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Overhauling an Academic Medical Center HRPP with Simple Process Changes

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In the fall of 2011, the Wake Forest School of Medicine (WFSM) Institutional Review Board (IRB) Office recognized a virtually free opportunity to dramatically improve turn-around time and increase the quality of full board reviews.[1] We developed the idea by observing processes utilized by central/independent IRBs.

The WFSM IRBs oversee approximately 2,400 active protocols for an academic medical center. The four IRBs are part of a human research protection program (HRPP) accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The convened IRB reviews nearly 900 submissions per year.

In June 2010, turn-around time for new applications at WFSM was 63 calendar days from submission to approval by the HRPP as a whole, which includes all ancillary reviews, IRB review time, and investigator response time. Time in the hands of the IRB Office alone was 34 days. Investigator response time was 27 days. All in all, this timeline was not too bad, considering that each of our four IRBs met only once per month and the pre-review process often worked at cross purposes to the board review.

IRB Office staff members had long been aware of study sponsors' concerns about long turn-around time at academic medical centers, but a practical solution had not yet appeared. Scholarly articles discussed the apparent inability of institutionally-based IRBs to adjust their practices to meet the research community's need for greater efficiency.[2] Other articles suggested the use of central IRBs for all multisite research to lessen review times.[3]

Overhauling the Process

By carefully examining central/independent IRB processes, we reached the conclusion that holding more IRB meetings is the key ingredient to improving turn-around time. Some central IRBs hold one or more meetings every weekday. In contrast, WFSM had four large boards, which met for several hours once each month to review long agendas.

Our idea was simple and cost nothing to implement. By splitting each of the four boards into two, and having each of the resulting eight boards meet twice per month, we could hold 16 IRB meetings per month. Thus, instead of one three- to four-hour meeting per month for four boards, we would have two one-hour meetings per month for eight boards. For example, Board 1 would meet on the first and third Mondays of each month. Figure 1 shows the schedule we developed:

Figure 1. IRB Schedule

	Monday	Tuesday	Wednesday	Thursday	Friday
Week 1	Board 1	Board 2	Board 3	Board 4	No Meeting
Week 2	Board 5	Board 6	Board 7	Board 8	No Meeting
Week 3	Board 1	Board 2	Board 3	Board 4	No Meeting
Week 4	Board 5	Board 6	Board 7	Board 8	No Meeting

After calculating the time savings and addressing anticipated questions and concerns, we obtained buy-in from the IRB Chairs, IRB members, and Medical Center administration. We estimated that each meeting could take place within a one-hour time-frame, with an average agenda consisting of four or five submissions.

The new review model would give each board member the opportunity to review each submission in more detail prior to the meeting and allow for better discussions, since every member of the board could review four or five submissions every two weeks with good recall, in contrast to 18 to 20 submissions prior to a monthly meeting.

The long monthly meetings were often poorly attended, so were susceptible to quorum interruptions when physician members had to attend to clinical matters. In addition, the long meetings required food breaks and other interruptions, distractions and lapses of concentration that reduced the time available for productive work. With one-hour meetings, attendance is better and all the time is spent productively. Meeting minutes show that mean discussion time for each submission increased by 33%, from 6.3 minutes to 8.4 minutes.

To facilitate the splitting of the four IRBs, we asked the existing IRB Vice-Chairs to become Chairs of the four new boards. All agreed. Previously, meeting times were fixed and not necessarily convenient for board members. In the new system, we allowed the eight Chairs to set the times for their own meetings.

We assigned members to boards based on board composition and member schedules. Because the original four boards were composed of a total of 80 members, including multiple experts in most important subject areas, we had enough members to staff most of each new board. We did have to fill a few seats with new experts, as well as add some community members and non-scientists. We also replaced a few members who were unable to attend during any of the new meeting times. Fortunately, several former members, who had resigned because of the length of the monthly meetings under the old process, were willing to return to service after the change.

Other Process Modifications

At the same time, we also implemented additional process modifications:

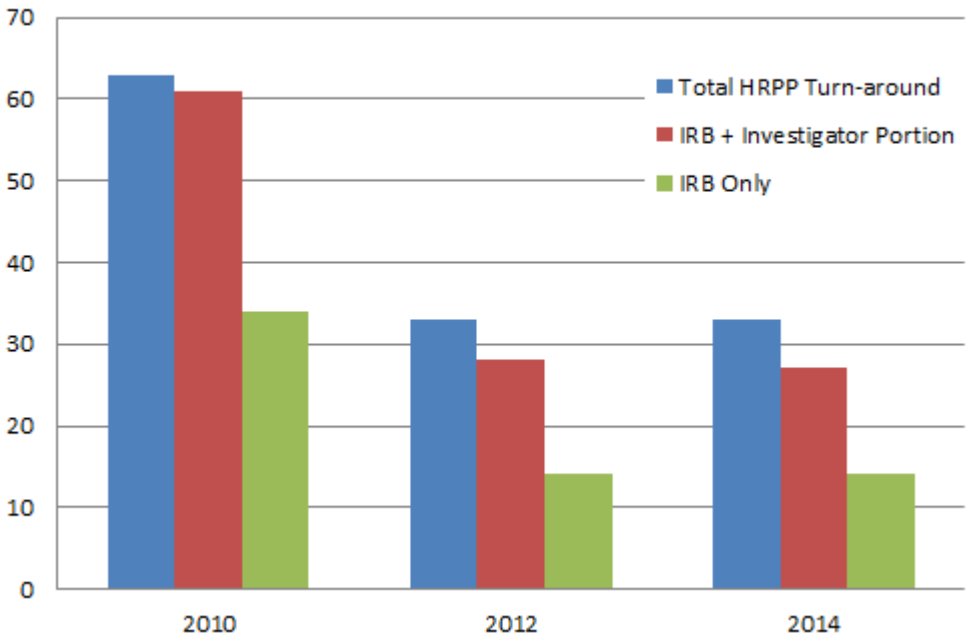
- **Ancillary Reviews.** We realigned the timing of ancillary reviews by the Radiation Safety, Cancer Center Review, and other committees, as well as the Medicare coverage analysis process. Prior to the changes, some ancillary committees reviewed the study prior to IRB review and others simultaneously to the IRB review. If a review was not completed before the IRB meeting, provisional approval had to be granted until the ancillary committee signed off. If an ancillary committee required any changes, the convened IRB often had to reconsider the study. Now, all ancillary committees simultaneously review the study prior to IRB review. Any revisions necessary for ancillary approval are communicated to the other ancillary groups so requests do not conflict.
- **Revision Requests.** Prior to the changes, the pre-review team sent any requests for revisions to the study team before the board review was scheduled. After board review, the study team might receive additional requests. As a result, the study team often sent proposed consent form revisions to the sponsor, waited for the sponsor's response, and then repeated the process after the board meeting. Now, pre-reviewers require the study team to make revisions prior to full IRB review only if the change is needed for board approval. We send non-critical stipulations to the study team after the board discusses the study. Therefore, the sponsor typically gets only one set of revisions to review, instead of the two or more rounds that were common under the previous model.

- **Remote Attendance.** To ensure that as many IRB members as possible can attend meetings, we introduced the option of attending by video conference or telephone. Most members still attend in person, but for those whose offices are across town, this option allows them to attend without the additional driving and hospital parking time. A few members always attend remotely due to their schedule and location, but others attend in-person as often as possible and remotely when necessary. Our video conferencing program is a secure commercial product that can be used with a laptop. We placed an inexpensive computer camera high in the board room so remote attendees can see all members. In-person attendees can also see remote attendees on a screen at the end of the table.

Results and Sustainability

Figure 2 shows the dramatic improvement in turn-around time measured for the month of June before the changes, after the changes, and this June, which is 2.5 years post-change.

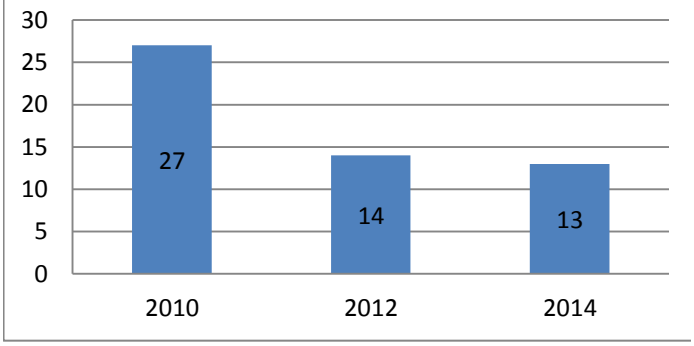
Figure 2. HRPP & IRB Turn-Around Time in Calendar Days



The mean turn-around time decreased by more than half for the IRB, and this improvement has been sustained. The work volume has remained steady, with about 2,400 active studies at any given time since 2010. No new staff members have been hired and review processes have not been altered since 2012.

Turn-around time improved not only for IRB review but also for study team response time. As Figure 3 shows, in 2010 study team response time averaged 27 days. In 2012 it was only 14 days. This improvement has been maintained as well, with the latest metrics showing 13 days for study team response. We attribute this reduction to the more efficient pre-review processes discussed above.

Figure 3. Study Team Turn-Around Time in Calendar Days

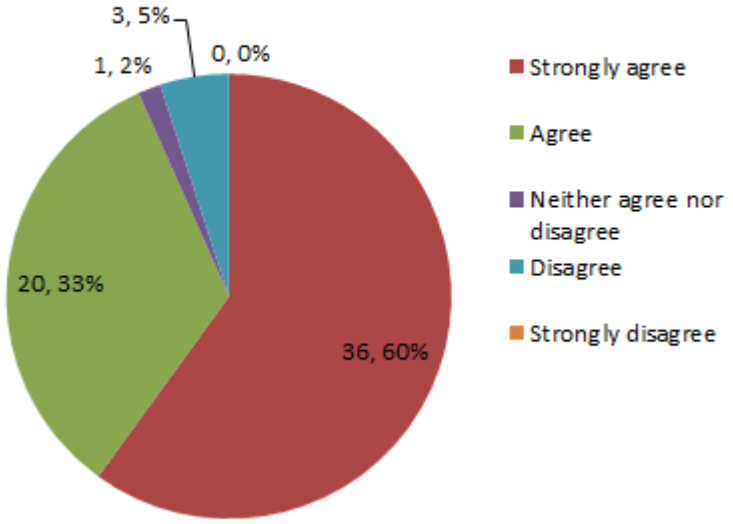


IRB Staff Roles

Previously, each of the four IRBs had a Protocol Analyst, who also performed pre-reviews on expedited submissions. Protocol Analyst workload spiked each month for two weeks, as they prepared large numbers of submissions for the meeting, coordinated the monthly meeting, took minutes for several hours of fast-paced discussion, and afterwards processed the minutes and dealt with large amounts of post-meeting documentation and communications with study teams. Meanwhile, pre-review stipulations and expedited submissions often had to wait.

In the new system, each Protocol Analyst manages one meeting per week, spreading the workload evenly across the month. Post-meeting work can be completed in a couple of hours and expedited reviews are not delayed.

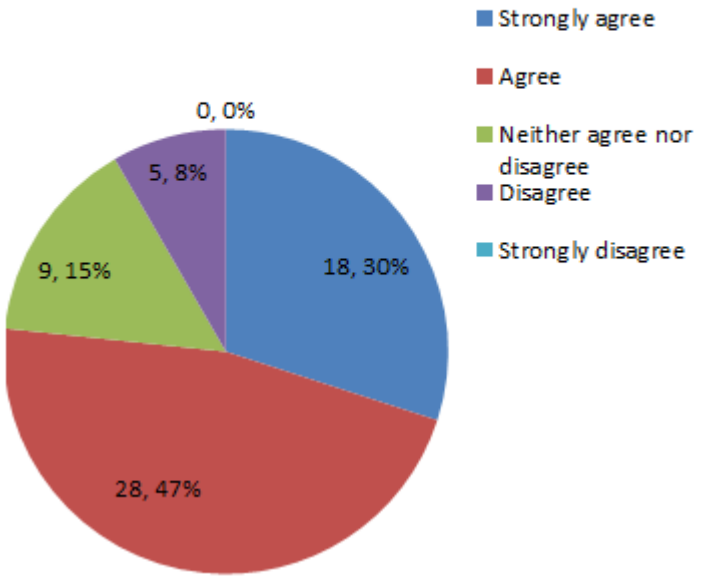
Figure 4. As a member of the Wake Forest School of Medicine IRB, I like the new 8-board structure.



Reactions

IRB members reacted very positively to the changes. Figures 4-6 present the results from our 2012 annual IRB anonymous Member Survey. These results show that two indicators of quality improved, along with the reduced timelines. Investigators, study team staff, and study sponsors have also provided very positive feedback.

Figure 5. With the new 8-board structure I am now more likely to be able to review all the agenda items, even those not assigned to me as primary reviewer.

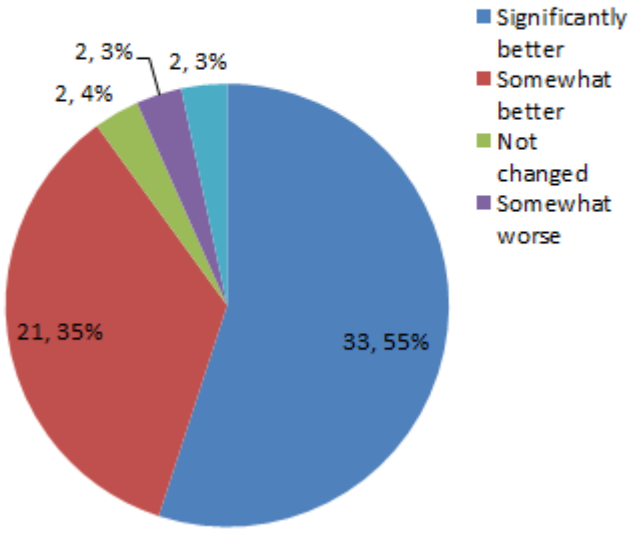


Conclusions

WFSM's IRB process improvements have significantly reduced the turn-around time for full-board submissions and expedited reviews. According to the latest metrics released by AAHRPP, the mean time from submission to the IRB until approval is 45 days.[4] This statistic includes all IRBs accredited by AAHRPP, including academic medical centers, central/independent IRBs, and non-academic hospital IRBs. The WFSM IRBs'

current 27-day average timeline is 40% below this number and 57% below our previous timeline. This achievement was nearly cost-free and required no additional staff or technology. In addition, based on the increase in productive discussion time, the quality of IRB reviews has probably improved. We believe other academic medical center IRBs could achieve similar results.

Figure 6. I believe that, since the 8-board model was adopted, the quality of discussion the IRB is able to have regarding each agenda item has improved.



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