Implementing Post-Approval Monitoring to Better Protect Human Research Participants
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Problem: The responsibility to protect the rights, safety, and welfare of human research participants extends beyond the review of a protocol by an IRB to ensure regulatory criteria for approval is met and participants aren’t exposed to unreasonable risks. Institutions are tasked with finding creative ways to identify opportunities for process improvement, address potential problems early, and promote best practices.

Description: In December 2012, our institution implemented a post-approval monitoring program (PAM) with a single focus: one goal and one outcome measure. Since problems relating to inadequate informed consent are frequently found in audits of clinical investigators, we elected to focus on this topic.

Goal: To identify areas of confusion or misunderstanding relating to the informed consent process, and provide education to improve processes and documentation.

Measure: Each month, the IRB staff randomly selected studies in which participants were enrolled during the last approval period.

Process: Investigators/research staff were contacted and asked to provide the consent forms and documentation of the consent process for review. Following a checklist, the IRB staff reviewed the consent forms and the adequacy of the documentation of the informed consent process. Afterward, findings were privately discussed with the designated research personnel in an educational, non-confrontational, and collaborative manner. Investigators were sent a follow-up e-mail providing findings/recommendations in writing with references to appropriate regulations/policies. At the end of a year, PAM participants were asked to complete a survey regarding their experience and impressions.

Results: In 21 of 23 studies reviewed, findings led to concrete recommendations for process improvement for investigators/research staff. Common themes/areas of misunderstanding also led to clarifications of IRB policies, procedures and forms, and more global education sessions. On the follow-up survey, the majority of respondents considered the interactions with the IRB staff to be positive and found recommendations helpful. As a result, most have implemented changes to their consent processes and/or documentation. While many were indifferent on whether or not these changes had a positive impact on their relationship with study participants, they are more apt to contact their IRB representative directly with questions going forward, and felt PAM was valuable to the institution’s Human Research Protection Program.

Conclusions: Implementing a focused PAM is a simple way to help identify problem areas early, educate investigators and research staff, and ultimately better protect human research participants.