Check Your Expiration Date: An IRB Process for Ensuring Timely Submission of Renewal Applications
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Problem Statement
A goal of the Institutional Review Board (IRB) is to help investigators ensure that annual review of active studies takes place in a timely fashion, understand what a “lapse” in IRB approval effectively means, and help prevent expiration of IRB approval. In addition to including the expiration date on all IRB determination letters, our current electronic human subject research system sends automatically-generated email messages to principal investigators and their study correspondents at seventy-five (75), forty-five (45), and thirty (30) days prior to IRB approval expiration. The thirty (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 advance notification system, the IRB commonly receives submissions from investigators at or after the expiration date.

To address this behavior the IRB staff implemented a more rigorous approach in order to identify those studies at imminent risk of approval expiration. The first step was to change the verbiage in emails and letter from “lapsing” to “expiring” to prevent any misunderstanding of the concept and to better indicate the severity of the regulatory state.

Program Description
A process for monitoring potential protocol expirations was developed. Each week, the IRB regulatory analysts (RAs) and administrative support staff receive a system-generated report, the Thirty Day Notification List, identifying all studies whose principal investigator (PI) had not responded to the thirty day email reminder by submitting a renewal or closure request. The report contains the name of the PI, his/her department, the IRB study number and the approval expiration date.

The Administrative Support Staff:
- Verifies that no submission has been received by the IRB
- Contacts the PI by phone to inquire about the study status and warn of the impending expiration via a standard telephone script.
- Sends a follow-up email to the PI, the study correspondent, and the department business office, copying the RA team assigned to the department. The email is saved in the protocol file. The standard email contains the regulations regarding possible non-compliance with continued, unapproved research.
  - 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.

The Regulatory Analyst:
- Determines the study funding
  - If there is sponsored funding, the RA determines all of the awards associated with the study and the expiration dates of the awards and notifies the appropriate Grants & Contracts representative, who investigates any possible unapproved spending.
- Refers the matter to the Research Quality Assurance & Compliance unit of the Human Research Protection Program if there is potentially serious or continuing noncompliance.

Evaluation
While this process can be initially burdensome to IRB staff to implement, work in this way offsets the work involved in managing expired studies, which involves: verifying that no research activities took place during the expiration period, potentially halting or worse returning federal funds and managing instances of non-compliance. Further, since a team model is utilized at the Yale IRB, this process is useful in identifying PIs who are frequently on the thirty (30) day list. Investigators are re-educated so that they are in compliance with the regulations.

The process can be useful for IRBs of any size, particularly those with studies that are federally funded.

Conclusion
Since implementation of the word “expiring” to emails and automatic notifications, coupled with the new process of reaching out directly to investigators whose studies are imminently expiring, fewer submissions are received at or after the expiration date.