Internal Centralized IRB for Multi Site Community Health Care Network

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ADDITIONAL INFORMATION

Our unique HRPP structure consists of 1 centralized IRB; 1 Institutional Official; we maintain a single corporate-wide FWA on which each hospital is listed as a component. The centralized IRB is a multidisciplinary compilation of members from each of the previous IRBs, as well as additional members from the community and throughout the corporation. By bringing on members of previously existing IRBs, we are able to utilize, not only their professional expertise, but also their knowledge of their local population. Combining previous members with the new greatly reduces the possibility of conflicts of interest such as those that can exist with local IRBs.

Suggestions for Implementing an Internal Centralized IRB:

- Meet with organization stakeholders to get buy in for centralization
- Evaluate processes and procedures at each site
- Involve leadership in the evaluation process
- Engage consultants to assist in assessment and implementation

DESCRIPTION OF THE RESEARCH

The organization approached these issues by developing a centralized corporate Human Research Protections Program. The two big challenges in meeting this goal were the consolidation of each of the hospitals’ IRBs into one corporate structure, and the implementation of an electronic IRB system throughout the corporation.

Our electronic system has the ability for one PI to submit for multiple sites, resulting in:

- Less paperwork for investigators to submit; allows 1 application and 1 ICF for multiple sites
- A local resource for investigators
- Lesser cost for investigators
- Elimination of duplicate reviews while providing review of local context
- Increased efficiency
- Streamlined review process focused on regulatory criteria

PROBLEM STATEMENT

For regional healthcare providers that are comprised of multiple research sites, conducting research can be costly in terms of time, money, and resources. Until 2012, 5 out of the 9 hospitals operated by our organization conducted human research under various local Institutional Review Boards (IRBs). Some of the same projects were conducted at more than one of our sites and were reviewed by more than one IRB. Additionally, each site had its own processes / procedures in place regarding the conduct of research. This resulted in regulatory oversight and subsequent FDA audits with warning letters at some sites. The need to eliminate duplicative and unnecessary IRB review while simultaneously enhancing compliance and operational efficacy across the research enterprise was identified.

BENEFITS OF CENTRALIZED IRB

- Less paperwork for investigators
- A local resource for investigators
- No duplicate reviews
- Review of local context; unlike commercial IRBs
- Increased efficiency
- Streamlined review process