



Title: Post-Approval Monitoring

Policy Number: 013

Policy Intent: The intent of this policy is to describe the responsibilities of the post-approval monitor.

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1. Purpose

As a member of the Animal Care Services department, the purpose of the post-approval monitoring position is to work with investigators in a supportive manner in order to assure that investigators are in compliance with Institutional Animal Care and Use Committee (IACUC) approved research protocols, and when applicable, grant funding agency requirements. This is a service-oriented position established to help investigators stay in compliance with approved protocols, guidelines, laws, and best practices. If animal use activities are determined to be non-compliant then the Post-Approval Monitor (PAM) will work in conjunction with the investigator to resolve the issue, and help the investigator get back in compliance quickly so that appropriate animal care is maintained and research is not compromised.

Post-approval monitoring of IACUC protocols is executed to provide assurance to regulatory agencies, Texas Tech University, and the broader community that animals are used in a humane manner that is consistent with IACUC approved protocols and all Federal and State Regulations.

2. Roles of the PAM:

- A. Correspond, document, maintain records, and consult with the IACUC such that the IACUC receives timely reports or updates on items of concern.
- B. Work in conjunction with investigators and research personnel to organize monitoring events to observe animal procedures and certify compliance with approved protocols.
- C. Work with, and in support of, investigators to assure research is conducted within the limits of approved protocols and in compliance with Federal Regulations.
- D. Assist investigators in understanding regulatory compliance and assure good science.

3. Required Protective Measures:

- A. The PAM, as well as other visitors, shall wear the PPE prescribed for the specific activity/procedure of the laboratory.

4. Expectations:

- A. Selection of Protocols for Review:
 - 1) Any active protocol involving the use of live animals may be selected for monitoring on a random basis or at the discretion of the IACUC and/or University Veterinarian. Precedence may be given to protocols with higher pain categories.



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- 2) The PAM will try to schedule monitoring sessions with the Principal Investigator in advance. PIs are encouraged to reach out to the PAM when they have on-going procedures.
 - 3) Unannounced PAMs may occur if:
 - i. The PAM observes ongoing research while in the facilities for other reasons such as weekly rounds.
 - ii. If any procedure, welfare, or protocol concerns are reported, the PAM may monitor the personnel/protocol immediately or shortly thereafter.
 - iii. If the PI has multiple non-compliances, or is requested by the IACUC and/or University Veterinarian.
 - 4) If non-compliance is suspected by other means (i.e. rounds or communications) the PAM may inquire of the PI to understand the situation in order to determine if further action is needed (i.e. conduct an official PAM, protocol amendments, take to the IACUC).
 - 5) The PAM may request the PI submit photos and/or video of the procedures (i.e. field work) to be reviewed for oversight when the protocol takes place somewhere the PAM cannot visit.
 - 6) If the PI is unresponsive or does not acknowledge a PAM request after two weeks of trying to schedule observations then:
 - i. The IACUC office may send a letter to the PI.
 - ii. After 3 weeks, the department chair may be notified of the PIs lack of response to the mandated TTU PAM Program.
 - iii. If 30 days pass without response, then the IO will be informed and can determine if corrective action(s) need to be taken.
- B. Process of Monitoring:
- 1) The PAM may use the “Post-Approval Monitoring Checklist” for the review which may be made available to all PIs upon scheduling of the PAM session. The PAM may also photograph and video tape the procedures or request the PI to submit photos and videos. This is to allow for a visual aid and better understanding of procedures for the IACUC. This information will not be shared with anyone outside the IACUC without the PI’s approval. If any materials are presented at the monthly IACUC meeting, they will be deleted immediately after the meeting.
 - 2) During each monitoring session, the PAM will compare procedures conducted with those listed in the approved protocol or referenced SOPs. Discrepancies between procedures performed and those listed in the protocol will be brought to the attention of the PI.
 - 3) Animal misuse, mistreatment or neglect (welfare issues), and discrepancies which result in animal welfare concerns (deliberate animal misuse, mistreatment or neglect, or those that involve willful disregard for appropriate animal care) will be immediately reported to the IACUC and/or University Veterinarian. The IACUC staff, in conjunction with the University Veterinarian and IACUC Chair, will gather information to present to the IACUC for review and, if necessary, further investigation.
- C. Process of Sharing Information Concerning the Review:
- 1) The PAM shall discuss monitoring results with the PI and/or other research personnel before leaving the laboratory. If issues can be resolved during the monitoring session, the PAM will address them before leaving so that the investigator may remain in compliance. The PAM may make suggestions for



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improved procedural techniques and animal well-being. Issues that pose an immediate threat to animal welfare shall be referred to the IACUC and/or University Veterinarian.

- 2) The PAM shall send a copy of the checklist or an email outlining the monitoring results to the PI if non-compliance is found. The PAM will make recommendations to the PI to reach or maintain compliance. Investigators will have an opportunity to respond and submit any necessary amendments within *one week*. The response and all correspondence thereafter will be filed with the report.
- 3) The PAM will follow up on any issues that require protocol modifications, orientation of new personnel, or training. The PAM will support the corrective action by providing required training and/or assistance with form preparation (amendment submission).
- 4) On occasion, additional monitoring sessions may be included as part of the follow-up to *facilitate corrective* actions.
- 5) At the next monthly IACUC meeting, the PAM will report a summary of monitoring sessions performed. The IACUC will evaluate the recommendations suggested by the PAM, but has the authority to require additional corrective action, and determine if there is a need for non-compliance reporting to regulatory agencies.

D. Non-response Process:

- 1) If the PI does not acknowledge the PAM findings of non-compliance (non-animal welfare issues) within the allotted one week, the PAM will follow up with the PI for a second week.
- 2) After two weeks of non-response and/or submitting the appropriate amendment, the IACUC Office and/or Chair will send a letter to the PI.
- 3) After three weeks, the PI's department chair will be notified of the non-compliance, and that corrective action may be taken if the PI does not submit the appropriate documentation.
- 4) After 30 days, the IO will be informed of the non-response to the non-compliances. Depending on the severity of the non-compliances, the IO can determine what corrective action(s) to take (i.e. freeze funding, report to regulatory agencies, etc.).

E. Recordkeeping:

- 1) A PAM database and any reports shall be kept in the PAM's files and shared with the IACUC office. The database may be used for tracking institutional trends or follow-up and determination of general training or informational needs.