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

Description:

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

PAM Objectives:

- Ensure **adherence to IRB-approved protocols**
- Confirm that required reports are submitted to the IRB
- **Evaluate the informed consent process** and documentation
- Identify training needs and deliver **targeted educational programs**
- Assess completeness and accuracy of IRB-related documents

Study Selection Criteria:

- **Not-For-Cause Monitoring:** 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.

- **For-Cause Audits:** Initiated in response to specific concerns including, but not limited to:
    - Noncompliance
    - Incomplete or inaccurate reports
    - Subject complaints
    - External audit findings

PAM Process:

1) The PI will be informed via email that their study was selected for review
2) The Investigator Assessment Checklist 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
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