1.21 Post-Approval Monitoring of Research

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for post approval monitoring of research.

2.0 Policy

- **2.1.** It is the policy of the Organization that a Post Approval Monitoring Program will be conducted in order to measure, maintain, and improve human subject research protection effectiveness, quality and compliance with all applicable regulations and HRPP policies.
- **2.2.** It is the policy of the Organization that the Post Approval Monitoring Program 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.

3.0 Post Approval Monitoring Program Objectives

- **3.1.** Determine if the PI and other study personnel adhere to the research protocol as approved by the IRB.
- **3.2.** Determine if the PI has filed all required reports to the IRB.
- **3.3.** 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.
- **3.4.** Identify the educational and training needs of the research community and determine the best methods for meeting those needs through:
  - **3.4.1.** Individualized training to meet the specialized needs of specific PIs and their research personnel.
  - **3.4.2.** General education programs designed for the research community at the Organization.
- **3.5.** Assess the completeness and accuracy of IRB files which are linked to studies selected for Post Approval Monitoring.

4.0 Procedures

- **4.1.** Study Selection Criteria
  - **4.1.1.** Not-For-Cause Monitoring of Non-Exempt Research
    - **4.1.1.1.** Categories of non-exempt research that will be considered for Post Approval Monitoring will be randomly selected, in order of priority listed below:
      - **4.1.1.1.1.** Investigator-initiated research
      - **4.1.1.1.2.** Research which would meet the criteria for increased monitoring and/or interim continuing review per HRPP policy 3.1 (Assessing the Need for Increased Monitoring, Interim Continuing Review, and Verification from Sources Other than the PI).
      - **4.1.1.1.3.** Research involving vulnerable populations
      - **4.1.1.1.4.** Greater than minimal risk research
      - **4.1.1.1.5.** Research conducted under emergency waiver of informed consent (FDA regulations at 21 CFR 50.24)
      - **4.1.1.1.6.** Minimal risk research
    - **4.1.1.2.** Selected research must be currently IRB-approved and normally have been actively accruing subjects for at least one year.
  - **4.1.2.** For-Cause Post Approval Audit
    - **4.1.2.1.** "For-Cause" audit will generally be scheduled based upon recommendation by the IO, IRB Executive Chair, or the IRB. Indications for audit include, but are not limited to:
      - **4.1.2.1.1.** Noncompliance (as per HRPP policy 8.4: Review of Noncompliance Involving the PI and Study Personnel).
      - **4.1.2.1.2.** Errors, inconsistencies, omissions in continuing review (HRPP policy 2.7: Continuing Review of Research) or AE/UP reporting (HRPP policies 8.1: IRB Review of Adverse Events and Adverse Device Effects and 8.3: IRB Review of Unanticipated Programs Involving Risk to the Subject or Others).
      - **4.1.2.1.3.** Complaints (as per HRPP policy 8.2: IRB Review of Study Related Complaints).

    - **4.1.3.** Monitoring reports issued by outside agencies (pharmaceutical sponsors, FDA, OHRP or others) that revealed or suggested problems areas.
- **4.2.** Post Approval Monitoring Process
    - **4.2.1.** Post Approval Monitoring will generally be performed by a designated IRB Administrator. Other IRB representatives may be included as necessary.
    - **4.2.2.** “Not-For-Cause” Audits
        - **4.2.2.1.** It is expected that at least twelve non-exempt studies will be selected for “Not-For-Cause” audit per year, however the actual number of audits will be contingent on available manpower
        - **4.2.2.2.** The Post Approval Monitoring visit will be scheduled at a time mutually acceptable to the PI and the designated IRB Administrator. Unannounced visits will not occur.
        - **4.2.2.3.** Prior to the Post Approval Monitoring visit, the PI will be informed, in writing, that a Post Approval Monitoring visit has been scheduled, including the date, time, place, and protocol(s) selected for review. The PI will also be provided a description of the audit process and criteria, as well as a copy of the Checklist for Post Approval Monitoring of On-Going Research to be completed by the designated IRB Administrator during the visit.
        - **4.2.2.4.** The PI will be asked to complete the Investigator Assessment Checklist for Regulatory Documentation and submit it to the ORA prior to conduct of the Post Approval Monitoring visit.
        - **4.2.2.5.** Visits must occur within 30 days of notification, unless delay is approved by the IRB Executive Chair.
        - **4.2.2.6.** Failure to comply with the Post Approval Monitoring Request constitutes non-compliance subject to HRPP policy 8.4 (Review of Noncompliance Involving the PI and Study Personnel).
        - **4.2.2.7.** The designated IRB Administrator will utilize the Checklist for Post Approval Monitoring of On-Going Research during review of investigator records.
        - **4.2.2.8.** If the assessment visit will include observation of the process of informed consent or interviews with subjects, the PI will be asked to arrange this in advance with one or more subjects. All subjects who have agreed must give written informed consent in advance by signing the Consent for IRB Observation of the Informed Consent Process. The designated IRB Administrator will utilize the IRB Observation of Consent Process Form to evaluate the process of consent.
        - **4.2.2.9.** Failure of the investigator or the research staff to cooperate with PAM, or interference with PAM by the investigator or the research staff, constitutes serious noncompliance subject to HRPP policy 8.4 (Review of Noncompliance Involving the PI and Study Personnel).
        - **4.2.2.10.** Following completion of the Post Approval Monitoring visit, the designated IRB Administrator will present preliminary findings to the investigator and/or staff, obtain additional clarifications and corrections, and provide education concerning IRB requirements as needed.
        - **4.2.2.11.** The designated IRB Administrator will prepare a written report of the PAM visit, including, as needed, a request for a corrective action plan. The written report will be given to the investigator, the IRB Executive Chair, and the IO.
        - **4.2.2.12.** The designated IRB Administrator, in consultation with the IO and the IRB Executive Chair, will evaluate the PAM report and the investigator’s corrective action plan, if provided.
            - **4.2.2.12.1.** Reports which suggest serious noncompliance or other concerns will be referred to the IRB for review in accordance with HRPP policy 8.4 (Review of Noncompliance Involving the PI and Study Personnel).
            - **4.2.2.12.2.** Reports which demonstrate few or no deficiencies, and/or the use of “best practices” will be reported to the IRB as a notification item, and will be communicated to the investigator.
        - **4.2.2.13.** The Post Approval Monitoring Program will include appropriate follow-up to ensure that deficiencies are corrected in a timely manner. This follow-up may include only a written report of corrective action(s) implemented by the PI, or it may require additional monitoring by the IRB. In some cases, the PI and/or other study personnel may be required to undergo specific training in order to assist in achieving the desired level of compliance.
    - **4.2.3.** “For-Cause” Audit
      “For-Cause” audits will follow the same procedure as above, except that unannounced visits may occur if authorized by the IO, and all PAM reports will be reviewed by the convened IRB.

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