

Concurrent Session A5-1

**Progress in the HMO Research Network Toward Streamlined
Multi-site IRB Review**

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Introduction: The will is building in the HMO Research Network toward a more coordinated approach to institutional review board (IRB) review of multi-center studies. Over the last 12 months, progressive discussions among researchers and IRB administrators helped establish willingness to test a new model for IRB review, in which a lead site initiates IRB review at their local IRB, and other participating IRBs complete an expedited review, or may choose to cede to the lead site. Planning and execution of a pilot-test of a "consortium-model" multi-site IRB review for selected low-risk, data-only studies is described.

Methods: Various alternative models of multi-site IRB review were identified in meetings with IRB administrators and researchers in October 2006. Barriers and facilitators to the use of these different models were vetted in small group and full group discussion sessions. Stakeholders reached agreement to pilot a consortium-model with a carefully-selected set of data-only studies that include at least three HMO sites. Studies will be identified in 4th quarter 2006, and reviewed by the lead & participating IRBs in 1st quarter 2007. A blueprint will be developed to guide the process.

Results: We will provide preliminary outcomes of the pilot test, and identify newly emergent issues that may promote or impede further exploration and utilization of a consortium model.

Discussion: The HMORN is in the vanguard of research consortia willing to explore alternative models for multi-site IRB review. Key factors influencing the success of different multi-site review models are an assurance that the quality of the review would be preserved and that any new processes that are developed will be more efficient than current approaches. Additionally, it is essential to develop a clear understanding of institutional liability among all constituents, as well as each site's local context and culture. The pilot will provide an opportunity to examine both of these issues in depth.