Not-for-Cause Reviews

Overview
The Human Subjects Protection Program (HSPP) conducts not-for-cause reviews of human research protocols as part of our ongoing efforts to educate on human research compliance issues. These reviews are meant to be informative and educational, not punitive. HSPP staff review items related to consent documentation, storage, and records retention. Any items that are inconsistent with the approved protocol or HSPP procedures will be noted, discussed, and fixed with the investigator. Our goal is for researchers to find these reviews as instructional tools to improve research records and management.

Identification of protocols
The HSPP focuses on federally funded or supported projects first and then all other projects second. Projects that already receive monitoring from a sponsor or agency are lower priority than investigator initiated studies.

Items Reviewed
The types of materials to be reviewed include informed consent documentation, enrollment numbers, IRB approval letters, and storage and records retention among other items.

Procedures
• HSPP initiates email correspondence requesting a designated time to meet with the PI and research staff.
• On the day of the review, HSPP staff meet the researcher(s) at an agreed upon location.
• A tentative agenda includes:
  o Introduction: HSPP reserves this time for introductions and to answer any questions.
  o Review all signed consents (if applicable): HSPP staff review all signed consent forms and verify that the correct versions were used, all documents were properly signed, and stored according to the IRB approved protocol.
  o Review of IRB approval letters: Verification that the researcher maintains a complete research file of IRB correspondence. Items such as renewals, amendments, and reportable item approval letters are reviewed.
  o Conclusion: HSPP reserve this time to ask any pending questions and answer any questions the research team may have.

HSPP staff compiles a report of the review findings and forward this report to the HSPP Director. The Director reviews the report and sends out the review findings to the PI and research staff present at the review. Any discrepancies that are inconsistent with the approved protocol will be discussed with the research team and fixed with the investigator. The IRB Committee receives a report of all reviews.