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Amila Tutundzic
Washington University School of Medicine in St. Louis

Jeanne Velders
Washington University School of Medicine in St. Louis

Abby Keeley
Washington University School of Medicine in St. Louis

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Washington University School of Medicine-St. Louis, MO

Amila Tutundzic, RRT, Jeanne Velders, JD, CIP and Abby Keeley, MS, CIP

QA/QI Goals

- To maintain a systematic, data-guided auditing process to implement real-time improvements in our HRPO review procedures.

- Identifying performance trends based on regulatory or policy issues

- Maintaining a continuous, uninterrupted auditing process by onboarding a full-time Quality Assurance Specialist, in return alleviating additional burden on other staff

Background

- Monitoring staff performance is a necessity, but creating a sustainable monitoring program can be a challenge.

- Prior efforts to maintain a QA/QI program were unsuccessful due to staff limitations. Previously, various senior staff members would do monitoring on top of their day-to-day work activities, with monitoring never being able to take precedence.

- Previously, completed monitoring feedback was stalled due to an overly complex approval process that involved individual team managers, in addition to quality assurance staff.

Program Development

- Revamped QA/QI program implemented after hiring a QA Specialist in late 2021
- The Director, Associate Director of Compliance and Education, and the QA Specialist helped create a program that focuses less on individual errors and more on issue based trends identified during monitoring
- Restructuring of the approval and feedback process allowed for more harmonious discussion and re-education process (if needed)

Three Key Changes in Sustaining the Program

Hiring a Full-Time QA Specialist

- Individual responsible solely for continuous monitoring across all HRPO staff members and policies/procedures
- Eliminated the "competing demands" problem that existed when various staff members had to allocate extra time for monitoring

Shifting Monitoring to Issue Based

- Previously, each staff member had a set number of submissions monitored
- Current program was reframed to focus on issues such as "Research with Children" or "Investigational Device Determinations."
- The reframing ensured areas of greater regulatory risk are monitored at an appropriate frequency with a sufficiently sized sample

Restructuring the Feedback and Approval Process

- Previously, finalizing the monitoring report suffered from "too many cooks in the kitchen". Team managers were present when feedback was provided to staff. This made staff feel "called out".
- Now, when possible feedback and re-education is delivered on a team level, or if necessary, individual staff members are counseled by the Associate Director.
- Separating direct mangers from this process increases staff engagement and alleviates tension.

Next Steps: Current Effort for Improvement

- While we have been successful at implementing sustained monitoring, our next goal was auditing in a more timely manner, providing staff with real-time feedback
- In 2024, we are piloting a change in structure for monitoring that prepares the monitoring schedule for the entire year, allowing the QA Specialist to continuously "roll" into the next audit.
- Previously, monitoring was on a quarterly basis, where now audits are happening on bi-weekly, monthly, quarterly, and annual basis-choosing studies approved as recent as the day before the audit.
- Additionally, with this new schedule, we are projected to conduct double the amount of audits than the previous year.

HRPO Internal Audit Schedule
*Example Schedule Only

Audit Type	Frequency of Audit	Detail of Audit	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Number of Audits to be Conducted in this Month			5	5	5	4	5	4	4	5	4	4	4	6
PI Grant Consistency	Annual	5% sample/yr												X
SWAT	Bi-Weekly	Sample Varies-2x/m												
Continuing Reviews	Monthly	Last week of every month												
Meeting Minutes	Quarterly	2 wks in mid Quarter												
ICFs	Quarterly	End of Quarter			X			X			X			X
HIPAA	Annual													X
Funding	Semi-Annually	Jan/July (R-6M)	X						X					
Exempt	Annual	Apr (R-6M)				X								
NHSR	Annual	Oct (R-6M)										X		
IRB Reporting	Annual	Jan (R-1Y)	X											
IRB Suspensions	Annual	Jan (R-1Y)												
Vuln. Populations	Annual	May (R-1Y)					X							
Medical Devices	Annual	Aug (R-1Y)								X				
Drug Studies	Annual	Nov (R-1Y)											X	
Modifications	Monthly	Last week of every month												

*This is subject to change as audits can be added due to new developments