



Improving Turn-Around Time for Initial IRB Review of Minimal Risk Studies

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Problem/Issue Statement

Established turn around time goals for review of expedited and exempt studies were not being met. The initial response time for exempt studies was 10 business days (goal is 4 business days) and expedited studies was 14.6 business days (goal is 10 business days). The benefits of improving the turnaround time goals include: Increase new study submissions, increase customer satisfaction, prevent loss of funding, increase compliant research and increase patient treatment options.

Description of Program

The "program" in this project was the process by which the IRB conducted reviews of minimal risk studies. An excel spreadsheet was used to track type of review (exempt or expedited), IRB study number, date of initial IRB receipt of the project, date of initial IRB response to Principal Investigator, and total number of business days that it took the IRB to provide the PI with a response. Each IRB staff member tracked their reviews and the data was used to identify the length of delays.

By meeting individually with the IRB Chairs and Office Staff, the causes of the delays in providing Principal Investigators (PIs) with the initial response were identified. These causes were assessed to identify the following improvements which could provide the highest benefit with the least amount of effort.

- Rotation of exempt studies amongst four (rather than one) IRB staff members for review,
- Increased use of all IRB Committee Members on expedited reviews,
- Develop reviewer sheet for expedited review to assist Committee Members,
- Develop office checklist to standardize initial review process,
- Established process for coverage when staff is out of the office, and
- One on one meetings with the director to hold staff accountable and provide education.

We also began publicly reporting turn around time frames on our website to increase transparency for the research community. After three months of program implementation the data was reviewed again. The average turnaround time for initial response on exempt studies decreased from 10.1 to 3.1 business days. The average turnaround time for initial response on expedited studies decreased from 14.6 business days to 7.5.

Future Program Usage: The project's goal was to meet the established turnaround time goals 100% of the time. These were not met 20% of the time. The causes of delays were: staff issues, unexpected staff days off, IRB Committee Members not providing review in a timely manner, and lack of following process for staff vacation. The improvement plan will continue to be used within the IRB office and issues causing delays will continue to be addressed. IRBs may often struggle with balancing the demands of providing investigators with a timely review without sacrificing the quality of the ethical review. Using the currently available IRB Committee members, addressing the causes of delays at their sites, and simple tracking and evaluation of metrics can decrease delays in reviewing minimal risk studies. By decreasing IRB turn around time, researcher compliance with human subject regulations may be increased as the IRB process would not be prohibitively long.

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