

An Unrealized Opportunity: Non-acceptability of Federated IRB Review

A Zadell, M Walsh. CWRU Study Center

Introduction: NCS is one of the largest multi-center studies ever. Despite being observational, the scope, evolving protocol and longitudinal evaluations have challenged IRBs. Duplicative reviews add cost and delays yet do not enhance subject protection. Originally developed by CTSA's, a Federation of IRBs with the NICHD as the IRB of record may reduce redundancy and cost.

Purpose: To describe CWRU experience and barriers to Federated IRB.

Context: CWRU has 3 large academic centers with OB service. Health care is highly integrated with 2 large systems (UH, CCF) with multiple hospitals, 1 county hospital (MHMC) and 2 independent hospitals. CWRU CTSA collaborates with the 3 IRBs and runs Cancer IRB for all. Each IRB has independent software. We anticipated acceptance of Federated approach. Instead, each opted for Tier 3, and independent review of submissions, amendments, and advertising. Barriers cited were lack of AHARP certification. IRBs agreed that UH IRB would review all submissions first, and share reviews with others to reduce delays. (Fig) One independent hospital chose NICHD Tier 1. In May 2011 the CTSA opened an electronic hub. CWRU NCS requested use but was denied: *"This study does not qualify for facilitated review.... The Boards found the length of the study, complexity of design, and the scope of potential testing to be too extensive to review the study in such a way"*.

Conclusions: A federated IRB approach is not currently viewed as feasible. Staggered review has reduced time to approval, but not the cost of duplicative submissions.

(247 words)

