Post-Approval Monitoring (PAM)

General Description:

The purpose of auditing IRB approved studies is to ensure that state and federal research requirements are being met. Additionally, audits are conducted to ensure that approved protocols are not or have not deviated from approved procedures during the course of a study.

There are two types of audits that can be conducted for IRB approved studies:

1. Evaluation audits – also known as not-for-cause, these audits are conducted as part of compliance surveillance.
2. Investigation audits – also know as for-cause audits, these are conducted in response to substantiated allegations or indications of noncompliance.

Conducting Post-approval Monitoring (PAM) Visits

During the PAM visit process, the IRB office staff reviews current study procedures (compared with IRB-approved study procedures) and may also review research records including, but not limited to:

1. Screening records and logs
2. Enrollment logs
3. Signed consent documents
4. Research subject files
5. Sample storage
6. Study data records and transmission procedures
7. Recruitment materials

Goals of PAM Visit

The goals of a PAM visit are to ensure that (1) the research is conducted in accordance with federal regulations and George Mason University Standard Operating Procedures for the conduct of human subjects research; (2) to facilitate communication between the IRB and researchers at GMU, and (3) to provide individualized education regarding the conduct of human subject research.

The following criteria increase the likelihood that a study will be reviewed:

- FDA regulated investigator-initiated studies
- Studies with more than minimal risk to participants
- Studies involving vulnerable participant populations (e.g., children, prisoners)
- Studies initiated by faculty investigators who are new to research
- Inquiry or information received by IRB from an outside source that would call the study into question
- Active studies in which a continuing review/amendment has been submitted to the IRB and the IRB staff has not received a response to questions/revision requests

Procedures:

1. Once a study has been selected for compliance monitoring, an IRB office staff member sends an email notice to the Principal Investigator (PI) and contact persons for the study. The IRB

staff will work with the PI to arrange a time to review the study, generally within 2-4 weeks. Visits may be conducted on site, virtually, remotely, or a combination of the aforementioned methods.

2. The compliance monitoring process consists of:
    - An introductory meeting to discuss the study with the PI and any other study staff who should attend. The PI is required to attend this meeting and may invite any members of the research team to attend - typically the study coordinator and persons conducting the recruitment and consent process or study procedures.
    - A review of the informed consents and other study materials. Based on the number of participants enrolled, the IRB office staff will inform the team of the approximate time needed for the review.
    - An exit meeting to review any preliminary findings.
3. The PI is responsible for providing the research binder with all study procedures laid out sequentially in addition to all supplemental study materials at the initial meeting.
4. If a follow up meeting is necessary to further discuss the study documents and procedures, the IRB office staff will arrange a meeting with the PI and/or study staff.

5. Within two weeks, the IRB office staff submits a report to the IRB Chair to include required actions for the research team, summary of the information discussed throughout the process, additional educational information, and regulations and guidance that pertain to the conduct of research involving human subjects.
6. Monitoring reports will be available to the PI in IRBNet for review and response and will be tagged by IRB staff. The PI will submit a response to the IRB for any corrective actions within two weeks of receiving the report.

Related Forms, Guidance, and SOPs:

- GMU Quality Improvement Study Review General Study Information Worksheet
- Post Approval Monitoring Checklist
- Noncompliance and Deviations
- Research Participant Complaints

Responsibility:

Principal Investigators
IRB Office Staff
IRB Chairperson

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

Date First Effective:	February 24, 2016
Revision Date:	[August 8, 2023]
Current Version #:	2

Approved By	Title and Division	Date Approved
Chris DiTeresi, PhD	Assistant Vice President, Office of Research Integrity and Assurance	August 8, 2023
Charlotte Gill, PhD	IRB Chairperson	August 8, 2023