**PAM IRB 02\_101 PAM Review Process Description for Principal Investigator Routine PAM**

The following information outlines what to expect during a Routine PAM protocol review. This general PAM process description may change based on the research field and methodology. While the PAM visit is required, we will work with you throughout the process to ensure it runs well and can be flexible to accommodate schedules if needed.

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

**Pre-PAM Protocol Review Visit**

1. **Provide a list of all enrolled participants** (without names or other PHI). The monitor will select specific subject files to review. The list of selected files will be provided to you in advance, so please have their complete study file/binder available for review. At the time of the visit, additional records maybe requested for review.

**2. Please have all study and participant documents, binders, and files available at the time of review.** Please do not make paper copies for this review if any of these documents are stored electronically (e.g., SharePoint, REDCap, 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:

* IRB Documentation (e.g., submissions, action letters, PI responses, approval letters, acknowledgments, unanticipated event reports, significant deviations)
* Signed consent forms (current and expired versions)
* Management and/or monitoring logs.
* Participant recruitment material
* Research team staff training
* Study records (including participant eligibility determination & documentation and screening procedures)
* Study procedures (including conduct & documentation of procedures)
* On-site record keeping (including storage of documents and participant files)
* Regulatory documentation for Investigational Drug/Device trials (if applicable)

**3. 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. Depending on the study and the number of participants, the review can last a few hours or be conducted over a few days.

**Summary of Review Process**

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

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

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

**c. 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.

**d. Final Meeting Scheduled.** Ideally, it should be scheduled at the end of the Study/Subject Review or within one week of the meeting, when any study findings will be reviewed with the PI and staff.

1. **Study and Subject Records Review** ~4–6 hours (depending on the study)

**a. The monitor will review the study and subject materials in the reserved space.**

PI and staff do not need to be present, but please have one study staff available. Once the review is complete, study files/records will be returned as instructed by the research team.

Note: The length of the Routine Visit depends on multiple factors, such as the type of study, how long the study has been open, and number of subjects enrolled. We aim to complete the review of the study and subject files within one day. To facilitate this, we try to schedule the start time during the morning. If we think the review may take longer, we will let you know as soon as possible.

1. **Final Meeting** ~45 minutes–1 hour
2. **The monitor will review the findings and observations noted from the review.** At this time, the research staff can make any clarifications as needed.
3. **PI and Research Staff will be encouraged to ask questions and offer feedback.** At this time, the PI and research staff 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 research staff 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. The report will be kept at the Office of Research Compliance and will not be shared with any other departments without PI permission and/or notification.

**A Note on Confidentiality of the Final Report and PI Responses.** Any observations made by the monitor, the Final Report, and PI Responses will be kept CONFIDENTIAL. They will not be shared with the regulatory committee unless serious or continuing noncompliance is noted or if a PI repeatedly fails to adequately address corrective actions required by regulations and The University of Texas Rio Grande Valley policies. In both cases, the PI will be notified before the regulatory committee is notified. The report will not be shared with others unless the PI requests it.

**VI. Examples of Regulatory Documents to Review During Monitoring.**

| **Review Category** | **Study documentation** |
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| Regulatory documentation/study management tools | |
|  | Enrollment log |
|  | Delegation of responsibility |
|  | Staff qualifications (CV, medical/clinical licensure) |
|  | Laboratory certification and normal value ranges |
|  | Sponsor correspondence |
|  | Regulatory Committee documentation (all significant correspondence submitted to or received from the IRB, including submission, investigator responses, notification letters, and approved consent forms) |
|  | Documentation of data and safety monitoring, including logs of monitoring activities, meeting agendas, minutes, and reports of the data monitoring committee |
| Subject informed consent | |
|  | Informed consent document |
|  | Documentation of informed consent |
|  | Re-consent, if required |
| Subject eligibility information | |
|  | Source documentation verifying inclusion and exclusion criteria according to IRB-approved protocol (e.g., screening form, intake questionnaire, medical record information, self-report |
| Protocol adherence | |
|  | Study procedure according to regulatory committee approved protocol. |
|  | Pretreatment/therapy requirements |
|  | Follow-up visits/communications |
|  | Treatment administration and dose modifications |
|  | Adverse events |
|  | Unanticipated events |
|  | Protocol deviations and exceptions (e.g., one-time modifications) |
| Drug/device accountability | |
|  | Receipt of drug/device |
|  | Storage conditions |
|  | Administration/implant |
|  | Disposal (including destruction of expired product) |
| Data security | |
|  | Data security provisions implemented to protect confidentiality |
| Subject payment records | |
|  | Payments receipts |
|  | Payment or reimbursement logs |
| Grant/funding documentation | |
|  | Grant (salaries may be redacted) or attestation that there has not been a change to the grant or a progress report |
|  | OHRP declaration of assurance of the grant |
|  | Sponsor correspondence |