Towards Total Quality Management in Human Research Protection Programs:

IRB Administrative and Reviewer Activities

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Institutional Human Research Protection Programs (HRPPs) are under increasing pressure to evolve their processes and procedures into a more efficient framework. Government funding is in decline, cutting into many HRPP budgets; the NIH has issued a mandate for single IRB review, forcing a re-evaluation of IRB office staffing and resource priorities; and proposed changes to the Common Rule are further increasing focus on IRB activities.

Institutions that are focused on better serving their investigators (both clinical and social/behavioral) and attracting sponsored research, find themselves in a position where they must drive measurable and sustainable improvements in the performance of their research oversight function.

Quality management techniques teach that achieving process consistency, together with ongoing training, education and continuous improvement efforts, lead to higher quality results and operational transformation. In our work with hundreds of HRPPs and their local institutional review boards (IRBs), we have observed a variety of best practice measures and total quality management (TQM) techniques for ensuring continuing improvement of IRB review activity.

This paper highlights select administrative practices, committee review techniques and associated technology-enabled solutions that, in our observations, contribute to improved regulatory compliance and more efficient operations. In addition, implementation of technology solutions provides greater insight into process and performance, and inform efforts toward continuous improvement.

Quality Management and HRPP Activities

ISO 9001, the internationally recognized standard for TQM, adopts a number of management principles that can be used by local IRB leadership to guide their organizations towards improved performance. As discussed in the ISO Quality Management Principles, these principles[1] are:

Seven Criteria for Performance Excellence	TQM Statement[2]	Application to HRPPs
Customer Focus	The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.	IRB office "customers" include investigators and their study teams (both clinical and social/behavioral), sponsors and CROs, regulatory agencies, and internal audit and compliance professionals.
Leadership	Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives.	Leaders of the HRPP include the Institutional Official, IRB Chair, and IRB Director, as well as Research Administration.
Engagement of People	Competent, empowered and engaged people at all levels throughout the organization are essential to enhance its capability to create and deliver value.	For most institutions, these people include IRB members and staff, and research personnel engaged in human subjects research.
Process Approach	Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system .	Operational practices should be measured relative to written processes, and one or the other changed as needed.
Continuous Improvement	Successful organizations have an ongoing focus on improvement.	By measuring key performance indicators, both practices and processes can be improved continuously.
Evidence-Based Decision Making	Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.	It is imperative to determine what will be measured both before and after change, to know if decisions make a difference.
Relationship Management	Relationship Management: For sustained success, an organization manages its relationships with interested parties, such as suppliers.	For IRBs, this concept embraces investigators and their teams, and sponsors and CROs. Honest and open feedback not only from research staff but also from IRB staff and members will help to manage relationships.

The backbone of Quality Management is objective data gathering to continuously inform and measure progress on each of these principles. A robust, electronic IRB workflow solution enables and enforces institutional requirements for quality by seamlessly collecting meaningful data.

Compliance Workflow Technology Solutions

Innovative HRPPs provide compliance professionals and reviewers with the necessary tools and resources to continually improve the review process and enhance the quality of reviews conducted by their IRB. Chief among these tools is a workflow solution technology platform that delivers transparency, accountability, and continuous improvement tools for users, committees and the HRPP. Following are some of the most important features of a robust compliance workflow technology solution:

Training and Credential Tracking

Leading systems should be able to pull credentials from other systems (e.g. CITI, WCG Academy) into the review system. Streamlined, integrated access to training credentials and individual records within your online compliance workflow has many advantages. These include:

- Clear indication for the research team of their team's relative qualifications for the research prior to submission;
- Greater oversight for the IRB administrator of researcher/staff/board member capabilities due to workflow integration and associated transparency;
- Reduction in the number of investigator qualification errors by presenting investigator credentials together with the submission documentation for IRB review;
- Simplified and straightforward assignment of IRB reviewers based on appropriate skills and experience; and
- Greater administrative processing efficiency and reduction of errors through the elimination of wasted steps incurred by legacy approaches (e.g., review documentation offline or in disparate systems).

Online Training Tools for Board Members

Systems should do more than present information for review. A well-designed system presents training tools, instructions and guidance for the reviewers. This is typically done via a library of institution-specific documentation. HRPP content might include:

- The presentation of your institution's continuous improvement and performance expectations online, as needed; and

- Instructions for compliance with your institution's requirements for conducting a review in a consistent and comprehensive manner.

Online Review Worksheets

Beyond the mechanics of review, leading institutions provide their administrators and board members with worksheets and checklists within the electronic system. These tools promote a consistent, quality review process across individual members and committee panels.

Review Assignment Tracking

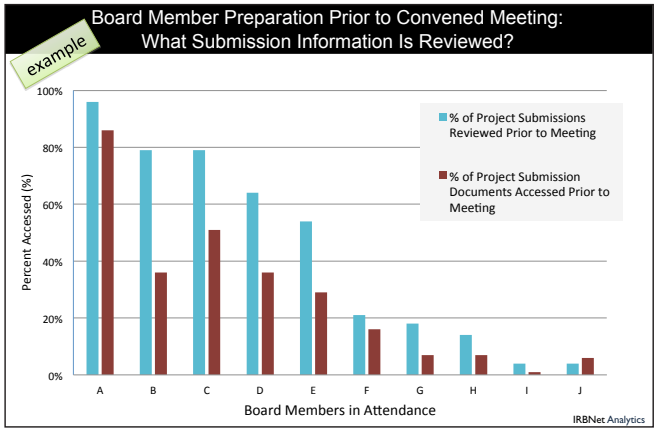
A state-of-the-art electronic workflow solution will support the assignment of reviews within its system. With this knowledge, staff may comprehensively balance the review load across IRB panel members, and track outstanding assignments and their completion.

Recorded Reviews Electronically with Timestamping

The system should enable reviewers to record their comments related to controverted issues within the system. This information should be time stamped. The content should be available online with visibility across the staff and relevant board members. Once in the system, controverted issues should be assembled into a single document for discussion and, if appropriate, attribution.

Assurance That Reviewers Have Reviewed Documents

Convened Review Scorecard Summary



An advanced system should identify whether board members have reviewed documents prior to meetings. This information not only aids in the evaluation of review habits and performance of board members across committees, it also informs compliance professionals of who has and who has not reviewed crucial documents (such as the protocol) prior to the meeting.

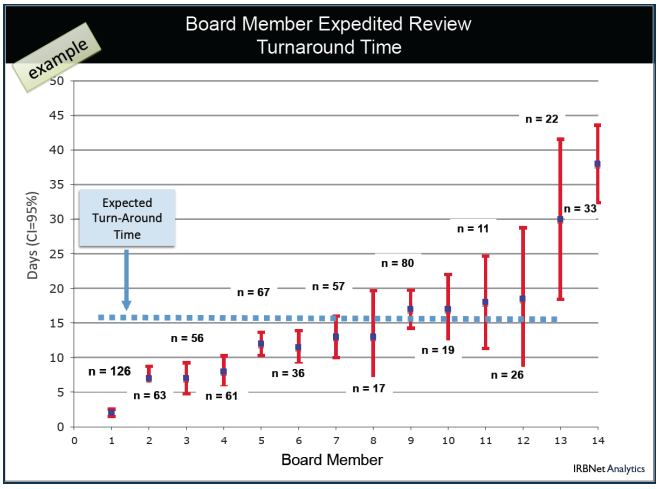
Effective IRBs will clarify expectations for review engagement prior to meetings, and manage board member rosters accordingly. Those members not meeting expectations can then be counseled or removed from the committee.

A Convened Review Scorecard Summary may indicate, for a given board meeting, the percentage of assigned protocols reviewed by each member, both in attendance and not in attendance. IRB members who have not reviewed crucial documents for a protocol may not vote. Further review detail may be shown to indicate the number of documents, and which specific documents, were reviewed by each member.

- How long was the review period?
- How consistent are board members in the timely completion of reviews. (Note the 95% Confidence Interval for a given reviewer's performance.)
- Which of your board members are consistently meeting expectations, and which are falling short of performance expectations?

Turn-around Time and Statistics for Committee Member Reviews

Board Member Expedited Review Performance Scorecard



Another benefit of comprehensive review workflow solutions is access to objective information, including when review documents are shared with committee members, and when reviews are complete. With this information, administrators can measure individual committee member review turn-around times, and manage researcher and committee member expectations accordingly.

Automated Board Attendance Reports

Your software system should provide committee member attendance data as well. By reporting and documenting regular IRB meeting attendance over a period of time, one can demonstrate performance trends against established expectations, and manage accordingly.

Conclusions

A comprehensive HRPP compliance workflow solution goes beyond routine workflow functionality to provide data, tools and insight that drive continuous improvement using best practice measures and total quality management (TQM) techniques for ensuring improvement of IRB review activity.

[1] ISO Quality - Quality Management Principles. International Organization for Standardization (ISO), 2015

[2] IBID

About the Author

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Mr. Olmsted has over 20 years of experience aligning cutting-edge technology to business need, and almost a decade of experience consulting in the clinical research space. Since 2007, Mr. Olmsted has led IRBNet, the most widely-used research compliance management solution in the industry. At IRBNet, Mr. Olmsted helps clients to achieve the efficient, compliant management of their institutional research. Active in the industry, Mr. Olmsted is the co-founder and vice president of the Alliance for Clinical Research Excellence and Safety (ACRES).

References

[1] ISO Quality - Quality Management Principles. International Organization for Standardization (ISO), 2015

[2] IBID