Establishing a Central IRB: Triumphs and Tribulations
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Problem Statement: The US federal government is considering revised regulations that would mandate centralized IRB review of research. In addition, the National Institutes of Health (NIH) is encouraging grantee coordinating centers to implement centralized IRB review. As the coordinating center for an NIH-funded research network, we established a mechanism for centralized IRB review. Here we share the mechanism we used, our successes, and our challenges. In 2006, we conducted formative research to inform the design and implementation strategy for centralized review.

Methods: During this phase, we: conducted an extensive literature review; interviewed established central IRBs; and met with key stakeholders at our institution, within community groups, and at research sites. From this, we designed the central IRB review mechanism, allowing institutions deferring review to the central IRB to contribute and advise on the process. Once the infrastructure was in place, we launched the central IRB review for an upcoming US multicenter trial. Three years after launch, we surveyed the researchers involved to assess the overall opinion of the mechanism we established. Survey results were reviewed, and used to implement system and communication improvements. Responses from those sites opting in showed overall satisfaction with the process, highlighting that centralized review saved time. Of the responses from those sites opting out, the main reason given was the refusal of their institution to rely on an external IRB. A review of our mechanism noted the following benefits of using the central IRB for a large multicenter study: the ease of adding new study sites, as the scientific and ethical review had already occurred, and allowing all sites access to IRB-approved advertising developed by other sites using the central IRB. Through this process, we also noted the following challenges: finding issues that were not initially contemplated when dividing responsibilities between the site’s human subject protections program and the central IRB, and working with sites that had a pre-existing relationship with the central IRB.

Findings: Through this experience, we found that centralized review helped streamline the IRB review process for large, domestic multicenter trials. With the completion of these trials along with operational transitions, our network elected to let the centralized IRB go dormant. However, the infrastructure remains in place, and may be utilized for future trials. Moreover, because our local IRB now has the capacity to provide centralized IRB review, other research groups at our institution continue to rely on the central IRB we established.