**PAM IBC 02\_101 PAM Review Process Description for Principal Investigator**

The following information outlines what to expect during a routine (not-for-cause) protocol review. This general description is subject to change based on factors such as type of research and availability. While the PAM visit is required, we will work with you throughout the process to ensure it goes smoothly and can be flexible to accommodate schedules if needed.

If you have any questions, please contact Mirayda Torres-Avila at mirayda.torresavila@utrgv.edu and/or (956) 665-2093.

**Pre-PAM Protocol Review Visit**

1**. Please have all protocol documents available for the monitor to review.** Please do not make paper copies for this review if any documents are stored electronically (e.g., SharePoint, RedCap, or the department shared drive). We will send a checklist before the visit asking where documents are stored and, if electronic, how we can access them at the time of the visit.

This may include any of the following:

* IBC Documentation (e.g., submissions, action letters, PI responses, approval letters, acknowledgments, unanticipated event reports, significant deviations)
* Management and/or monitoring logs.
* Research team staff training
* Study records of procedures documentation
* On-site record keeping
* Inspections and calibration of instruments
* Laboratory Standard Operating Procedures
* Chemical inventory and controlled substances inventory record (if applicable)
* Regulatory documentation for Investigational Drug/Device trials (if applicable)
* Permit and licenses (if applicable)

**2. Ensure there will be available space (e.g., desk or room) for the monitor during the review.** The monitor will need space to review the study documents on the date schedule.

**Summary of Review Process**

**Initial Meeting with Principal Investigator** ~30–45 minutes

1. **The monitor will present a summary and explain the review process.** The PI and staff will be encouraged to ask questions throughout.

**2. The monitor will ask protocol-specific questions.** The questions will pertain to protocol information not easily observed from study documents and regarding actual study practices.

**3. The PI and staff will be encouraged to ask questions and provide feedback.** The PI and research staff will be allowed to ask questions and offer opinions about the review and other questions about the PAM program.

**4. Final Meeting Scheduled.** Ideally, it should be scheduled at the end of the Protocol Review or within one week of the visit, when PI and protocol personnel will review any study findings.

**Study Review** ~1-2 hours (depending on the study)

**1. The monitor will review the study materials, interview protocol personnel, and/or observe procedures.** The length of the visit depends on many factors, such as the type of study and how long the study has been open. We aim to complete the review of the study in less than 2 hours. If we think the review may take longer, we will let you know as soon as possible.

**Final Meeting** ~45 minutes–1 hour

**1. The monitor will review the findings and observations noted from the review.** At this time, the research staff can make any clarifications as needed.

1. **PI and Protocol Personnel will be encouraged to ask questions and offer feedback.** At this time, the PI and protocol personnel will be encouraged to share feedback about the review experience and offer general opinions and ideas regarding research at the University of Texas Rio Grande Valley.

**Final Report and PI Response**

**1. Within two weeks, FINAL REPORT and PI RESPONSE FORM.** After the final meeting, the monitor will incorporate any changes to the report based on clarifications and discussion provided by the PI and protocol personnel and will be sent out within two weeks.

**2. PI Response to Final Report.** Once the PI has reviewed the report, all Required Corrective Actions must be addressed and Recommended Actions considered. The PI must complete, sign, and return the PI Response Form within two weeks of receipt unless more time is requested and approved. The Response Form allows the PI to explain what actions were taken and why certain recommended actions were not implemented.

**3. PI Responses Reviewed.** Once the monitor receives the signed PI Response Form, the monitor will review the responses to ensure all actions are adequately addressed. The monitor will contact the PI for clarification or further resolution if any issues are still unresolved.

**4. PAM Review Approved and Closed.** Once all actions are adequately addressed, the review will be formally closed.