory Contacts (aka POCs) | - IRBRely.org  
  (Informational website)  
  - Mechanism to join  
  - End-to-end, workflow-based platform (in development) for study teams and sites to request and determine IRB reliance | - Duke University served as Reviewing IRB; 15 sites ceding review  
- Obtaining feedback from participating sites on agreement and SOPs for roll out beyond the pilot  
- Testing forms and workflows developed in support of reliance to revise and enhance processes |
| - Reliance model: single IRB of record, chosen on study-by-study basis, for life of study; a “reviewing IRB” and “relying institutions” | | | |
IRBrely by the ####

7 participating major IRB networks represent

- 74 institutions
- 19 states
- 25 of the 62 CTSA institutions

48 institutions sent comments and suggested edits to the agreement and SOPs

✓ 19 of the 48 would have accepted the agreement as-is
Next Steps for IRBrely

**Finalize and Expand**
- Finalizing the edits from the 48 institutions
- Sending the agreement for final review
- SIGN
- Expand agreement to other sites
- Ensure that we have participation from all states

**Look to the Future**
- Identify sustainability funding
- CTSA Network - Trial Innovation Centers (TICs)
  
  “TICs will be lead centers of excellence in clinical trials and will facilitate the implementation of multi-site clinical studies by the CTSA Program network.”

Next Steps for YOU

We are learning as we go! Contact us to:

• Review and join the agreement and SOPs
• Set up meetings and presentations to discuss the agreement and SOPs
• Identify studies to pilot the study and workflow
• Identify opportunities to harmonize with other existing IRB networks
• Commiserate and share stories and wisdom to inform and influence the final products! ☺

Sabune Winkler
Sabune_Winkler@hms.harvard.edu

Nichelle Cobb
nlc@medicine.wisc.edu