Improving the IRB Expedited/Exempt Review Process
By Joseph E. Andrews, J. Brian Moore, Paula Means, and Richard B. Weinberg

In 2012, expedited reviews constituted 80% of total reviews — including all initial submissions, continuing reviews, and amendments — by the eight Wake Forest School of Medicine IRBs. Other local IRBs see similar ratios. Despite their name, expedited reviews often take as much calendar time as full-board reviews. However, IRBs can adopt two simple measures to increase the efficiency of expedited/exempt reviews, while providing IRB Chairs with more convenient times to conduct high-quality reviews.

Improving the Expedited Review Process
In 2011, the Wake Forest School of Medicine IRBs improved full-board-review quality and efficiency. At the same time, we also focused on improving expedited and exempt review processes. As a result, we developed two simple improvements that reduced turn-around time by over 40% for expedited/exempt reviews and also improved IRB Chair, IRB office, and study team satisfaction.

At our institution, a protocol analyst pre-reviews expedited/exempt protocols and, after any concerns have been addressed, forwards them to an IRB Chair. Until 2011, our eight IRB Chairs took turns in pairs reviewing these submissions during a specified week of each month. However, if the IRB Chair’s other obligations interfered, submissions might be reviewed hastily, accumulate until the end of the week, or roll over into the following week.

Wake Forest investigators submit IRB applications to “the pool,” which is part of an online IRB administration system. Until 2011, IRB protocol analysts selected submissions to pre-review. More experienced analysts were eager to take on the most challenging submissions and often completed a greater number of reviews than did their less experienced counterparts. It was, therefore, difficult for inexperienced analysts to gain experience with unusual or difficult reviews. As a result, there were inequities in the workload and gaps in training that needed to be addressed.

To solve these problems, we implemented two simple work-flow modifications:

- **The Chair’s Calendar.** Each IRB Chair now selects any two or three business days during the upcoming month during which he or she will be responsible for expedited/exempt reviews received after 3:00 PM of the previous day and before 3:00 PM that day. Prior to the beginning of each month, the Chairs receive a reminder message to select their days on a shared online calendar on a first-come-first-served basis. They are free to later swap days with other IRB chairs.

- **The Daily Dealer.** First thing each morning, the Assistant Director of the IRB Office (or designee) pre-pre-screens all submissions for completeness and assigns them to protocol analysts in a balanced manner. This process normally takes less than 30 minutes. If an analyst finishes early, he or she can pull late-arriving submissions from the pool or mentor a less experienced analyst.

Results
As shown by the bars in the Chart 1, these workflow modifications have reduced expedited/exempt review times to 52% of the time previously required. As shown by the whiskers in the chart, variability in review times has also decreased.
The chart shows the improvement in turn-around time from the period July 1, 2010 through June 30, 2011 (blue bar) compared to the post-process-modification period of July 1, 2011 through August 31, 2012 (red bar).

IRB Chairs have expressed increased satisfaction with the new process, as evidenced by these typical comments:

- “The chairs calendar has helped me schedule and prioritize my IRB review responsibilities, such that I complete them in a much more timely fashion.”
- “I like the ability to pick the days that work best in my schedule. It gives me time to review the expedited studies thoroughly without feeling rushed and stressed about my other work.”

The Daily Dealer has been equally successful in solving the issues of equitable work distribution, training and quality improvement. Protocol analyst satisfaction has increased, as evidenced by these typical comments:

- “The Chairs Calendar has been a huge improvement in our overall IRB review process. Chairs are prepared to process studies on the day they have selected. This has led to prompt resolution of concerns and a shorter approval time for expedited, exempt and other studies.”
- “A more balanced workload means more time for detailed reviews and faster approval for all assigned submissions.”
- “The ‘Dealer’ makes it easy to prioritize our work, thus decreasing turn-around time and increasing study team satisfaction.”

**Conclusions**

The Chair’s Calendar and Daily Dealer have substantially improved our IRBs’ efficiency, timeliness and quality. The transition to the new systems was straightforward and supported by all personnel.

At sites with only one or two IRBs, the Chair’s Calendar could include experienced IRB members. Similarly, the Daily Dealer could be implemented in a simplified manner.
References


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