TEXAS A&M UNIVERSITY KINGSVILLE	**SOP: Post Approval Monitoring**	
	Section IV: Post-Approval Monitoring and Non-Compliance	
	Number	Date
	IRB IV-001	9/13/2025

1. PURPOSE

1.1. This SOP outlines the process for post approval monitoring of IRB protocols and processes for research compliance by the Texas A&M University-Kingsville (TAMUK) IRB.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. The Post Approval Monitoring (PAM) program is under the general direction of the TAMUK IRB Chair. The PAM Program includes the following:

3.1.1. PAM: Routinely conducted based upon risk, category, or type of study. Circumstances where PAM may occur include, but are not limited to:

3.1.1.1. Periodic and randomized selection of active human research studies;

3.1.1.2. Investigator Initiated Studies (minimal risk and greater than minimal risk);

3.1.1.3. Studies assessed by the IRB to include a high degree of risk (adverse events, protocol deviations, type of study, or vulnerable populations); or

3.1.1.4. New or inexperienced investigator or research staff.

3.1.2. Directed or For-Cause Review: Conducted at the request of the Institutional Review Board (IRB), IRB Chair, Institutional Official, or designee. Circumstances where a For-Cause Review may occur include, but are not limited to:

3.1.2.1. As part of an ongoing corrective action;

3.1.2.2. To support a review associated with Reportable New Information or the IRB's assessment of potential non-compliance, including failure to follow the approved protocol, and/or;

3.1.2.3. When there are concerns regarding whether the rights and welfare of participants enrolled in research are adequately protected.

3.1.2.4. When there are concerns about the validity or integrity of the data collected.

4. RESPONSIBILITIES

4.1. The IRB Chair (or designee) and research compliance staff assigned to the IRB is responsible for ensuring these procedures are carried out.

5. PROCEDURE

5.1. Post Approval Monitoring (PAM):

5.1.1. Selection and Scheduling:

5.1.1.1. The IRB Chair (or designee) or research compliance staff assigned to the IRB selects studies as follows:

5.1.1.1.1. A random sampling from a list of active studies. Studies selected in this manner will go through an initial review to determine appropriate areas for review.

5.1.1.1.2. Through request by the IRB members, IRB Chair, or Institutional Official (or designee), to assess general programmatic compliance with regulatory and institutional requirements based upon specified study characteristics.

5.1.1.2. The IRB Chair (or designee) or research compliance staff assigned to the IRB contacts the Principal Investigator's (PI) research team in writing (email) to:

5.1.1.2.1. Schedule the review in a timely manner;

5.1.1.2.2. Provide an overview of the scope, process, and required workspace needed for the review; and

5.1.1.2.3. Provide a list of materials that will be used as a general guide for review to the PI and research team. These materials may include any current protocol documents, review of consent procedure and documents, and any other information the IRB deems relevant based on the original submitted protocol. This is described in greater detail in section 5.1.2.3.

5.1.2. Review Procedures:

5.1.2.1. In advance of the review visit, the IRB Chair (or designee) or research compliance staff assigned to the IRB reviews the protocol information on file with the IRB;

5.1.2.2. On the day of the review, the IRB Chair (or designee) or research compliance staff assigned to the IRB will meet with the PI and designated study staff at the open and close of the review, if possible. The PI will arrange for a private work area to facilitate the review. At a minimum, designated study staff should make themselves available for documentation retrieval, to answer any questions, or to provide clarification as may be needed;

5.1.2.3. The PI will provide the following study files (as applicable/requested) for the PAM's review:

5.1.2.3.1. All study-related regulatory documents;

5.1.2.3.2. Subject screening/enrollment log;

5.1.2.3.3. Case report forms;

5.1.2.3.4. Source documents;

5.1.2.3.5. Informed consents, assents, and HIPAA for all enrolled and screened participants

5.1.2.3.6. Study drug/product accountability logs, as applicable;

5.1.2.3.7. Device accountability logs, as applicable;

5.1.2.3.8. Lab logs, as applicable; and

5.1.2.3.9. Other documents/files as requested that support the study administration;

5.1.2.4. Research records are expected to be maintained by the study team in a review-ready state at all times. The study team will have an opportunity to locate and provide materials or documents that are not present in the files at the time of review, but the initial absence of material or documentation will be noted in the findings.

5.1.3. Findings

5.1.3.1. Finding types may include, but are not limited to:

5.1.3.1.1. No further action necessary;

5.1.3.1.2. Minor administrative issue(s) with best practice or additional education recommendation for corrective action;

5.1.3.1.3. Finding that meets the definition of 'Reportable New Information' with best practice or other recommendation for corrective action.

5.1.3.1.4. Major finding indicating potential harm or imminent risk of harm to participants' safety and well-being. These findings will be reported immediately by the IRB Chair (or designee) or research compliance staff assigned to the IRB and, when necessary, to the Institutional Official or designee.

5.1.4. Documentation and Distribution of Findings

5.1.4.1. The IRB Chair (or designee) or research compliance staff assigned to the IRB will document observations, findings, and any concerns.

5.1.4.2. At the conclusion of the review, the IRB Chair (or designee) or research compliance staff assigned to the IRB verbally debriefs the investigator and/or designated study team members regarding findings, applicable recommendations, and next steps.

5.1.4.3. The research compliance staff assigned to the IRB generates a written report of findings, including recommendations. The written report of findings is shared with the PI and IRB chair.

5.1.4.4. The research compliance staff assigned to the IRB submits a copy of the written report into the IRB submission system and references all applicable research through the Reportable New Information activity TAMUK SOP: Reportable New Information Items (IRB SOP IV-003).

5.1.4.5. The PI is asked to review the written report and provide a response and a corrective action when necessary.

5.1.4.6. In the event the PI disagrees with the factual findings or wishes to provide clarification, the PI may provide the rebuttal and/or clarifications, in writing. The provided information and any corrective action plan will be submitted to the IRB submission system.

5.1.4.7. The PI is also asked to submit each incident of Reportable New Information found through the review that has not already been reported to the IRB.

5.1.4.8. Follow-up reviews may be scheduled to confirm ongoing adherence to corrective action recommendations and to ensure continued compliance.

5.2. Directed or For Cause Review

5.2.1. Selection and Scheduling

5.2.1.1. The IRB Chair, Institutional Official, or designee (hereafter referred to as the 'Requestor') may request a directed or for-cause review.

5.2.1.2. The Requestor will notify the IRB Chair (or designee) or research compliance staff assigned to the IRB of the PI whose study will be subject to a directed or for-cause review. An official notification will be sent to the PI with a copy to their department head. This notice will include the scope, timing, scheduling process, and next steps.

5.2.1.3. Unless directed to contact the PI sooner, the research compliance staff assigned to the IRB will contact the PI by the next business day following receipt of the review request to schedule the review and coordinate with the PI and study team to schedule the review within the timeline established by the requestor.

5.2.1.3.1. If scheduling and/or completion of review will not be possible within the established timeframe due to circumstances beyond the PI's control, the research compliance staff assigned to the IRB will notify the Requestor and request additional guidance.

5.2.1.3.2. As research records are expected to be maintained in an audit-ready state at all times, the time needed for record preparation is not an acceptable reason to request a delay.

5.2.2. Review Procedures

5.2.2.1. Review procedures will follow those outlined in 5.1.2, above.

5.2.3. Documentation and Distribution of Findings

5.2.3.1. The report and associated findings are shared with the Requestor, IRB Chair, and the Institutional Official as needed. The findings are also provided to the PI and their department head.

5.2.3.2. The Remainder of Documentation and Distribution of Findings procedures will follow those as outlined in 5.2.1, above.

6. REFERENCES

6.1. 21 CFR §56.108(b), 21 CFR §56.109(f),

6.2. 45 CFR § 46.103(b)(5), 45 CFR §46.109(e),

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