



IACUC SOP:	TAMU-S-007	Title:	Post-Approval Monitoring Performed by AWO Staff
	Location	Effective Date	Review By
	College Station/Dallas/Galveston/Kingsville	01/01/2024	12/31/2026
	Houston	01/01/2024	12/31/2026

1. PURPOSE

- 1.1. To describe the performance of post-approval monitoring by AWO staff in support of the IACUC’s mission of continuing programmatic oversight.

2. SCOPE

- 2.1. This SOP applies to post-approval monitoring performed by AWO staff of activities with live vertebrate animals under the direct oversight of a Texas A&M University IACUC.
- 2.2. This SOP does not describe other forms of IACUC programmatic oversight, such as facility inspection (see TAMU-S-010), triennial continuing protocol review (see TAMU-S-013), review of unanticipated or adverse events (see TAMU-S-015), and investigation of animal welfare concerns and potential noncompliance (see TAMU-S-012); or oversight activities performed by the Attending Veterinarian (or designee).

3. RESPONSIBILITY

- 3.1. The **IACUC Chair (or designee)** is responsible for reviewing reports of post-approval monitoring activities performed by AWO staff. This responsibility may be delegated to an appropriate designee as described in TAMU-S-002 and TAMU-S-006.
- 3.2. The **IACUC** is responsible for determining the best means and appropriate schedule for performing programmatic oversight, including the use of ad hoc consultants in the performance of post-approval monitoring; as well as evaluating findings and trends and taking appropriate action as necessary.
- 3.3. The **AWO Staff** is responsible for the coordination, scheduling and performance of post-approval and other monitoring as described in this document; preparing and maintaining documents utilized for this process, including sample checklists; maintaining documentation of the performance and outcome of the monitoring process; conveyance of the monitoring results to PI/core support unit managers and following-up as applicable on corrective actions needed; reporting the outcome or findings of monitoring activities to the IACUC, as applicable.
- 3.4. **Principal Investigators** and **Animal Facility Care Personnel** or **Core Support Managers** are responsible for participating in the PAM process when requested. **Principal Investigator Staff** or **Study Contacts** may participate on behalf of the PI

4. DEFINITIONS AND/OR ACRONYMS

- 4.1. **Amendment:** Significant change to on-going animal activity or research project as described in an approved animal use protocol.
- 4.2. **AUP:** Animal Use Protocol. Document submitted by the PI indicating the housing and procedures involving animals.
- 4.3. **AV:** Attending Veterinarian. Individual designated by Texas A&M University to fulfil the regulatory role of AV. May also describe veterinary staff who report directly to, and have delegated authority from, the AV.
- 4.4. **AWO:** Animal Welfare Office. Supports the IACUC administratively.
- 4.5. **Category D:** USDA pain categorization in which animals are expected to experience more than momentary pain and distress as a function of the study, and for which appropriate anesthetic, analgesic, tranquilizing drugs or other palliative therapy is utilized to alleviate pain or distress.
- 4.6. **Category E:** USDA pain categorization in which animals experience more than momentary pain and distress that cannot be relieved for study-related reasons.

- 4.7. **Core Support:** Individuals performing professional activities such as husbandry or technical services as a function of a dedicated service organization.
- 4.8. **IACUC:** Institutional Animal Care and Use Committee. Institutional body responsible for ensuring adherence to federal regulation and institutional policy relating to the care and use of animals in teaching, testing and research. Appointed by the Institutional Official.
- 4.9. **IACUC Chair:** Chair of the IACUC appointed by the Institutional Official.
- 4.10. **IACUC Leadership:** Committee comprised of the IACUC Chair, IACUC Vice-Chair(s), Attending Veterinarian and Animal Welfare Office Director.
- 4.11. **Minor Deficiency:** In the context of this SOP, refers to a finding which may be inconsistent with federal regulations but in the judgement of the IACUC Chair (or designee) does not represent a threat to the health or safety of the animals.
- 4.12. **Noncompliance:** Accidental or intentional failure to comply with state and federal regulations, System policies or regulations, University rules or procedures, IACUC guidance, or the requirements to conduct research, teaching or testing using animals; including adherence to the approved animal use protocol. **Serious noncompliance** has a negative impact on the welfare of an animal and/or is in direct violation of a federal standard regulating animal activities, including provisions of the Occupational Health and Safety Program, and may require reporting to federal regulators, funding agencies and accrediting bodies. (Also see Federal Notice NOT-OD-05-034 for examples of situations that constitute reportable noncompliance under the PHS Policy.)
- 4.13. **PAM:** Post-Approval Monitoring. Mechanism used for continuing IACUC oversight of animal activities within the animal care and use program.
- 4.14. **PI:** Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.
- 4.15. **SFI:** Suggestion for improvement
- 4.16. **Significant Deficiency:** In the context of this SOP, refers to a finding which is inconsistent with federal regulation and in the judgement of the IACUC Chair (or designee) and IO is or may be a threat to the health or safety of the animals.
- 4.17. **SOP:** Standard Operating Procedure. SOP documents are developed by the IACUC to provide procedural standards for the activities performed by the committee.
- 4.18. **Unanticipated or Adverse Event:** Any happening that is not consistent with routine expected outcomes that results in any unforeseen animal welfare issue that impacts the health or safety of animals (unintended injury or illness, unrelieved pain or distress, death). May require reporting to federal regulators and accrediting bodies.
- 4.19. **USDA:** United States Department of Agriculture. USDA Animal Care, a unit under the Animal and Plant Health Inspection Service, administers the Animal Welfare Act (AWA) and associated Animal Welfare Act Regulations (AWAR).
- 4.20. **USDA Regulated:** Species or activities which fall under the AWA/AWAR.
- 4.21. **VVC:** Veterinary Verification and Consultation. Process by which the AV or designee confirms adherence to approved IACUC SOPs or Guidance documents. Does not apply to Houston animal program.

5. PROCEDURE

5.1. General

- 5.1.1. Designated AWO staff are authorized by the IACUC to perform PAM on behalf of the committee.
- 5.1.2. PAM is structured to assist animal users in preventing and correcting minor departures from the AUP and/or regulatory, institutional or IACUC standards that do not negatively impact animal welfare; and to help the PI ensure the approved AUP(s) accurately reflects activities performed with live animals.

- 5.1.3. The AV is notified by the AWO staff if it appears that the health or well-being of animals is in immediate or on-going jeopardy (“animal concern”) as described in TAMU-S-012. Follow up procedures will be as described in that SOP.
- 5.1.4. The performance of PAM must not interfere with the AV’s oversight of animal care or guidance to investigators regarding animal handling, relief of pain and distress, procedural refinement, post-operative care, immobilization and anesthesia, etc.
- 5.2. **Protocol Selection** (in order of emphasis)
 - 5.2.1. PIs, AUPs or activities of concern to the IACUC
 - 5.2.2. AUPs with USDA regulated species or activities with an emphasis on pain categories D and E
 - 5.2.3. AUPs with non-USDA regulated species or activities where if USDA regulated would be classified as pain category D or E
 - 5.2.4. All other AUPs
- 5.3. **Frequency**
 - 5.3.1. PAM should be performed on a schedule to ensure that at least 10% of all PIs with approved AUPs are monitored annually.
 - 5.3.1.1. The IACUC acknowledges that the performance of PAM is dependent upon 1) adequate AWO staffing and availability of qualified individual(s), and, 2) willing participation by PIs when the audit is not performed for cause
 - 5.3.1.2. The selection of PIs audited should vary over time to ensure a broad overview of research, teaching and testing activities within the animal care and use program
 - 5.3.1.3. Repeat PI participation in a single year by PIs with multiple AUPs may be included to achieve 10%
 - 5.3.2. PAM of core support units will occur at the request of the core support unit manager or the IACUC
- 5.4. **Monitoring Process and Outcome**
 - 5.4.1. A checklist is used by the AWO to standardize the audit process and ensure consistency and resolve administrative or other noncompliance issues that do not negatively impact animal welfare, provided the PI has no previous serious noncompliant incidents.
 - 5.4.1.1. Any incident with a negative impact on animal welfare will be immediately reported to the AV, IACUC Chair and the Assistant Vice President for Research
 - 5.4.2. AWO staff will confirm completion of corrective actions (if any) by the timeline for correction
 - 5.4.2.1. Incomplete corrective actions or those not meeting the timeline for correction are reported to the IACUC Chair (or designee) for additional action as appropriate
 - 5.4.3. Examples of activities that may be included in the PAM process, but are not required for all PAM audits, are:
 - 5.4.3.1. Review of individual procedures or full AUP(s) to confirm the description in the AUP accurately reflects the animal activities performed
 - 5.4.3.1.1. Note: For PIs with more than one AUP, a representative AUP may be monitored rather than all AUPs
 - 5.4.3.2. Review of IACUC related posted signage in animal use locations
 - 5.4.3.3. Record review, including daily care, sanitation, temperature and humidity logs for housing locations, sanitation logs for PI maintained equipment, health, surgical, and/or monitoring records, training records, other logs or records related to the maintenance of animals or the performance of AUPs
 - 5.4.3.4. Discussion regarding the performance of procedures with live animals and any issues or adverse events encountered, as applicable
 - 5.4.3.5. Animal area walk-through and/or cage side evaluation
 - 5.4.3.6. Procedure observation

5.4.3.6.1. Note: Observation of each and every animal activity listed on the protocol, or activity performed by the core support unit staff, is not required

5.4.3.7. Other activities identified by the AWO staff as supporting the performance of PAM or as directed by the IACUC on a case-by-case basis

5.4.4. The AWO staff may:

5.4.4.1. Provide guidance where it does not impinge upon the AVs authority, the authority of the IACUC or another compliance committee or office

5.4.4.2. Identify findings that must be corrected and suggest a timeline for correction

5.4.4.3. Make SFIs that may be implemented at the PI/core support unit managers discretion

5.4.4.4. Assist the PI in the completion of an amendment, PCR or VVC request to address findings and SFIs

5.4.4.5. Assist the PI in identifying training opportunities for protocol participants

5.4.4.6. Assist the core support manager in the completion of a request for programmatic exception (TAMU-F-013)

5.4.4.7. Perform other outreach and support activities that are standard to AWO operations

5.4.4.8. Identify for the PI, PI staff, or core support staff when potential serious or continuing noncompliance has been identified

5.4.5. The AWO staff may not:

5.4.5.1. Represent their views or opinions as being that of the IACUC

5.4.5.2. Represent themselves as IACUC members

5.5. Reporting

5.5.1. A written report of the audit outcome will be provided by AWO staff to the:

5.5.1.1. PI or core support unit manager

5.5.1.2. IACUC Chair

5.5.2. The AWO staff will report activities in the form of metrics or other summary format to the IACUC semiannually

5.5.3. The AWO staff will report animal concerns as indicated above

5.6. Review

5.6.1. The IACUC Chair will review AWO PAM reports and determine if further action is needed, such as:

5.6.1.1. Reclassification, addition or removal of audit results (SFIs, Findings)

5.6.1.2. Modification, addition or removal of corrective actions and timelines for correction

5.6.1.3. Initiation of the IACUC noncompliance procedure as described in TAMU-S-012 for audit findings that meet the threshold for potential serious or continuing noncompliance

5.6.1.4. Notification to the IACUC of the outcome of a specific audit outside of the AWO semiannual reporting procedure in the absence of potential serious or continuing noncompliance

5.6.2. The IACUC Chair may request additional review of PAM reports by the Attending Veterinarian (or designee), AWO Director, or individual IACUC member(s)

5.6.3. The PI/core support unit manager will be notified of modifications to previously relayed audit reports by the IACUC Chair (or designee) or AWO staff

5.6.4. The IACUC will review audit and metric reports and take appropriate actions, such as, developing new Guidance documents or modifying existing guidance, modifying training requirements, reviewing animal concerns and potential serious or continuing noncompliance, or taking other actions deemed appropriate.

5.7. Process Finalization

5.7.1. The PAM audit will be considered complete and the audit report closed when all corrective actions (findings only) have been addressed



5.7.1.1. Note: Report closure may occur prior to completion of IACUC review and approval of amendments and/or IACUC review of potential serious or continuing noncompliance

5.8. Process for Appeal

5.8.1. Pls/core support unit managers that disagree with PAM audit findings and/or recommendations may appeal to the IACUC by contacting the IACUC Chair in writing within 10 business days from the date of the communication from the AWO staff and detailing the basis of the appeal.

5.9. Record Retention

5.9.1. Document management, including record retention, follows TAMU-S-001

6. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

6.1. Regulatory resources:

- 6.1.1. [USDA Animal Welfare Regulations 9 CFR Ch.1 Subpart C § 2.31](#)
- 6.1.2. [PHS Policy on Humane Care and Use of Laboratory Animals](#)
- 6.1.3. [USDA Animal Welfare Inspection Guide](#)
- 6.1.4. Notice [NOT-OD-05-034](#) Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals
- 6.1.5. [Guide for the Care and Use of Laboratory Animals](#)
- 6.1.6. [Guide for the Care and Use of Agricultural Animals in Research and Teaching](#)
- 6.1.7. [AVMA Guidelines for the Euthanasia of Animals](#)
- 6.1.8. TAMUS Policy 15.99.07 [Use of Vertebrate Animals](#)
- 6.1.9. TAMU Rule 15.99.07.M1 [Use of Vertebrate Animals in Research, Teaching and Testing](#)

6.2. References:

- 6.2.1. OLAW FAQ - [Is Post Approval Monitoring Required?](#)
- 6.2.2. *Postapproval Monitoring Practices at Biomedical Research Facilities*. Davis et al. Journal of the American Association for Laboratory Animal Science. 2019. Vol 58 (4) pgs 469-474.

6.3. [IACUC/AWO Referenced Documents](#): (requires TAMU NetID authentication)

- 6.3.1. TAMU-F-013 Request for Programmatic Exception from Animal Welfare Standards
- 6.3.2. TAMU-S-001 Document Management
- 6.3.3. TAMU-S-010 Semi-Annual Facility Inspections and IACUC Oversight of Animal Use Locations
- 6.3.4. TAMU-S-012 Review and Investigation of Animal Welfare Concerns and Potential Noncompliance
- 6.3.5. TAMU-S-013 Continuing Review of Animal Use Protocols - Triennial
- 6.3.6. TAMU-S-015 Review of Unanticipated or Adverse Event Reports

7. HISTORY

Effective Date	Version #	Description
02/25/2021	000	College Station/Galveston: New Document
03/22/2021	001	Houston/Kingsville: New Document
04/20/2021	002	Dallas: New Document
12/27/2021	003	Houston/Kingsville: Removal of annual continuing review process with no modification to expiration date. Approved on 12/13/2021 with delayed start date to match final rule effective date.
12/27/2021	004	Dallas: Removal of annual continuing review process with no modification to expiration date. Approved on 12/14/2021 with delayed start date to match final rule effective date.
12/27/2021	005	College Station/Galveston: Removal of annual continuing review process with no modification to expiration date. Approved on 12/16/2021 with delayed start date to match final rule effective date.



03/24/2022	006	College Station/Dallas/Galveston: Merging of Dallas animal care and use program with College Station/Galveston
10/20/2022	007	College Station/Dallas/Galveston/Kingsville: Merging of Kingsville animal care and use program with College Station/Dallas/Galveston.
01/01/2024	008	College Station/Dallas/Galveston/Houston/Kingsville: Renewal; updated Responsibility, Definitions and Resources sections. Reviewed and approved via TEAMS.