University of Massachusetts Boston
Post-Approval Monitoring
(PAM)
Version 9/26/2024

Purpose

The purpose of the Post-Approval Monitoring (PAM) program is to ensure compliance with ethical standards, regulatory requirements, and the University of Massachusetts Boston's policies governing human subjects research after IRB approval has been granted. This policy aims to:

- Protect the rights and welfare of human subjects.
- Enhance the quality of research.
- Facilitate compliance with applicable regulations.
- Educate and support the university's research community.

Scope

This policy applies to all research involving human subjects that has been approved by the UMass Boston IRB, regardless of the source of funding or whether the research is subject to federal regulations.

Procedures

1. **Selection for Monitoring:** Projects may be selected for PAM based on various criteria, including but not limited to: random selection, complexity of the research, level of risk to participants, complaints received, and previous history of non-compliance.
2. **Monitoring Activities:** PAM may involve a range of activities, such as:
    - Review of study documents and records for compliance with the approved protocol and consent process.
    - Interviews with researchers and research staff.
    - Observations of consent processes and research procedures.
    - Review of adverse event reports and how they are managed.
3. **Reporting:** Findings from the PAM activities will be documented in a report summarizing the compliance status of the research project, including any recommendations for corrective actions or areas for improvement. Results are sent to the IRB manager and Institutional Official/ Organizational Official (IO/OO) or designee.
4. **Corrective Actions:** If the results of any evaluations demonstrate inconsistency, recurring noncompliance or misinterpretation of HRPP requirements, high variability, or are outside performance targets, work with the IRB and IO/OO to implement an intervention. Interventions may include policy and procedure modifications, education and training efforts, system modifications, or other corrective actions. Actions may range from additional education and training to modification of research protocols, suspension, or termination of IRB approval.
5. **Education and Support:** The PAM program is designed to be educational rather than punitive. The Associate Director of Research Compliance and Integrity and IRB staff will

provide resources and support to researchers to facilitate compliance and promote ethical research practices.

Responsibilities

- **Associate Director of Research Compliance and Integrity:** Oversees the PAM program, schedules reviews, and maintains records.
- **IRB:** Selects projects for monitoring, reviews findings, and ensures corrective actions are implemented.
- **Researchers and Research Staff:** Cooperate with PAM activities, provide requested documentation, and implement corrective actions as required.
- **Institutional Officials:** Support the enforcement of PAM policies and the implementation of corrective actions.

Confidentiality

All information obtained during PAM activities will be treated as confidential to the extent permitted by law and university policy.

Policy Review and Revision

This policy will be reviewed annually and revised as necessary to reflect changes in regulatory requirements, university policies, and best practices in human subject's research.

Standard Operating Procedure for Post-Approval Monitoring Program

Purpose

To provide a structured process for the Post-Approval Monitoring (PAM) of approved human subjects research projects to ensure compliance with ethical principles, federal regulations, state laws, and University policies.

Scope

This SOP applies to all human subjects research projects approved by the UMass Boston IRB and encompasses all disciplines and departments within the University.

Definitions

- **PAM:** Post-Approval Monitoring, a systematic review of research activities to ensure compliance with approved protocols.
- **IRB:** Institutional Review Board, responsible for the review and approval of human subject's research.
- **Non-compliance:** Failure to adhere to the approved protocol, policies, or applicable regulations.

Responsibilities

- **Associate Director of Research Compliance and Integrity:** Oversees the PAM program, schedules reviews, and maintains records.

- **IRB:** Selects projects for monitoring, reviews PAM reports, and determines necessary actions for non-compliance.
- **Researchers:** Cooperate with PAM activities and implement recommended changes or corrective actions.

Procedures

1. **Selection of Projects for Monitoring**
    - Projects are selected based on criteria such as random selection, risk level, complexity, and history of non-compliance.
    - Researchers will be notified in advance of a PAM review.
2. **Preparation for Review**
    - The Associate Director of Research Compliance and Integrity and/or designee of the Associate Director of Research Compliance and Integrity will prepare a checklist tailored to the project's specifics, including review of consent forms, protocols, and any previous IRB correspondence.
3. **Conducting the Review**
    - Reviews may include document inspection, interviews with research personnel, and observation of consent processes.
    - Emphasis will be placed on education and collaboration to address potential issues.
4. **Reporting Findings**
    - A report detailing findings, areas of concern, and recommendations for improvement will be compiled.
    - The report will be shared with the researcher and the IRB for review.
5. **Corrective Actions**
    - If non-compliance is identified, a timeline for corrective actions will be established.
    - Follow-up reviews may be scheduled to ensure compliance with corrective measures.
6. **Documentation and Record-Keeping**
    - All PAM activities, findings, and follow-up actions will be documented and stored securely by the Associate Director of Research Compliance and Integrity.
7. **Education and Training**
    - The PAM program will provide educational resources and opportunities for researchers to enhance their understanding of compliance requirements and best practices.

Confidentiality

All information obtained during PAM activities will be handled confidentially, in accordance with university policies and applicable laws.

Policy Review and Revision

This SOP will be reviewed annually and revised as necessary to reflect changes in regulations, policies, and best practices.

This SOP serves as a guideline for conducting effective and efficient post-approval monitoring of research projects at UMass Boston. It emphasizes the collaborative and educational nature of the PAM process, aiming to foster a culture of compliance and integrity within the research community.