Common Findings from an Initial Year of Post-approval Monitoring of Research Protocols and its Impact on Organizational and IRB Policies and Procedures
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Problem Statement: The IRB is tasked by federal and international regulations and ethical guidelines to protect human research participants. Our institution initiated a post-approval monitoring and quality improvement program for reviewing IRB-approved protocols in fiscal year 2013. The program was created with the goal to build a collaborative, mutually educational, platform to improve the implementation of research and promote compliance. Our first period of monitoring has focused on reviewing the execution of informed consent and documentation according to best clinical research practices.

Methods: Studies in which participants were enrolled during the previous IRB approval period were randomly selected for review and included both expedited and full board (more than minimal risk) protocols. Investigators were notified 10 days in advance; consent forms and documentation of the consent process were reviewed by IRB staff utilizing a systematic checklist. Findings and suggestions were briefly discussed with the investigator/staff afterward. A formal written report was provided within four days detailing areas for improvement and specific recommendations referencing applicable regulations and policies.

Results: Key findings from 23 studies monitored revealed specific gaps in knowledge: 1) in 87% of studies, documentation of the informed consent process was either missing or inadequate; 2) 70% of studies had consent errors relating to the signing and dating of the forms (e.g., subject signing wrong line, Principal Investigator (PI) not co-signing, dates not matching, etc.); and 3) there was notable confusion (in 13% of studies) on obtaining consent from non-English speaking participants when a translated consent was not available (i.e., missing the translated short form; participants signed the English consent form).

Conclusions: The key findings led to targeted education to investigators and research personnel on adequately documenting the consent process, properly obtaining signatures, and appropriately consenting non-English speaking participants. In addition, the IRB revised policies and consent templates for clarity, added instructions for enrolling non-English speaking participants, and removed an institutional requirement for the PI to sign off on participant enrollment when not directly obtaining consent. The initial period of our post-approval monitoring and quality improvement program was successful in increasing awareness and promoting compliance. The success has inspired us to expand our focus to other regulatory areas. Our monitoring program has had direct and lasting impact on both the conduct of research at our institution and the ongoing efforts to improve policies and procedures for efficiency and clarity.