

Post Approval Verification and Education - UTEP	
Title: The Post Approval Verification Education Program	
Policy#: 001	Date in Effect: October 27, 2025
Version #: B	Rev Date: June 5, 2026
In Effect ☒	Date Rescinded:

A. RESPONSIBILITIES

It is the responsibility of all personnel conducting animal subjects, human subjects, or biosafety research at the University of Texas at El Paso (UTEP) to abide by this policy.

B. APPLICATION

This policy applies to all research protocols overseen by the Institutional Animal Care and Use Committee (IACUC), the Institutional Biosafety Committee (IBC), and the Institutional Review Board (IRB), and all personnel involved with research under the jurisdiction of UTEP.

C. BACKGROUND

Post-approval monitoring is a critical element of a comprehensive research oversight program. While initial review and official approval by the oversight committees are important first steps, ongoing compliance and protocol adherence must be maintained throughout the duration of the study. Post-approval monitoring enables institutions to verify that research is carried out in accordance with applicable regulations, guidelines, and institutional standards.

Post-approval monitoring is widely recognized as a best practice by accrediting bodies such as the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

Post-approval monitoring programs are further justified by the *Guide for the Care and Use of Laboratory Animals*, the Public Health Service Policy, the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, and federal regulations (e.g., 45 CFR 46, 21 CFR 56).

UTEP's PAVE Program takes a collaborative and educational approach. While preserving the essential oversight functions of post-approval monitoring, the PAVE Program emphasizes proactive support and partnership with researchers, positioning itself as an internal resource that is supportive and educational rather than punitive.

D. OBJECTIVES

By partnering with researchers to ensure congruency between approved protocols and actual research activities, the PAVE Program is designed to promote ethical research practices, safeguards animal welfare, supports biosafety, and enhances protections for human subjects by ensuring adherence to approved protocols.

The PAVE Program is dedicated to supporting principal investigators and research teams by providing tools, training, and tailored guidance to address identified gaps and promote excellence in research practices. Through pattern analysis, identification of strengths, and recognition of areas for improvement, the PAVE Program contributes to the continuous enhancement of institutional research quality and compliance.

E. POLICY

The PAVE Program is administered by the Office of Research Compliance and Regulatory Assurances, in collaboration with the IACUC, IBC, and IRB.

The scope of the PAVE Program does not include addressing concerns or allegations related to research misconduct, individual performance, budgetary oversight, or legal matters.

The PAVE Unit routinely selects protocols for review, prioritizing those that involve more than minimal risk, and initiates for-cause evaluations in collaboration with oversight committees when specific concerns arise (e.g., potential noncompliance, subject safety, or animal welfare issues).

PAVE evaluations may include, but are not limited to, site visits, interviews with Principal Investigators and research teams, documentation reviews, and evaluations of approved research practices. As part of the institutional compliance review process, study documentation may be provided to PAVE for review purposes. This may include consent-related documentation or other study records that contain respondent or participant information, as applicable to the scope of the evaluation. In addition, the PAVE Program provides individualized and group training and education for investigators, staff, and students on regulatory responsibilities and compliance expectations. It offers resources and tools to support ethical, safe, and procedurally consistent research, and works collaboratively with research teams to share best practices and implement improvements in research conduct.

F. PROCEDURES

Monitoring evaluations are conducted as a supportive and educational process, rather than as punitive inspections aimed at identifying errors. The objective is to collaborate closely with Principal Investigators to ensure adherence to regulatory requirements, provide constructive and informative feedback, and thereby enhance the institution's scientific research endeavors.

Routine monitoring evaluations involve the random identification of an active protocol from the applicable oversight committee's database. These evaluations are not prompted by specific concerns and are part of proactive standard monitoring procedures. Notifications for routine monitoring evaluations are issued directly by the PAVE Unit.

For-cause monitoring evaluations are initiated based on specific criteria, such as concerns, complaints, history of prior noncompliance, or requests by oversight

committees. These evaluations are prompted by specific concerns and are part of responsive monitoring procedures.

Notifications of for-cause monitoring evaluations are issued by the appropriate oversight committee, with the PAVE Unit included in the communication to the Principal Investigator.

Upon notification of a monitoring evaluation, the Principal Investigator is provided with detailed instructions outlining the next steps in the review process. This includes guidance for uploading study documents for digital reviews, coordination of an on-site visit, and scheduling of an exit interview, depending on the scope and nature of the evaluation. The PAVE Unit may, at its discretion, evaluate additional areas, activities, or records.

All final reports are submitted to the appropriate oversight committee for review, discussion, and any further action deemed necessary. The monitoring evaluation is considered complete upon issuance of the final report; however, the PAVE Unit remains engaged in subsequent steps of the process to support the resolution of findings.

Review History	
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