The For Your Information (FYI) Process: Reporting and Evaluating Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) and Serious Adverse Events (SAEs)

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Problem Statement: Our Institution wanted to further enhance an existing system for educating researchers on the process of reporting and reviewing reports of UPIRSOs and SAEs. While our policy and procedure on reporting requirements and IRB review are clearly articulated, we sought to provide researchers with education that is embedded into their reporting process.

Program: UPIRSOs and SAEs are reported to the IRB through a FYI notification function. For FYI submissions involving a UPIRSO or SAE, HRPP Compliance staff worked with IRB regulatory analysts, IRB Chairs, and HRPP leadership to develop a single form incorporating reporting and review. The form is used for the initial report, the assessment of the event, and the determination of level of review required. In addition to the report itself, the form includes several sections: (a) basic protocol information; (b) a description of the process for evaluation (so that a regulatory analyst new to the system has clear guidance on both the process of review and the use of the form); and (c) the initial regulatory analyst assessment, which is subdivided by category: serious adverse event, reportable adverse event, and unanticipated problem involving risks to subjects or others. Each category includes the criteria that must be met to satisfy that classification. Check boxes are provided for each criterion. If the review confirms that the event meets the threshold for IRB consideration, the report and any accompanying information is forwarded to the IRB Chair or other qualified IRB member for review. This reviewer then considers whether the report raises new concerns about risks, and recommends further review by the convened IRB, as necessary, for final determination. Our investigator report for UPIRSOs and SAEs also requires a Corrective and Preventive Action (CAPA) plan. Review of the CAPA (whether it was submitted, was acceptable, and whether changes are required) is included in the regulatory analyst assessment. Finally, the form asks whether, if the event does not meet all the criteria, further action is required, and provides a section for reviewer comments. Use of the form has provided researchers with immediate incident-specific education on UPIRSOs and SAEs, and assured their consistent review. UPIRSO and SAE reporting and review are part of the daily function of all IRBs. A reporting form that also provides education to the research community has universal value.