**UTRGV Post Approval Monitoring**
**Office of Research Compliance**
**Standard Operating Procedure**

## I. Post Approval Monitoring Program

### A. Policy Statement:

1. The University of Texas Rio Grande Valley (UTRGV) Post Approval Monitoring (PAM) Program supports the institution's efforts to ensure that ethical and regulatory requirements are followed according to institutional policies and procedures and local, state, and federal regulations and guidelines. This program is designed to improve the quality of the research by ensuring congruency between what is described in the approved protocol and what occurs during the actual performance of research activities. The PAM Program has three pillars: protocol review, education, and assessment for operational improvements.

### B. Purpose:

1. The purpose of the PAM is to promote research best practices on studies approved by the UTRGV Institutional Animal Care and Use Committee (IACUC) and Institutional Biosafety Committee (IBC) and approved or under a reliance agreement by the UTRGV Institutional Review Board (IRB).
2. The program serves as an internal review process for proactive identification and assessment of potential problems and the development and provision of educational support and training to research personnel.
3. The PAM program aims to verify and document:
   a. the rights and well-being of research participants.
   b. the humane treatment of animals.
   c. safeguards for human health and the environment.
   d. availability of assistance for researchers to maintain or improve the quality and integrity of the research.
   e. compliance with institutional, local, state, and federal regulations and guidelines.
   f. congruence between approved protocol and research activities.
   g. the identification of resources for educational support to investigators and the research community.

### C. PAM programs are further justified as follows:

1. *IACUC*
   a. The Guide (p. 33) – Post Approval Monitoring (PAM)
   b. 9 CFR 2.31 (d) (5)
   c. PHS Policy IV.C.5 5
2. *IBC*
   a. NIH GUIDELINES FOR RESEARCH "Section IV-B-2-b-(1)
   b. NIH GUIDELINES FOR RESEARCH “Section IV-B-2-b-(5)
3. *IRB*
   a. 45 CFR 46.109 (e)
   b. 45 CFR 46.109 (g)
   c. 45 CFR 46.111 (a)(6)

d. 21 CFR 56.109 (f)
e. 21 CFR 56.111 (a)(6)
f. Single IRB (SMART IRB Agreement)
   i. Master Common Reciprocal Institutional Review Board Authorization Agreement
      1. 4. Responsibilities of the Participating Institution(s)
      2. 5. Responsibilities of the Reviewing IRB(s) and Reviewing IRB Institution(s)
         5.12 Audits, Investigations; Corrective Actions.
      3. 6. Responsibilities of the Relying Institution(s)
         6.13 Audits, Investigations; Corrective Actions.

D. **Applicability and scope:**
   1. PAM applies to all active research protocols approved by UTRGV IACUC and IBC and approved or under a reliance agreement by UTRGV IRB.
   2. PAM does not include concerns or allegations of research misconduct. Please refer to UTRGV HOP ADM-07-102 for the appropriate procedure. If research misconduct is identified or suspected during a PAM protocol review, the PAM compliance staff will refer the issue to the Research Integrity Officer (RIO).

E. **Responsibilities and obligations of the various affected parties:**
   1. PAM Program Monitor
      a. PAM protocol reviews are conducted by at least one PAM compliance staff member (Monitor/s) within the Office of Research Compliance (ORC). The Monitor is not a member of the regulatory committees but may participate in the convened meetings to provide a report of findings or at the request of the committee.
      b. In the case of an emergent or serious event that requires additional oversight or reporting, the Monitor will work in conjunction with the regulatory committee.
      c. The regulatory committees will receive an annual report with aggregated findings of the PAM protocol reviews at the committee meetings.
      d. The Monitor will randomly select the protocol for PAM review emphasizing in more than minimal risk and may request feedback from the regulatory committees.
      e. The Monitor will coordinate with the Principal Investigator (PI), assess the research activities and documents, identify weaknesses, review the implement of a corrective action plan in the case of non-compliance, report findings, provide educational tools, and suggest best practices.
      f. Depending on the nature of the research study, the Monitor may be accompanied by a member of the regulatory committee (or designee) who has experience conducting research and/or expertise in the specific field of study under review.

g. The Monitor will work closely with the other offices or stakeholders to not duplicate efforts and to maximize institutional resources.
h. The Monitor will report to the Institutional Official (IO) through the Institutional channel the outcomes of the PAM protocol review program activities annually and submit recommendations.

2. PI and research project personnel
   a. The PI is responsible for all research activities and ensuring compliance with regulations and guidelines. The PI will fully cooperate with the Monitor to coordinate the PAM protocol review, provide all the required documentation, and design a corrective action plan, if necessary.
   b. Research project personnel must conduct research protocols in compliance with applicable regulations and guidelines and, if requested, participate in the PAM review, as needed.
3. The IO is responsible for assigning adequate resources for the PAM program.
4. The regulatory committees will collaborate closely with the PAM program, receive recommendations, and provide feedback as needed.

**F. Procedures:**

1. *Selection of projects*
   a. IACUC
      i. All IACUC active approved protocols are eligible for PAM protocol review.
      ii. Routine selection – An annual random sample of a percentage (to be determined on an annual basis in consultation with the Division of Research and IACUC) of the active protocols will be selected, focusing primarily on the following:
         1. Externally funded studies that are not monitored by other entities.
         2. Studies involving new or changes in PI or key research staff.
         3. Studies classified under USDA pain categories D and E
         4. Studies with surgical procedures
         5. Studies utilizing USDA-covered species
         6. PI request
      iii. Direct selection – Studies can be selected for PAM based on the following criteria:
         1. Studies with non-compliance reports or concerns.
         2. Studies designated by the IACUC committee or Office of Research Compliance.
   b. IBC
      i. All IBC active approved protocols are eligible for PAM protocol review.

ii. Routine selection – An annual random sample of a percentage (to be determined on an annual basis in consultation with the Division of Research and IBC) of the active protocols will be selected, focusing primarily on the following:
   1. Externally funded studies that are not monitored by other entities.
   2. High-risk studies as determined by IBC review (including, but not limited to, BSL/ABSL2+/3).
   3. Studies involving new or changes in PI or key research staff.
   4. Studies active or distributed at multiple locations.
   5. Studies involving the transfer of hazardous biological agents or rDNA.
   6. Studies at approved locations which were not originally intended (for example, recently remodeled or adapted) to meet the risk assessment determined for the project.
   7. Studies at locations where access to critical safety equipment or infrastructures is not as readily available as in core research facilities.
   8. PI request

iii. Direct selection – Studies can also be selected based on the following criteria:
   1. Studies with non-compliance reports or concerns.
   2. Studies designated by the IBC committee or Office of Research Compliance.

c. IRB

i. All IRB active approved protocols are eligible for PAM protocol review.

ii. Routine selection – An annual random sample of a percentage (to be determined on an annual basis in consultation with the Division of Research and IRB) of the active protocols will be selected, focusing primarily on the following:
   1. Emphasis will be given to greater than minimal risk protocols approved by IRB at a convened meeting, followed by protocols approved by expedited procedures, with less emphasis on protocols determined to be exempt.
   2. Externally funded studies that are not monitored by other entities.
   3. Studies involving new or changes in PI or key research staff.
   4. Studies involving vulnerable populations.
   5. FDA regulated studies.
   6. Studies with multiple sites.

7. PI request

iii. Direct selection – Studies can also be selected based on the following criteria:
1. Studies with non-compliance reports or concerns.
2. Studies designated by the IRB committee or Office of Research Compliance

2. Direct selection may include an unannounced PAM visit, and all PI regulatory research protocols may be subject to PAM review.
3. Due to the nature of some research protocols, approval may be needed from more than one regulatory committee. In this case, the PAM review process and review of documents for all involved committees may apply.
4. Studies will not be selected more than once in the same year for PAM protocol review unless major deviations are found or require a direct selection.
5. If a study has been identified as having significant issues during the PAM process, a follow-up review may be conducted within three months following the report. The definition of significant issues is determined at the discretion of the Monitor.
5. *Notification*
   a. The PI and the Office of Research Compliance director will be notified via email that a study has been selected for PAM protocol review.
   b. The email will contain the following information:
      i. the study number and title
      ii. the estimated anticipated length of the Monitor visit
      iii. the potential dates and times for the Monitor visit
      iv. the list of the approved protocol personnel that should be available during the visit
      v. a PI self-assessment tool
      vi. a list of the documents that will be reviewed
   c. The PI must acknowledge receipt of the email and coordinate the visit with the Monitor conducting the review within two weeks of receiving the email notification.
   d. If the PI does not acknowledge receipt or fails to coordinate the visit within two weeks, a second email notification will be sent with a carbon copy to the respective Director/Chair of the department/Department.
   e. If the PI does not respond to the second email within two weeks, the IO and corresponding Dean will be notified.
6. *Visit and review*
   a. The Monitor will review and become acquainted with the approved protocol and related documents prior to the visit, as well as select the PAM tools and specific questions based on the nature of the protocol. This procedure will include a review of the meeting minutes where the study was approved and amendments, if any.
   b. An initial meeting will be held with the PI to provide awareness of the process and what to expect.

c. If a visit to research facilities is needed, the PI should provide access to the facilities and a private area to review documents and discuss the protocol. The PAM protocol review may also include a general evaluation of any facility approved in the study.
d. During the PAM review, researchers should participate in the monitoring process and will be encouraged to ask questions. The Monitor will review the required documents and discuss or observe the approved protocol activities and procedures with the project research personnel.
e. If the Monitor finds protocol deviations during the PAM review, the Monitor will inform the PI of those as soon as they have been discovered and will provide an opportunity for the PI to disclose those to the respective committee, as required.
f. At the end of the PAM review, the Monitor will meet with the PI and provide a verbal, preliminary report of findings. The Monitor will then work with the PI and project research personnel to reconcile any issues or discrepancies prior to final report preparation.

7. *Findings and report*
   a. The outcomes of the PAM protocol review will follow under one of the following categories:
      i. Category 1 – No protocol deviation found. Operations are consistent with best practices, and no further action is necessary.
      ii. Category 2 – No protocol deviation found. Recommend implementation of best practices.
      iii. Category 3 – Minor deviation found. Require implementation of corrective actions.
      iii. Category 4 – Major deviations with corrective actions requested.
   d. The PI will receive a final report from the Monitor within two weeks of the PAM protocol review date. In the event the final report is delayed, the PI will be notified and informed of the expected report date. The report will consist of the findings and may include the required corrective action and best practice recommendations. If the corrective actions are completed during the visit, it will be noted in the corrective action section as "Corrective actions completed during the visit."
   c. If the results of the review fall under Categories 3 or 4, the PI will submit a response with the corrective actions to the Monitor no longer than two weeks after receipt of the final report. The PI may request more time to respond. Based on the PAM findings, the monitor can decide whether to approve the extension.
   d. Follow-up reviews may be scheduled to confirm compliance or provide revision to the corrective action plans.

e. If the PI does not respond with the corrective action plan within the allotted timeframe, the Director of Research Compliance will be notified to determine further actions.
f. The PAM process ends after all corrective actions have been addressed.
g. In the case of IRB Reliance protocol, the ORC may report the findings to the Reviewing IRB.
h. Final reports will be maintained in the ORC in accordance with applicable record retention schedules.
i. Aggregated findings for the PAM protocol reports will be presented to the regulatory committee and leadership for program evaluations and improvements.
j. The retention schedule and disposition of PAM documents will be in accordance with the UTRGV Policy for Records Management and Retention (ADM 10-102).

**G. Definitions:**

1. *Principal investigator (PI)* - primary individual leading and administrating a research project, regardless of the job title, and ultimately responsible for assuring compliance with applicable UTRGV, local, and federal regulations and guidelines as approved by the UTRGV regulatory committees.
2. *Institutional Official (IO)* - the UTRGV official responsible for ensuring that UTRGV's research regulatory programs have the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects, animal welfare, and recombinant DNA and government-regulated biological agents in research. The IO is legally authorized to represent UTRGV, is the signatory official for all assurances, and assumes the obligation.
3. *PAM Protocol Review* - involves a collegial discussion of the approved protocol with the PI and research personnel, visits to the research site or laboratory, evaluation of documents, confirmation of the completion of required training, observation of approved animal or human procedures, evaluation of hazardous biological materials research activities, facilitating the communication between researchers and regulatory committees, and providing educational training.
4. *PI Self-assessment tool* – a review form to help the PI and research team prepare for the PAM Protocol Review.
5. *Major deviation* – a serious failure to comply with the protocol, standard operating procedures, federal, state, local, or institutional regulations and guidelines including, but not limited to, 1) performing unapproved procedures without the regulatory committee approval, 2) performing a procedure with an improper technique that compromises the right and well-being of research participants, research project personnel safety, animals' welfare, or the environment, or lack of validity or integrity of the data. A major deviation requires notification to the regulatory committee and a prompt response or action by the PI.

6. *Minor deviation* - a deviation that does not compromise the right and well-being of research participants, research project personnel safety, animals' welfare, the environment, or data integrity and validity.