Decreasing Time from Submission to Exempt Determination through the Use of a Submission Checklist
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Background: The average time from submission to exempt determination was 14 days at our institution. While this is below the average HRPP turnaround time of 17 days, according to Association for the Accreditation of Human Research Protection Programs’ 2012 published metrics, many of the items frequently holding up determinations in the institution could be easily avoided. The most common delays in exempt determinations include submissions missing complete applications, data collection sheets, information sheets, required investigator education, and institutional approvals. In addition, some investigators will request for an exempt determination when their project could not qualify. Correcting or preventing these common deficiencies prior to submission could greatly help reduce the time required for an exempt determination.

Methods: In order to prevent the common deficiencies in exempt submissions, a 10-item submission checklist was developed and added to the Application for Exemption. The checklist lists all of the requirements for an exempt determination and includes guidance for completing each one. The checklist is meant to serve as a reminder for investigators to complete and submit all requirements and as a helpful tool for new investigators who are unfamiliar with exemption process. Instructions at the start of the checklist state, “If any of the below items have not yet been completed, do not submit this application to the IRB until they are resolved. A complete application allows the IRB approval to be granted faster, the research to start sooner, and also decreases inefficiencies in the IRB process.” Stopping points are also incorporated into the application to prevent investigators from continuing if their submission will not qualify for exemption.

Findings: After the implementation of the new checklist, the average and median times from submission to exempt determination are 11 and nine days, respectively, a decrease from the initial turnaround time of 14 days. Because all investigators are aware of exactly what is required for an exempt determination prior to submission, there is decreased back and forth between the study team and IRB staff. All anecdotal feedback about the new application from researchers has been positive. Other IRBs and HRPPs can easily adapt the submission checklist from the Application for Exemption to address the most common deficiencies they experience in exempt determinations. The submission checklist can also be modified to be included in expedited and full board submission applications. Decreasing turnaround times throughout the institution and across institutions can allow research studies and scientific advancement to occur without preventable delays in the review process.