The Impact of Submission Assistance on IRB Review Turnaround Time

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Problem/Challenge: Turnaround time is a common measure used when evaluating IRB operations. Organizations may even establish “target” turnaround times for their research community; however, these times often do not account for variability in the quality of IRB submissions. With this in mind, the Harvard Longwood Campus Quality Improvement Program (QIP) set out to improve IRB submissions to facilitate the IRB review and approval process.

Solution: QIP provides a variety of human research support services, including IRB Submission Assistance. This service provides investigators and their study staff with general consultation as well as hands-on assistance preparing IRB applications, responding to the IRB’s queries, and drafting and editing study documents (e.g., protocol, recruitment materials, and consent documents). IRB Submission Assistance has been a popular service with our research community. In the past year, our office responded to more than 170 formal requests for Submission Assistance.

While qualitative data, including customer service surveys and informal feedback, have demonstrated a positive and enthusiastic response to this service, quantitative data also confirm that Submission Assistance facilitates the IRB review and approval process. This is evidenced by shorter turnaround times for assisted submissions.

Approach: Our analysis included a total of 2,096 IRB reviews and determinations made between September 1, 2013, and September 8, 2014. Study closures, “not engaged” determinations, and protocols ceded to another institution for IRB review were excluded from the analysis. Of the 2,096 reviews, a total of 170 (8.11%) received Submission Assistance prior to or during the IRB submission process. 1,926 protocols did not receive Submission Assistance.

<table>
<thead>
<tr>
<th>Review Type</th>
<th>Submission Assistance</th>
<th>No Submission Assistance</th>
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<tbody>
<tr>
<td>Full Board</td>
<td>5</td>
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<tr>
<td>Expedited</td>
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<td>Exempt</td>
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<td>255</td>
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<tr>
<td>Not Human Research</td>
<td>18</td>
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Results: Submission Assistance reduced review times. Overall, average approval times for initial applications with Submission Assistance were 14.33 calendar days sooner for Full Board reviews, 9.44 days sooner for Expedited reviews, 10.25 days sooner for Exempt determinations, and 4.34 days sooner for Not Human Research determinations.

Expedited modifications/amendments did not show a similar improvement in turnaround time. In examining this group more closely, we found three outlier data points for applications that received Submission Assistance. All belonged to a single investigator whose response time to requests for additional information was on average 50 days. When we controlled for these outliers, Expedited modifications receiving Submission Assistance were approved 2.93 calendar days sooner.

Conclusion: Submission Assistance has a positive impact on IRB review turnaround time. In addition to reducing review time, this service promotes communication between investigators and the IRB office and fosters partnership with the research community. Organizations can replicate this model with little or no FTE support. An existing QA/QI program may accomplish this by offering Submission Assistance with a prescribed focus, e.g., consent form review and editing, preliminary review of the research protocol prior to IRB submission, or assistance for a specific review type (Full Board or Exempt).

Some limiting factors:
- Investigator response time varies and cannot be controlled.
- IRB Reviewers may prioritize incoming submissions differently (e.g., responding first to Full Board or continuing review applications rather than modifications or initial applications).
- Review times for protocols going to the Full Board can be impacted by the meeting schedule, consequently increasing the total time from submission to approval, regardless of the quality of the submission.

Further Information:
This site includes a description of our Human Research Protection Program (HRPP) as well as an expanded explanation of the results of our analyses.