

Office of Research Support and Compliance

Vice President for Research, Scholarship and Creative Endeavors

University of Texas at Austin Institutional Animal Care and Use Committee IACUC Policy # 5.0

Title	Post Approval Monitoring (PAM)		
Date of Approval	04-10-23	Version	3.0

Background: Federal regulations and University policies govern the use of animals in research and require investigators to submit Animal Use Protocols when using animal subjects to the Institutional Animal Care and Use Committee (IACUC) for review and approval. The IACUC evaluates each protocol to ensure compliance with these regulations and policies. The Post Approval Monitoring plan is an important component of a comprehensive animal care and use program, which provides a well-defined, complementary method for ensuring Institutional regulatory compliance, facilitating research activities, and providing Principal Investigators (PIs) and their staff with an opportunity to discuss changes or revisions to ongoing projects and the animal care program. PAM is a formal component of IACUC oversight and researcher participation in the PAM program is mandatory.

Objectives: The goal of the PAM program is to foster a congenial, collaborative relationship between the IACUC and the research community that fosters communication, enhances animal research protocol compliance and ensures that animals are being used as approved by the IACUC. PAM is a conduit for communication and education between the research staff and the IACUC committee.

Procedures: UT's PAM program encompasses protocol reviews, semiannual facility evaluations, designated monitoring based on IACUC recommendation, veterinary oversight, records review and quality assurance visits. The IACUC may also at any time require that a protocol receive a quality assurance visit to help a research group improve compliance with IACUC policies and procedures. At the conclusion of the PAM visit, the QA liaison will provide an informal, verbal assessment of any concerns to the PI. When applicable, the liaison will provide assistance with submitting an amendment and/or arranging for additional training. The QA liaison will communicate visit outcomes and findings to the IACUC. If any animal welfare concerns are identified during a QA visit those finding will be reported to the IACUC. UT's PAM program encompasses three main arms as described below:

1. Quality Assurance (QA) Visits – conducted by the Office of Research Support and Compliance, Quality Assurance Assistant Director (QAAD).

The QAAD will conduct scheduled QA visits on behalf of the IACUC to carry out an in-depth review of study procedures and records, provide education, and maintain a positive relationship between the IACUC and research labs. The following types of protocols will receive a QAAD visit as needed (in order of decreasing priority):

- Survival and non-survival surgery
- USDA-covered species
- Pain/distress category E
- Food/fluid restriction

- Tumor monitoring/endpoints
- Prolonged physical restraint
- Behavior/ other manipulation
- Breeding colonies
- Field and teaching protocols

2. IACUC Designated Post Approval Monitoring- conducted by CVA or QAAD

- a) **Close Veterinary Assistance (CVA)** - conducted by the Animal Resources Center veterinary staff.

The IACUC may at any time determine that a research group performing particular procedures would benefit from close interaction with the veterinary staff of the Animal Resources Center as the studies commence. When CVA is required, the PI will be notified and required to contact veterinary staff before scheduling and attempting procedures that require CVA. As the monitored work is performed, the veterinary staff will provide direct observation as well as education, guidance and follow-up to investigators. Feedback regarding progress, outstanding concerns, and recommendation for removal of oversight will be provided to the IACUC by the ARC veterinarians. Protocols will be removed from this process by the IACUC when oversight is no longer required.

- b) **Quality Assurance Assistance (QAA)** - conducted by the QAAD ORSC staff

Protocols that are recommended for oversight by the IACUC but do not need close veterinary assistance will be administered by the QAAD. Examples of such protocols are those involving previous issues with non-compliance, record issues, rigorous documentation requirements or other issues identified to need assistance and monitoring by the IACUC. Feedback regarding progress, outstanding concerns, and recommendation for removal of oversight will be provided to the IACUC by the QAAD. Protocols will be removed from this process by the IACUC when oversight is no longer required.

3. IACUC Semi-Annual Inspections and Protocol review - conducted by the IACUC and ORSC staff

The IACUC provides ongoing oversight to animal research when reviewing protocols and when conducting semi-annual inspections of animal housing, use, and vivarium support spaces. As the IACUC carries out its responsibilities, the committee may determine that additional oversight for a specific protocol is needed. At such time, the IACUC may require the protocol be placed on the PAM monitoring list for CVA or QAAD oversight based on the concern identified.

QA Visit Description

1. Overview:

- a) The QAAD conducts in-depth QA visits on an ongoing basis and in a collegial manner that helps to promote compliance, education, and to assist the research community. The QAAD brings detailed knowledge of the approved IACUC protocol to each visit, engages in a discussion with the investigator and the research team about research procedures, and review study records (i.e., surgical records, monitoring logs). The QAAD will be available to answer questions and will provide input on refining procedures based on

IACUC guidelines or refer questions/educational opportunities to veterinary staff. The advantages to this in-depth approach of ongoing oversight are two-fold:

- i. The QAAD will serve as a liaison between the IACUC and the research community. The QA visits will serve to build relationships through a collaborative approach and provide education to the research community in evolving IACUC guidelines.
- ii. The QAAD will identify potential issues or concerns such as protocol drift or animal welfare concerns before they become more significant and/or noncompliance occurs.

2. QA Visit Procedures:

- a) The QA visit will entail discussing protocol(s) and review of lab records, animal medical records, personnel training records, husbandry procedures, drug storage and documentation, and any other applicable topics. The QAAD will utilize this time to keep investigators apprised of current guidelines and policies and review deficiencies identified during previous inspections or QA visits and corresponding corrective action. The QAAD will evaluate laboratories based on criteria set forth in a QA checklist, which will be made available to the laboratory members before the QA visit. The PI or senior research staff must be present to facilitate the QA visit. Visits may occur in person or virtually.
- b) The IACUC and the laboratories will receive feedback from QA visits classified under the following categories:
 - i. Compliant – Work is completed in accordance with an approved protocol
 - ii. Minor – No harm to animals expected, can be addressed through education
 - iii. Potentially Serious – Animals may be harmed; will be reported to IACUC leadership
 - iv. Serious – Animals were harmed or work is outside of scope of protocol; will be reported to IACUC leadership
- c) Visit findings may be resolved by (but not limited to): modifying the protocol to reflect needed amendments, requiring additional training of personnel, changing lab/protocol procedures, or recommended CVA with ARC veterinary staff to provide education, oversight and ensure animal welfare. The QAAD will work closely with researchers to correct identified deficiencies.

Approval Date	Major Change(s) Approved
10/11/2021	• Policy updated throughout to incorporate QA program.
04/10/2023	• Updated policy to include that it was a mandatory component of the IACUC.