

Post Approval Monitoring

Summary/Purpose: This policy describes procedures for Post Approval Monitoring Site Visits (PAM). The purpose of PAM is to ensure that protocol activity remains compliant with appropriate regulations and to improve the quality of research by detecting errors and/or omissions to be corrected.

Procedures:

A. Standard Procedures

1. The IRB Executive Committee (EC) will select protocols for PAM based on the following criteria:
 - a. Random selection utilizing the IRB protocol database;
 - b. Protocols with history of noncompliance with federal regulations or IRB requests;
 - c. Protocols that have had numerous adverse incidents;
 - d. Protocols involving greater than minimal risk;
 - e. Protocols involving vulnerable subject populations; and
 - f. Protocols from new Principal Investigators (PIs).
2. When a study has been chosen for PAM, a letter of notification will be sent to the PI with a request for a mutually agreeable date and time to meet with the PI and any available research personnel. The letter will also include areas and records to be examined.
3. The EC will assign EC and/or IRB members to conduct the PAM visit.
4. The PAM team will review the protocol file, including informed consent and assent forms, CITI human subjects protection training, etc. prior to the visit.
5. Areas examined during a PAM visit include but are not limited to:
 - a. Adherence to protocol;
 - b. IRB documentation (e.g., approval letter, protocol, subject recruitment materials);
 - c. Signed and dated consent and assent forms;
 - d. Subject study records and data (e.g. confidentiality, number of subjects matches consent forms);
 - e. Correspondence with the IRB;
 - f. Unanticipated problems or adverse events documentation (if applicable);
 - g. Annual Progress Reports;
 - h. Data management/storage system (e.g. locked cabinet, data encryption);
 - i. Changes to the original protocol and applicable amendments;
 - j. The consent process and/or data collection.
6. At the conclusion of the PAM visit, the team will discuss findings directly with the PI.
7. Actions after a PAM visit include, but are not limited to:
 - a. Acknowledgement/acceptance without further recommendation;
 - b. A request for modification of the research protocol or procedures;
 - c. A request for modification of the consent/assent process or consent/assent form;
 - d. Providing additional information to current and past research participants;
 - e. Scheduling an additional PAM visit after a predetermined period of time;
 - f. Education for the investigator or research staff;
 - g. Limitations on the research activities;
 - h. Suspension or termination of the research.
8. A report detailing the findings and the outcome of a PAM visit will be sent to the PI, the PI's chair or director, the full IRB, and institutional officials as appropriate.

B. Alternative Procedure

Another form of PAM occurs when an IRB member volunteers to participate as a subject in a study. In that case, the member will provide verbal feedback immediately after participation in the study. This will be followed by written feedback on observations made during participation in the study, and this will be sent to the PI, the PI's chair or director, the full IRB, and institutional officials as appropriate.