

Institutional Animal Care & Use Program - UTEP	
Title: Non-Compliance	
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1. RESPONSIBILITIES

It is the responsibility of all personnel using animals at The University of Texas at El Paso (UTEP) to abide by this policy. Exceptions to this policy must be approved by the Institutional Animal Care and Use Committee (IACUC) before implementation.

2. APPLICATION

This policy applies to all faculty animal users engaged in research and teaching at UTEP.

3. INTRODUCTION

The University of Texas at El Paso's (UTEP's) Animal Care and Use Program maintains standards to comply with Federal Law of United States Department of Agriculture (USDA) and the Office of Laboratory Animal Welfare (OLAW). The University adheres to the Public Health Service (PHS) policy on Humane Care and Use of Laboratory Animals (PHS Policy), Animal Welfare Act and Regulations (AWAR), and the *Guide for Care and Use of Laboratory Animals* (the *Guide*). All individuals using animals at UTEP must follow the standards set forth in these regulatory and guidance documents. In addition, all internal policies and procedures must be followed. If the University becomes aware of potential non-compliance, comprehensive investigation and possible corrective actions may protect animal welfare, laboratory staff, and laboratory and university funding and research goals.

The Institutional Animal Care and Use Program (IACUP) has developed this policy to establish consistent guidance on investigating and managing potential non-compliance concerns. As situations vary considerably, determinations are made on an individual basis based on the circumstances, including self-reporting, voluntary corrective actions, and any other relevant considerations. It is recognized that isolated instances of noncompliance can occur as the result of a simple and minor error with no intent to

circumvent applicable requirements. As such, Institutional Animal Care and Use Committees (IACUCs) have the discretion to determine that a full investigative process and formal corrective measures are not required in certain circumstances. This policy is intended to address compliance issues that, in the determination of an IACUC, and in specific cases the Institutional Official (IO), go beyond a simple and minor oversight.

4. DEFINITIONS

Non-compliance: The failure (intentional or unintentional) to comply with applicable federal, state, or local laws or regulations, IACUC Guidelines, Standard Operating Procedures, or Policies within an approved IACUC protocol.

Minor non-compliance: Typically arises in instances where policy has been violated, but the risk of harm to researchers or animals is minimal and the IACUC authority or function has not been compromised.

Serious non-compliance: Any non-compliance event that has a negative impact on the welfare of an animal constitutes a direct violation of federal standards regulating animal activities. These standards include provisions of the Occupational Health and Safety program or the *Guide*, or the conduct of a significant animal procedure without IACUC approval. Adverse events or unforeseen outcomes (i.e., natural disasters, unexpected phenotypes) are not considered non-compliance and should be dealt in conjunction with the veterinarian. Serious non-compliance issues require reporting to the IO. The IO will submit to federal agencies and accrediting agencies, as required.

Continuing non-compliance: Repeated episodes of non-compliance involving the same principal investigator (PI). Continuing non-compliance issues may require reporting to federal agencies and accrediting bodies. The committee will consider all non-compliance events over the last 3 years when evaluating compliance history for a PI. Continuing non-compliance issues require reporting to the IO. The IO will submit to federal agencies and accrediting agencies, as required.

Corrective Actions: Remediation steps proposed by PIs, the IACUC, the IACUC Chair and/or Attending Veterinarian that describe how labs will resolve non-compliance concerns. These are voted upon by the IACUC.

5. POLICY

1. Reporting Non-Compliance

- a.** In compliance with federal requirements, any individual with concerns involving the care and use of animals at UTEP may have those concerns reviewed by the IACUC. The concerned party may remain anonymous and will be protected from discrimination and retaliation.
- b.** Self-reporting is highly encouraged. Self-reporting allows the investigator to self-identify areas of potential non-compliance, develop a plan to remedy the issue, and implement self-corrective measures taken to prevent recurrence.
- c.** See IACUC policy on Reporting Animal Welfare Concern.

2. Inquiry Process

- a.** The IACUC compliance specialist, or alternate, will contact the PI and/or individuals involved in the non-compliance allegation via email and will provide all relevant information regarding the alleged incident. The compliance specialist or alternate will also request the PI to provide a Corrective Action/Preventive Action plan to resolve the issue(s). A response is expected from the PI within 48 hours.
- b.** A subcommittee containing at least the IACUC Chair, IACUC Vice Chair, AV (Attending Veterinarian), and one IACUC member will decide on the best course of action based on the information obtained during the inquiry. This may include one or more of the following:
 - i.** Dismissal of the allegation (unsubstantiated)
 - ii.** Referral to other appropriate university process
 - iii.** Immediate corrective action required (implemented by AV, IACUC Chair, and/or IO). Immediate action is always taken if there are animal welfare concerns.
 - iv.** Review at a convened IACUC meeting
 - v.** Further investigation required by the IACUC compliance specialist
- c.** The PI will be informed, in writing, of any recommended actions based on the inquiry findings.

- d. The IACUP compliance specialist or alternate will also create a formal written report for each substantiated inquiry. The PI will be given 5 business days to provide a written response to the inquiry report and will be given the opportunity to attend the IACUC meeting.
- e. If applicable, the IO will file a report with federal and/or accrediting agencies.

3. IACUC Investigation Process

- a. Prior to the next convened IACUC meeting, the IACUP compliance specialist will distribute the final report to all IACUC members. At the IACUC meeting, the compliance specialist will discuss the inquiry report with the IACUC members.
- b. If available, the response letter from the PI will be provided to the committee members. The PI may join the meeting if s/he wishes to provide information relevant to the IACUC review of the issue. The IACUC may discuss the incident with the PI during this time but deliberations regarding the incident by the IACUC will only occur in the absence of the PI.
- c. Following IACUC deliberations, the members may vote on the following outcomes:
 - i. Is the concern non-compliance (Yes, No, or Tabled)?
 - ii. If further information is required to vote on this issue (tabled), IACUP compliance specialist gathers more information for next meeting
 - iii. If the committee votes no, no further action is needed.
 - iv. If the committee votes yes and deems non-compliance occurred, the committee votes on the degree of non-compliance:
 - 1. Serious non-compliance
 - 2. Continuing non-compliance
 - 3. Minor non-compliance
 - v. Is the issue satisfactorily resolved? If not, what corrective actions will be required?
 - vi. Are programmatic changes needed to prevent future occurrences?

- d. Once the investigation is completed, the IACUC Chair or Vice Chair will provide a written formal notification to the PI within 5 business days of the IACUC decision.
- e. The PI will have 5 business days to appeal the decision in writing (extensions can be granted by the IACUC Chair in certain circumstances). Appeals will be considered at the next convened IACUC meeting.
- f. If the decision is being appealed, the IO will file a preliminary report with federal and/or accrediting agencies (when required).
- g. Once finalized, a written report will be sent to relevant federal and/or accrediting agencies through the IO (when required).

4. Corrective Actions and Validation of Corrective Actions

- a. Specific corrective actions are determined on a case-by-case basis.
- b. Implementation of corrective actions should be checked (validated) to ensure implementation.
- c. Minor Non-Compliance, examples of corrective actions include but are not limited to:
 - i. The PI receives formal notification from the IACUC that emphasizes the importance of maintaining compliance.
 - ii. Additional training may be required by completing Collaborative Institutional Training Initiative (CITI Program) training or one-on-one training by Laboratory Animal Resource Center (LARC) staff.
 - iii. PI will provide a written response to the committee outlining a plan to prevent this from occurring in the future. The response will be reviewed by the IACUC.
 - iv. Extra monitoring by the veterinary staff may be implemented if necessary.
 - v. Modification (i.e., amendment) submitted to the protocol.
- d. Serious and/or Continuing Non-Compliance, examples of corrective actions include but are not limited to:
 - i. The PI receives formal notification from the IACUC Chair (or Vice Chair) that emphasizes the importance of maintaining compliance which will be copied to the AV, IO, IACUC compliance specialist, and department chair.

- ii. The compliance specialist will conduct for-cause Post Approval Verification and Education (PAVE) visit(s) with the laboratory.
- iii. Federal and/or accrediting agencies will be notified when required.
- iv. Modification (i.e., amendment) submitted to the protocol.
- v. PI will provide a written response to the committee outlining a plan to prevent this from occurring in the future. The response will be reviewed by the IACUC.
- vi. Additional training may be required (CITI and/or LARC training).
- vii. Extra monitoring by the veterinary staff may be implemented if necessary.
- viii. Direct oversight of procedure(s) by veterinary staff or compliance specialist.
- ix. PI presence/enhanced oversight of lab members during certain procedures.
- x. Meeting with PI, AV, IACUC Chair (or Vice Chair), IO and department chair to discuss non-compliance corrective actions.
- xi. Suspension or termination of protocol.
- xii. Suspension or termination of personnel on protocol.