Doing Less with Less: A Process for Evaluating IRB Tasks
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Problem Statement
Like other academic institutions grappling with reduced resources, budget constraints resulted in a decrease in our IRB staffing, and we were unable to replace a regulatory analyst’s position. At the same time, the volume of submissions increased due to a faculty hiring initiative.

Program
While the common charge is to do more with less, the reality is that constraints offer the opportunity to assess the scope of activities performed by the IRB, and to determine which activities can be modified or eliminated in order to provide timely review of submissions while still maintaining a system of review that ensures conformance with federal regulations and institutional policies.

The HRPP leadership initiated a process to evaluate the current activities and responsibilities of each departmental component. Leadership was charged with identifying and prioritizing activities that could be eliminated or modified in order to reduce workload without compromising the mission of the HRPP and the integrity of the research protocols.

We reviewed the following areas: Operations, Staffing Models, Education and Compliance. The HRPP Director and Managers:
* Examined the full process of IRB protocol review, assessing each of the steps from submission through approval. At each step we questioned who performed the step and if the step was necessary, performed as an essential IRB function or as a courtesy to another department, able to be completed more efficiently.
* Reviewed the existing staffing model considering the following: which staff were assigned to attend full committee meetings, the current system for managing expedited reviews, the current system for managing select minor amendments (e.g., personnel changes, advertisement modifications).
* Reviewed the travel budget for staff conference attendance.
* Reviewed the current process for new member orientation.
* Reviewed current in-person educational offerings to identify those sessions which could be eliminated or replaced by online offerings.
* Reviewed Compliance Unit activities, assessing the number of not-for-cause audits and study start-up consultations.

Following identification of a large number of possible changes, leadership prioritized the changes by potential effect and ease of implementation. The advantage of a prioritized list is that it provides a coherent structure for change, allowing for a stepped approach.

The “Stop Dos”
Fifteen activities were identified as possible change items. Implementation of items varied greatly from the simple to the complex. From the fifteen items, the following were chosen for initial action:
1. Extend the annual review requirement to two years for specifically qualified non-federally funded minimal risk research.
2. Reduce the requirement for regulatory analysts to conduct and formally report on researcher consultations.
3. Appoint more alternate committee members from experienced IRB staff to review personnel amendments and minor changes to protocol advertisements.
4. Develop decision trees for exemptions and not human subjects research applications, to produce clearer researcher requests, eliminating “back and forth” emails.

And More
5. Eliminate the requirement for researchers to submit a complete new application every five years for active protocols.
6. We initiated the use of a commercial IRB for selected industry sponsored trials (and instituted a fee for local context review, to compensate for staff effort).
7. We developed a pilot project for the Psychology Methods Class, creating an umbrella protocol. The umbrella protocol under one faculty member becomes the overarching protocol for several student projects, reducing the number of individual submissions, while ensuring appropriate IRB review.

The Result
Each of the measures we adopted is effective in decreasing the workload for IRB staff. Equally as important, six of the seven actions resulted in less work for the study investigators.

The Value
Beyond the time savings for IRB staff and study investigators, there was value in the process itself. Taking the time to identify each IRB function and assess its current value and process leads not just to ideas for improvement, but also to a fuller understanding of the scope of the IRB/HRPP responsibility and function.