Check Your Expiration Date: An IRB Process for Ensuring Timely Submission of Renewal Applications
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Problem: A goal of the IRB is to help investigators ensure that annual review of active studies takes place in a timely fashion, preventing expiration of approval. In addition to including the expiration date on all IRB determination letters, our protocol database sends automatically-generated email messages to principal investigators and their study correspondents at 75, 45, and 30 days prior to IRB approval expiration. The 30 day notification indicates that immediate action is required and includes a warning of noncompliance if the research activity continues beyond the IRB approval date (thereby conducting unapproved human subjects research). Despite this notification system, IRB staff implemented a more rigorous approach in order to identify those studies at imminent risk of approval expiration.

Program: A process for monitoring potential protocol expirations was developed. Each week the IRB regulatory analysts receive a system-generated report, the “Thirty Day Notification List”, identifying all studies whose principal investigator had not responded to the 30 day email reminder by submitting a renewal or closure request. The report contains the name of the principal investigator, his/her department, the IRB study number, and the approval expiration date. The regulatory analyst verifies that no submission has been received by the IRB; determines the study funding (if there is sponsored funding, the regulatory analyst determines all of the awards associated with the study and the expiration dates of the awards); contacts the principal investigator by phone to inquire about the study status and warn of the impending expiration. If the investigator indicates that all study interventions have been completed, and only analysis of de-identified data remains, the regulatory analyst instructs the investigator to close the study; sends a follow-up email to the principal investigator, the research coordinator, the grants and contracts office, and the department business office documenting the phone call; and files the documentation in the study file. Since implementation of this new process, fewer submissions are received at or after the expiration date. While this process can be initially burdensome to IRB staff to implement, work in this way offsets the work involved in managing expired studies: stopping funding, verifying that no research activities took place during the expiration period, and managing instances of noncompliance. It can be a useful tool for IRBs of any size, particularly those with studies that are federally funded.