TEXAS A&M UNIVERSITY
SAN ANTONIO

INSTITUTIONAL REVIEW BOARD (IRB) STANDARD OPERATING PROCEDURE (SOP)

SOP #: 9	**Version:** 2.0	**Effective Date:** June 4, 2024
Title: Post Approval Monitoring (PAM)		
Approved by: Dr. Vijay Golla, PhD Vice Provost for Research and Health Sciences		**Date:** June 4, 2024

1. Purpose

1.1. This SOP outlines the process to conduct IRB Post Approval Monitoring (PAM) for all protocol activities.

2. Scope

2.1. Federal, System and University policy are all formed and enforced for the ultimate purpose of human subjects' protection. The IRB PAM review process is subject to CFR 45, Chapter A, Part 46, Subpart A 46.101 - 46.124.

2.2. All IRB activities are subject to PAM. Studies chosen for monitoring visits are selected based on the activity of the IRB and the level of risk.
Risk factors include:
Vulnerable populations, deception, confidentiality concerns, waivers granted by the IRB (e.g. waiver of informed consent or waiver of documentation of informed consent), studies with more than minimal risk to subjects, or studies conducted by investigators with past IRB concerns. This list is not exhaustive.

2.3. PAM visits may also be "directed" by the Institutional Official (IO), the Director of Research Compliance (DRC), IRB Chair, or Vice Chair as needed. This is to assist in verification of findings in cases of potential noncompliance and to provide verification of implementation of corrective actions as outlined in the Corrective Action Plan (CAP). PAM may also be implemented to assist the IRB in monitoring studies requiring more frequent oversight.

2.4. A Principal Investigator (PI) may also request a PAM review to assist with 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 the PAM is to assist investigators in conducting compliant research. During these PI-requested visits, the PAM focuses on areas of improvement, and deviations self-reported by the PI to the IRB. This may require the submission of a protocol amendment.

3. Responsibilities

3.1. DRC or designee serves as the original reviewer of PAM and supervises the Research Compliance staff involved in the process.

3.2. Research Compliance Administrator (RCA) and IRB members may act as consultants in conducting the monitoring activities, receiving, and routing reports.

3.3. The PI is responsible for addressing all requests and actions required for the PAM visit. The PI may delegate a key study personnel to act as the study representative.

3.4. All listed investigators, key study personnel, and relevant personnel on the protocol are accountable for complying with and adhering to the directives of the PAM.

4. Procedures

4.1. Identifying protocols for PAM

4.1.1. Quarterly, the DRC or designee will identify three protocol activities for PAM.

4.1.2. The identified protocols, including the protocol number, title, and PI, will be emailed to the RCA.

4.1.3. The RCA will start the PAM pre-review to analyze the level and type of risk to subjects.

4.1.4. For-cause PAM visits will take place within one week of a potential noncompliance report.

4.2. Scheduling the PAM Visit

4.2.1. The RCA will notify the PI that the protocol has been selected for PAM and schedule the PAM in consultation with designated IRB members. The RCA will inform the PI of the nature of the review (random, for cause, investigator initiated, etc.).

4.2.2. The scheduled PAM visit should take place no more than three weeks after initial contact by the RCA or when the study begins.

4.3. Monitoring Procedures for Research Protocols

Pre-Visit

4.3.1. Prior to the visit, the RCA will verify the research team's training, review the protocol, and prepare other audit materials as required - i.e., PAM Checklist, protocol, key study personnel, study procedures, informed consent process, confidentiality measures, and general lab/record keeping. This list is not exhaustive.

Monitoring Visit

4.3.2. On the day of the visit, the RCA and designated IRB members will complete the PAM Checklist with the PI. Additionally, the RCA and designated IRB members will address any questions from the PI.

4.3.3. After the PAM review the RCA will compile and review the requested materials.

4.3.4. The RCA will draft a report in consultation with the designated IRB members within fifteen (15) business days and send it to the DRC and IRB Chair. The goal of this report is to outline any discrepancies from the IRB protocol activity, and offer suggestions or recommendations for areas of improvement, including any suggested protocol modifications identified during the PAM review. The RCA is responsible for following up on the CAP to ensure the PI has fully implemented the CAP.

4.4. Exit Briefing

4.4.1. After the DRC and IRB Chair have provided their feedback, the RCA and designated IRB members will conduct a debriefing meeting with the PI and provide an overview of preliminary findings and answer any questions that may occur.

4.4.2. If the PAM determines there are deficiencies, the IRB Chair and DRC may recommend an amendment to the IRB protocol activity.

4.5. Results

4.5.1. The PAM review and findings will be shared with the IRB Committee at the next convened meeting by the RCA, designated IRB members, and IRB Chair. The IRB Chair and DRC will share their recommendations and action plans, if applicable.

4.5.2. If the PAM CAP requires suspension or termination of the research due to noncompliance it should be voted on by the IRB Committee at the next convened meeting unless it is a medical emergency.

4.5.3. In the event of disciplinary action, the IRB Committee can place the PI on a cycle of monthly records review to assess whether the PI has effectively implemented the CAP. Further actions may be required per IO guidance or federal guidelines.

5. Revision History

5.1. Revised 06/29/20 JEF, November 2023, April 2024

6. References

6.1. Iowa State University. Office of Responsible Research. Post Approval Monitoring. Retrieved June 30, 2020 from: https://compliance.iastate.edu/research-ethics-compliance/irb/post-approval-monitoring-and-education/

6.2. Nova Southeastern University-Institutional Review Board. Standard Operating Procedures. Retrieved April 2024 from: https://www.nova.edu/irb/post-approval-monitoring.html

6.3. Western Illinois University. Post Approval Monitoring Policy. Retrieved April 2024 from: http://www.wiu.edu/sponsored_projects/postapprovalmonitoringpolicy.php

6.4. Purdue University. Human Research Protection Program. Institutional Review Board. Retrieved April 2024 from: https://www.irb.purdue.edu/docs/new/sops-web.pdf