The Impact of Submission Assistance on IRB Review Turnaround Time
Lisa Gabel, CIP; Leslie Howes, MPH, CIP; Stanley Estime, MSCI, CIP; Alyssa Speier, MS, CIP; Delia Wolf, MD, JD, MSCI
Harvard School of Public Health

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Problem Statement: Turnaround time is often a measure used when evaluating IRB operations. Organizations may even establish “target” turnaround times for its research community; however, these times often do not account for the variability in the quality of IRB submissions. With that in mind, our Quality Improvement Program (QIP) set out to improve IRB submissions at the onset in an effort to facilitate the IRB review and approval process. We wondered, specifically, will IRB submission assistance improve IRB review turnaround?

Program Description: QIP provides a variety of human research support services, including IRB Submission Assistance. This service offers investigators and their support staff general IRB submission consultation and assistance preparing IRB applications, responding to the IRB’s queries, and drafting and editing study documents (e.g., protocol, recruitment and consent documents, etc.). IRB Submission Assistance has been a popular service amongst our research community; QIP has responded to over 300 formal submission assistance requests since November 2008. While qualitative data, including customer service surveys and informal feedback, has demonstrated a strong and enthusiastic response to the service, quantitative data confirms that the IRB review and approval process is more efficient, as evidenced by quicker reviewer turnaround times. Specifically, we found that IRB review time (in calendar days) for several types of determinations, i.e., time from submission to not human subjects research determination, exemption determination, and expedited approval, was longer by several days as compared to applications receiving assistance from the QIP prior to submission.

Future Use: Organizations looking to improve their IRB review and approval process can replicate this model with little to no additional full time employee support. For example, an existing Quality Assurance (QA)/Quality Improvement (QI) program may scale back its auditing function in an effort to provide this service. Alternatively, a QA/QI program may offer this service with a narrowed focus as opposed to 100% complete review, e.g., offering consent form review and editing; offering preliminary review prior to IRB submission. In the future, we hope to explore whether QIP Submission Assistance improves review time for submissions requiring full board, and whether the service decreases the number and/or amount of clarifications requested from IRB reviewers.