Streamlining an Expedited Review Process of Minor Changes in Previously Approved Research
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Problem Statement: Development of an efficient and robust expedited review process is essential to the timely review of minor modifications to approved protocols, which is ultimately critical to subject safety and welfare. Prior to implementing changes that accompanied an electronic review process, our IRB utilized more staff in a complex workflow model to complete expedited reviews. As a result, the turnaround times for approval lagged. This analysis details our focus on significant process changes during the transition to a fully electronic system. We have identified improved and streamlined aspects of our expedited review process while closely adhering to both federal and institutional regulations and standard operating procedures.

Process Description: Our IRB utilizes expedited procedures to review minor changes to previously approved research. In 2012, a number of different IRB staff members were involved in preparing submissions for expedited review. Those responsible for submission intake, logging, and triaging had limited experience in IRB requirements for expedited review. Submissions determined to warrant review by the convened IRB were also assigned to a different IRB Coordinator to manage. Yet another IRB staff member was responsible for documenting the IRB’s determination and issuing correspondence to the research site. In 2013, our IRB improved the expedited review process by using electronic submissions forms to trigger alerts to a single, designated staff member, who in turn assigns the item to an IRB Coordinator for “end-to-end” processing. With more training and ability to pre-screen for expedited review eligibility, the Coordinator directly manages the submission from intake to documentation of the IRB’s determination, whether by expedited or convened IRB review. This assignment of all expedited review processes to one Coordinator allowed staff to identify problems earlier in the review process and become more familiar with each change being proposed to the research. Transition to the electronic system also eliminated the use of signed determination letters, further reducing process completion time.

Conclusion: Since implementation in early 2013, internal analyses show significant improvement in turnaround time from January 2013 (average = 18 days) to December 2013 (average = eight days). Also, measures have been established to promote consistency and compliance with regulations and standard operating procedures. We have developed an internal expedited review process that is efficient and streamlined. Future analyses will determine whether improved process cycle times are maintained and whether an increased number of submissions are able to be managed by the same number of IRB staff members.