SOP 2.6.6 **Post-Approval Monitoring and Education Visits**

General Description:

Conducting Post-approval Monitoring (PAM) and Education (Ed) Visits

During the PAM and Ed visit process, the IRB office staff reviews current study procedures (compared with IRB-approved study procedures) and may also review research records including:

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 and Ed Visit

The goals of a PAM and Ed 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, (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. Studies will be selected by the IRB/IRB office staff for PAM/Ed visits either due to a reported concern or randomly within categories (i.e. FDA regulated, more than minimal risk, etc.)
2. 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.
3. The compliance monitoring process consists of a meeting to review the informed consent documents and other study related documents as well as discuss the study with the PI and any other study staff who want to attend. Based on the number of informed consent documents, the IRB office staff will inform the team of the approximate time needed for the review. 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.
4. If a follow up meeting is necessary to further discuss the study documents and procedures, the IRB office staff will arrange a second 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.

Related Forms, Guidance, and SOPs:

- GMU Quality Improvement Study Review General Study Information Worksheet

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.

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Approved By	Title and Division	Date Approved
Aurali Dade	Assistant Vice President, Office of Research Integrity and Assurance	February 24, 2016
Greg Guagnano	IRB Chairperson	February 24, 2016