

POSTER ABSTRACTS

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11:45 am – 2:00 pm
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PS2 – 40

Evaluation of e-IRB Systems for Use in an HMORN Site

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Background: Federal regulations require complex record-keeping of communication between the Institutional Review Board (IRB) and scientific investigators. Current-state IRB record-keeping at Group Health Center for Health Studies (CHS) is mainly a paper-based system supplemented by various non-integrated customized databases, requiring extensive manual offline processes to manage an already highly sensitive area of compliance. This has resulted in burdensome administrative paper requirements and necessitated the development and use of manual and non-standardized interfaces and prompted the formation of a workgroup at CHS to define our needs for an electronic Institutional Review Board (e-IRB) system.

Methods: A cross-department evaluation team was formed. The first goal of the team was to assess our current IRB system and complete a needs evaluation. Input was gathered from surveys and meetings with key stakeholders and current system utilizers. One of the surveys collected information about other HMORN sites using or planning to use an e-IRB system. The second goal of the team was to conduct an evaluation of products to meet our needs. This included commercial electronic research administration products currently available, systems in development at other research sites, and the possibility of developing a system in-house. To accomplish the second goal, a Request for Proposal (RFP) was sent to 3 candidate vendors and, from this pool, an in-depth evaluation was performed on 2 vendors.

Results: The needs assessment revealed broad support for an e-IRB system. The HMORN survey showed that most HMORN members are using or planning an e-IRB system, mostly with a commercial product. Based on extensive interaction with vendors and e-IRB users, the evaluation team recommended purchase of one of the systems and created an implementation and maintenance plan. The evaluation process yielded several lessons about implementing a new electronic process. These lessons covered the entire process, from leadership support at the start to staffing support after the system has been implemented.

Conclusions: Our needs reflect the current industry-driven change towards an e-IRB system. This will decrease the inefficiencies inherent in a paper system while decreasing our risk for error in light of increasingly stringent documentation requirements. In time, the adoption of e-IRB systems within the HMORN may increase collaboration within and among institutions.