Program Description

Objective
The goal of compliance monitoring is to confirm, by observation, accurate and consistent protocol performance in a collegial and unobtrusive manner. The program is also designed to help investigators, their teams, and the University prepare for external audits by granting, regulatory, and accreditation agencies.

Background
PostApproval Monitoring (PAM) of Institutional Review Board (IRB)-approved protocols is achieved through several different mechanisms. The Research Assurances Monitor (RAM) from the Office for Responsible Research (ORR) is specifically charged with documentation of compliance. Additionally, the RAM assists the ORR and IRB in identifying areas of weakness in the program or the approval process. PAM is not designed to “catch” individuals; rather, it is designed to verify that research is being conducted as approved. The vast majority of noncompliance is a result of lack of understanding of the roles and responsibilities of individuals involved in research and inadequate training of staff. Monitoring will allow the IRB and ORR to respond to any identified trends.

The RAM is not a member of the IRB. The role of the RAM is to confirm by observation that research activity is being performed in accordance with approved IRB protocols and institutional Standard Operating Procedures (SOPs) and to assist the principal investigator in identifying any deviations and implementing any required changes.

Roles
- Investigators and their staff will work with the RAM to observe and confirm procedures of an approved protocol.
- The RAM will observe research activity, prepare accurate reports, provide recommendations for maintaining compliance, provide training or information on training options when needed, and assist in execution of corrective and preventative actions.
- The Director, Office for Responsible Research (DORR), shall provide oversight and management of the RAM and the PostApproval Monitoring Program, assure that the IRB and the Institutional Official receive reports or updates on items of concern, and provide training support as required to assure compliance.

Protocol Selection
All studies, even those determined to qualify for exempt status, are subject to monitoring. Routine monitoring visits will primarily be randomly selected by the RAM; however, an emphasis may be placed on monitoring studies involving vulnerable populations, or unusual levels or types of risks to subjects.

Monitoring visits may also be “directed” by the DORR (e.g., to assist in verification of findings in cases of potential noncompliance, to provide verification of implementation of corrective actions implemented in response to noncompliance, to assist the IRB in monitoring studies requiring more frequent review, etc).
A PI may also request an on-site review to help keep records and procedures in compliance with federal regulations and institutional policies or to prepare for an external audit by a sponsor or federal agency. Visits of this nature are encouraged as the goal of PAM is not to “catch” people, rather to assist investigators in conducting compliant research.

**Monitoring Process**

The RAM will schedule the PAM visit with PIs and their staff, making every attempt to facilitate schedules. “Directed” monitoring may or may not be scheduled.

During the PAM visit, the RAM will compare procedures being conducted in the laboratory or study area with those listed in the approved protocol and any approved modifications. This may include reviewing study records, visiting with the PI to review procedures being followed, observation of consent process, etc. Documented discrepancies between observed and approved activities will be brought to the attention of the PI. The RAM will review and assess areas such as, but not limited to:

- Research team composition and training
- Recruitment procedures
- Screening procedures
- Consent process
- Study procedures
- Publications from the study
- Current enrollment and verification of informed consent
- Reports of adverse events
- Storage of study documents and data
- Privacy and confidentiality issues
- Subject payment
- Questions and concerns from the PI and research team

**Information Sharing Process**

Following completion of the PAM visit, the RAM will discuss observations with the PI and/or their staff prior to leaving the laboratory. If the PI is unavailable, the RAM will schedule a time to discuss the results of the visit. Issues that pose an immediate threat to research participants will be brought to the immediate attention of the DORR and the IRB Chair(s).

A written report of the PAM visit will be prepared by the RAM. The aim will be to deliver an audit report in which any discrepancies or concerns have been resolved. This report will be reviewed internally by the DORR, and a final copy will be sent to the PI and the IRB Chair(s). The IRB will be informed of the progress of the auditing program including trends, general items of concern, etc.

**Follow-Up Process**

Additional monitoring visits may be required to ensure that corrective and preventative actions have been taken to prevent protocol drift in the future, or as directed by the DORR.

The ORR will assist, where able, in completion of required actions as a result of the PAM visit. Assistance may include providing guidance with protocol modifications and/or direction to appropriate training.

*In most cases, discrepancies observed during PAM visits can be addressed by modifying an existing protocol or reverting to procedures that were originally approved.*
Appeal Process
If a PI disagrees with the findings of the PAM visit or recommendations made, they can address these concerns with the RAM during the discussion at the end of the visit. If no satisfactory resolution to their concerns is agreed upon, the PI may contact the DORR to discuss these issues. Again, if no satisfactory resolution is agreed upon, the PI will have the opportunity to address the IRB in writing or at the next regularly scheduled meeting.

Recordkeeping
A copy of the final PAM visit report will be kept by the RAM, and a copy will be given to the IRB Administrator to be placed in the protocol file. Information will be entered into a database for trending or required follow-up.