Post-Approval Monitoring (PAM) of Research (HRPP 1.21)

Description:

This policy describes the requirements for post approval monitoring (PAM) of research.

Policy:

1) Conducted in order to measure, maintain, and improve human subject research protection effectiveness, quality and compliance with all applicable regulations and HRPP policies
2) Focuses on the education of investigators, staff, and students about ethical and regulatory responsibilities in the conduct of human subject research, as well as the identification and correction of problems and deficiencies.

PAM Objectives:

- Determine if the PI and other study personnel adhere to the research protocol approved by the IRB
- Determine if the PI has filed all required reports to the IRB
- Determine if the process of informed consent and the informed consent document(s) meet all federal, state, and local requirements, as well as HRPP policies.
- Identify educational and training needs of the research community and determine the best methods for meeting those needs through:
    - Individualized training to meet the specialized needs of specific PIs and their research personnel
    - General education programs designed for the research community at the Organization
- Assess the completeness and accuracy of IRB files which are linked to studies selected for PAM
- Designed to be collegial, proactive and nonpunitive

Study Selection Criteria:

Categories of non-exempt research considered for PAM will be randomly selected, in order of priority listed below:

- Investigator-initiated research
- Research meeting the criteria for increased monitoring and/or interim continuing review
- Research involving vulnerable populations
- Greater than minimal risk research

- Research conducted under emergency waiver of informed consent
- Minimal risk research

Selected research must be currently IRB-approved and normally have been actively accruing subjects for at least one year.

PAM Process:

1) The PI will be informed, in writing via email, that their study was selected for review
2) The Investigator Assessment Checklist for Regulatory Documentation will be uploaded to RSS for the PI to complete and submit to the ORA
3) The PI is to upload the completed checklist and associated documents (signed consent forms, documentation of the informed consent process, enrollment logs, etc.) to RSS OR provide a shareable file platform (i.e. SharePoint).
    a. The PI has 14 business days to provide these documents
4) If the ORA needs any additional documentation or information, the PI will be notified via the message portal
5) The PI will receive a letter via email with the PAM Initial Findings Report listing any deficiencies found and the corresponding corrective action required of the PI
    a. The PI has 10 business days to respond to this letter and complete the necessary corrective action steps
6) If no deficiencies are found or once the PI responds and completes the corrective action steps, the PI will receive a PAM Final Report letter via email