

Post Approval Verification and Education - UTEP	
Title: Establishing Processes Between the IACUC and the PAVE Program	
Policy#: 003	Date in Effect: October 27, 2025
Version #: A	Rev Date:
In Effect ☒ Rescinded ☐	Date Rescinded:

A. RESPONSIBILITIES

All personnel engaged in research involving animal subjects at The University of Texas at El Paso (UTEP) are responsible for compliance with this policy.

B. APPLICATION

This policy applies to the IACUC Chair, IACUC Committee members, staff of Research Compliance and Regulatory Assurances, members of the PAVE Unit, and all personnel engaged in animal subjects research under the jurisdiction of UTEP.

C. BACKGROUND

Post Approval Monitoring (PAM) is a critical component in comprehensive research oversight programs. It enables institutions to verify that approved research is carried out in accordance with applicable regulations, guidelines, and institutional standards, remaining compliant throughout its duration.

PAM is a recognized best practice endorsed by oversight and accrediting bodies such as the Office of Laboratory Animal Welfare (OLAW) and the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). It is grounded in the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* and the *Guide for the Care and Use of Laboratory Animals*, and is supported by additional federal, state, and institutional requirements for animal welfare.

At UTEP, the Post Approval Verification and Education (PAVE) Program expands on traditional PAM by emphasizing support, education, and collaboration. More than a compliance mechanism,

the PAVE Program serves as a proactive partner to researchers and oversight committees, fostering a culture of animal welfare, accountability, and shared responsibility in animal research.

D. OBJECTIVES

The PAVE Program is designed to support ethical and compliant research at UTEP. The PAVE Program aims to:

- Verify congruency between approved protocols and actual research practices;
- Provide education and guidance that strengthen the understanding of animal welfare and compliance;
- Identify and address gaps or training needs through constructive feedback; and
- Promote a culture of safety, accountability, and continuous improvement across UTEP's research community.

E. ROLES

The Institutional Animal Care and Use Committee (IACUC) is responsible for the review and approval of research involving vertebrate animals conducted under the jurisdiction of UTEP.

For detailed information regarding the specific responsibilities, authorities, and operational procedures of the Institutional Animal Care and Use Committee (IACUC), refer to the *Institutional Animal Care and Use Committee Guidebook*, 2nd Edition (2002), published by the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health.

IACUC Responsibilities Related to PAVE Activities

In fulfilling its regulatory oversight role, the IACUC collaborates with the PAVE Program to ensure continuous compliance with approved animal use protocols. In this capacity, the IACUC:

- Maintains open communication and coordination with the PAVE Program;
- Reviews PAVE Unit reports and evaluates instances of potential noncompliance;
- Requests for-cause monitoring evaluations from the PAVE Unit when concerns arise regarding protocol adherence, animal welfare practices, or research integrity;
- Notifies Principal Investigators (PIs) of upcoming for-cause evaluations, except when unannounced visits are warranted;

- Reviews and acknowledges final monitoring evaluation reports submitted by the PAVE Program;
- Discusses evaluation findings during convened meetings or subcommittee review;
- Serves as the final authority on regulatory determinations, including suspension or termination of research, and reports serious or continuing noncompliance to the appropriate institutional and federal entities.

PAVE Program Responsibilities Related to the IACUC

In support of the IACUC's full oversight authority and jurisdiction, the PAVE Program operates as an independent unit within the Office of Research Compliance and Regulatory Assurances (RCRA). In this capacity, the PAVE Program:

- Maintains open communication and collaboration with the IACUC;
- Conducts routine and for-cause post approval evaluations in accordance with institutional procedures;
- Notifies the IACUC of potential noncompliance, animal welfare concerns, or other issues observed during evaluations;
- Prepares objective, comprehensive reports documenting findings, observations, and recommendations;
- Submits final evaluation reports to the IACUC within established timelines;
- Responds to formal educational or corrective action requests issued by the IACUC;
- Identifies and communicates emerging compliance trends, risks, or areas for improvement across animal research programs.

F. POLICY

Post approval evaluations constitute a core element of the PAVE Program and are conducted to provide educational guidance and support. Monitoring evaluations are conducted as a supportive and educational process, rather than as punitive inspections aimed at identifying errors. All protocols approved by the IACUC are subject to the post approval evaluation process.

Routine Monitoring Evaluations

Routine evaluations are randomly selected, and priority focus areas may include:

- Research involving higher risk animal procedures or USDA-covered species
- Projects involving painful, complex, or distressful procedures (Categories D or E).
- Newly approved Principal Investigators
- Studies with personnel turnover or study/facility modifications impacting animal housing, population, or care,
- Externally funded studies that are not monitored by other entities.

For-Cause Evaluations

For-cause evaluations occur in response to:

- Allegations or observations of noncompliance with approved animal use protocols
- Reported animal welfare concerns, adverse events, or procedural deviations
- IACUC or administrative concerns

Post approval evaluations are distinct from the semiannual facility inspections required by the IACUC, which focus on physical space, equipment, and housing conditions. The PAVE Program specifically focuses on protocol adherence, study practices, and researcher education. The scope of the PAVE Program does not include addressing concerns or allegations related to research misconduct, individual performance, budgetary oversight, or legal matters.

G. PROCEDURES & NOTIFICATIONS

1. Evaluation Initiation

- **Routine Evaluations:** The PAVE Unit randomly selects active IACUC-approved protocols for proactive, standard evaluations. Notifications of routine evaluations are sent directly to the Principal Investigator (PI) by the PAVE Unit.
- **For-Cause Evaluations:** Initiated upon IACUC request using the official For-Cause Evaluation Request Form, these evaluations are triggered by concerns, complaints, a history of noncompliance, or specific incidents. Notifications are issued by the IACUC

using the official For-Cause Evaluation Notification Template, with the PAVE Unit copied on all correspondence.

2. Evaluation Process

- The PAVE Unit conducts evaluations utilizing standardized tools and checklists consistent with OLAW guidance, AAALAC expectations, and institutional policies, focusing on compliance with federal regulations, approved protocols, and animal care practices.
- Any immediate risks to animal welfare identified during evaluations are promptly escalated to the IACUC Chair and the Associate Vice President for Research.

3. Post-Evaluation Reporting

- Following evaluation completion, the PAVE Unit prepares a Final Evaluation Package summarizing the scope, findings, and recommendations.
- Both the IACUC and PAVE Unit shall retain all evaluation records and related correspondence in accordance with institutional retention policies and federal regulations.

Review History	
Revision Version:	Revision Date:
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