Finding Regulatory Flexibility with a Decentralized Exempt Reviewer Process
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Submission Type: Programmatic
Topic Area: IRB Operations
Poster Number: 44

Background: As a land-grant university with a large social and behavioral research component of primarily unfunded human research, the IRB office was overwhelmed with a large number of “exempt” and “not human research” submissions. Almost 30% of total submissions for calendar year 2010 and 2011 were exempt projects. In addition, 10% of projects in 2010 were deemed to be “not human research,” with that number increasing to 21% in 2011. The amount of resources dedicated to review of these submissions was done primarily by a senior staff, accounting for almost 75% of their time. In an attempt to increase utilization of resources, a solution was needed to minimize the amount of time senior IRB personnel spent on these projects. A secondary goal was to reduce the review turn-around time for exempt projects.

Methods: In spring 2011, a decentralized exempt reviewer model was developed. The model required a minimum of two faculty reviewers from each selected unit to become IRB members. Members were appointed by the Institutional Official and added to the IRB roster. The members received specific training on the requirements for conducting exempt research and the concepts of the Belmont Report, among other important items. Federally funded projects were not allowed to be reviewed via the exempt process. Units were selected based on the number of exempt submissions in the previous year, experience of the faculty in working with the IRB, and willingness to participate. Each unit created their own internal processes for handling documentation and record-keeping policies that were compliant with institutional policies. Each year, the units submit a report of the exempt submissions approved via this process to include in the annual metrics.

Findings: The model has been successfully implemented in seven units to date with one more unit ready to implement (five colleges and three departments). Satisfaction with the process has been extremely positive from the investigators, the reviewers, and the IRB office. Review time has decreased and the IRB staff time has been better utilized on riskier projects. An unexpected outcome has been the increased knowledge within each unit of IRB processes and procedures, and the increased quality of research within each unit. Overall, the model has been successful and additional units are being considered for implementation.