Research Concerns and Complaints: A Programmatic Approach
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Problem Statement: Managing participant complaints is a critical and sometimes challenging role of any HRPP. The HRPP receives a mean of 33 complaints annually and due to the unpredictable nature of research concerns and complaints, we developed a framework to facilitate complaint resolution and identify changes that may need to be made to HRPP guidance.

Program Description: The HRPP website includes information on reporting and responding to research-related concerns and complaints, which serves as a source of information for staff, research participants, and the community. A reporting form on the website assists complainants with providing relevant information. Complaints are received by phone, email, fax, or mail. When complaints are received by phone, a template script helps staff elicit useful information from complainants and successfully deal with difficult personalities. HRPP staff are trained to facilitate resolution, which may require involvement of (or referral to) other internal entities such as Risk Management, Patient Relations, Legal Affairs, and the Privacy Office to resolve an issue. A consultation form is used to track interactions with the complainant, plan next steps, and record the amount of time spent on the matter. Individual complaints are compiled on a yearly basis so that recurring issues can be identified, and the logs from 2011-2013 were analyzed. The types of complaints most commonly reported include: payment issues, non-responsive study teams, concerns about confidentiality and recruitment practices, injury, interpersonal issues with researchers, and requests to withdraw from the study. Complaints were primarily received from participants, but spouses, adult children, siblings, parents, and whistleblowers also raised concerns. Complaints may result in IRB protocol violations/incident reports, modification submissions, and in changes to HRPP guidance.

Suggestions for Implementation at Other Sites: Development of standard processes, scripts, and tracking mechanisms enables staff to facilitate complaint resolution in a minimum amount of time. If challenges arise while working through a complaint, HRPP staff are encouraged to hold a "troubleshooting" session with a manager or more experienced staff to strategize about the next steps and continue toward resolution.

Additional Information: The poster will include suggested content for template documents, a process map, and a description of our most compelling cases and their outcomes.