



Title: Reviewing Animal Care Concerns (Whistleblower) and Researcher Non-Compliance

Policy Number: 09

Policy Intent: The intent of this policy is to define IACUC responsibilities, as well as, circumstances, classification, and consequences of research non-compliance with regards to the use of live animals at TTU.

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1. Purpose

- A. The IACUC is required to ensure humane care and use of vertebrate animals used for research, instruction, demonstration and testing, and to adhere to the applicable federal and state regulations and institutional policies affecting such use at TTU. As a result, the IACUC monitors the animal care and use program and its various components for compliance and concerns with all the appropriate regulations and policies.
- B. The IACUC has developed this policy for evaluating issues of addressing concerns and non-compliance with IACUC protocols, policies and regulatory guidelines. Although uniform standards can serve as a guide to rectifying noncompliance, the IACUC recognizes that each individual case is unique and therefore a range of possible responses and/or solutions should be considered.

2. Authority

- A. Review concerns involving the care and use of animals (9 CFR AWR § 2.31 (c) (4); PHS IV. B. 4)
- B. The IACUC is charged with and is responsible for ensuring compliance with federal regulations in Research and Instruction Using Animal Subjects. In order to fulfill these obligations, the IACUC must exercise authority granted by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals and the Animal Welfare Act and Regulations (AWAR) to enforce policies and regulations. Under the PHS Policy on Humane Care and Use of Laboratory Animals, the IACUC must promptly report (via the Institutional Official) to the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) the following:
 - C. Any serious or continuing non-compliance with the PHS Policy;
 - D. Any serious deviation from the provisions of the Guide for the Care and Use of Laboratory Animals (the Guide); and
 - E. Any suspension of an activity by the IACUC.
- F. The AWAR also requires that if the IACUC suspends an activity involving animals, the Institutional Official (IO), in consultation with the IACUC, will review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to the United States Department of Agriculture (USDA) and any Federal agency funding that activity.



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3. Policy

- A. To review concerns involving the care and use of animals, the University has a whistleblower policy identifying procedures to report animal mistreatment or complaints without fear of reprisal. Signage is posted throughout animal facilities, and complaints can be received via email, phone or personal communications to any IACUC member or office, as well as, via anonymous hotline available through Ethics Point. No person shall be discriminated against or be subject to any reprisal for reporting perceived non-compliance or animal care and use concerns under the law and/or TTU's institutional whistleblower policy (TTU OP 74.08).

A preliminary investigation will be conducted by the IACUC Chair and AV to determine if a formal investigation is warranted. If the complaint is deemed to warrant a formal investigation, the Chair, in consultation with the AV, will appoint a subcommittee. The Chair will notify the individual(s) at whom the concern/complaint is directed as well as relevant supervisors and the IO. The IACUC will review the report produced by the investigative subcommittee and will determine what, if any, corrective action(s) will be taken. The report and any corrective action(s) approved by the IACUC will be communicated to the reporting party, IO and the accused person(s). Non-compliance findings may be reported to governing bodies as necessary.

- B. To determine whether an issue should be classified as non-compliant, the IACUC will initiate an investigation involving the Principal Investigator (PI), Attending Veterinarian (AV), Animal Care Services (ACS), and Post Approval Monitor (PAM), if appropriate. Any appropriate Federal Agencies will be made aware with initial contact as describe in IACUC Policy 24: Adverse Event Reporting and Unexpected Outcomes. If the activity in question is determined to be one of noncompliance, it will be categorized based on its severity (as described below), a Compliance Report will be presented to the IACUC, and necessary corrective actions will be taken.
- C. Minor issues involving documentation or animals (such as those that are not animal welfare issues) are not always initially deemed as non-compliant. If such issues are observed by ACS and/or the PAM staff, then the investigator or his or her staff will be notified and given an opportunity to immediately address it to avoid a finding of non-compliance.
- D. Self-reporting is encouraged. Self-reporting gives the IACUC notice and opportunity to investigate, and the PI a chance to remedy the issue before it becomes non-compliance or allows the PI to inform the IACUC of self-corrective measures taken to prevent recurrence. Monitoring and clarification of institutional policies and guidelines regarding the care and use of animals is routinely provided by the IACUC or ACS staff to assist the investigators and to maintain overall institutional compliance.

4. Non-Compliance Classification

- A. The IACUC classifies non-compliance incidents into one of two categories: Significant or Minor. Both categories are defined below with examples of non-compliance, as well as an outline for corrective actions that has been delineated by the IACUC. The examples are provided as a general guideline to help PIs and research staff in understanding this process. As situations vary considerably, determinations are made on a case-by-case basis based on the totality of the circumstances, including self-reporting, voluntary corrective actions, and any other relevant considerations.

1) Significant Non-Compliance:



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- a. Significant non-compliance: indicates a serious breach of laws, regulations, or university policy which compromises the function of the IACUC or puts researchers or animals at risk of undue harm.
 - b. Examples of Significant non-compliance include, but are not limited to:
 - Acquiring animals for research or performing unapproved procedures without the IACUC approval;
 - Performing a procedure in such a manner that animals endure pain or suffering that is not addressed by the approved protocol;
 - Willful acts of abuse
 - Performing a procedure with improper technique or safeguards which puts either the staff or animals at risk;
 - Failure to adhere to proper aseptic technique for survival surgery;
 - Repeated or willful incidents of minor non-compliance.
 - Failure to provide adequate anesthesia or analgesia according to protocol
- 2) Consequences and Resolution of Significant Non-Compliance Incidents
- a. If an occurrence of non-compliance directly results in a significant negative impact to animal welfare, the Attending Veterinarian has the authority to immediately stop all procedures necessary to protect the health and welfare of the animals. The PI will be contacted as soon as possible and the matter will be referred to the IACUC and Institutional Official for further investigation. The IACUC Chair may appoint a subcommittee to conduct the investigation.
 - b. Within the category of significant non-compliance, incidents will vary in their degree of seriousness. If warranted, issues may be referred to the Research Integrity Officer for review as research misconduct in accordance with University Operating Policy 74.08.
 - c. Following an investigation that includes a discussion of the situation with the PI; the IACUC will meet to determine the corrective actions that will be required of the PI. If the IACUC votes (majority with quorum) for protocol suspension, all procedures and ordering privileges encompassed by that protocol must cease during the period of suspension. If a protocol is suspended, the PI, his/her department chair, and the college dean will be contacted as soon as possible, and a letter will be sent from the IACUC that requires a written response from the PI regarding corrective action and future preventive measures. The PI also will be asked to meet with the IACUC, the IACUC Chair and/or the Institutional Official as a condition of reinstatement.
 - d. A majority vote of the IACUC with a quorum present, in consultation with the Institutional Official, may lift a suspension only after it has been determined that the protocol's activities can be accomplished in full compliance with the relevant rules and regulations and that adequate measures have been taken to prevent recurrence of the non-compliant activity.
- 3) Federal Reporting of Non-Compliance
- a. In the event of significant non-compliance, during the initial investigation the IACUC will determine the extent of the non-compliance. Incidents of significant non-compliance that are deemed serious or continuing, or represent a serious deviation from the provisions of the Guide, including suspensions, will require reporting to the OLAW and AAALAC through the Institutional Official and may be reported to the federal funding agency supporting the activity.



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- b. If a protocol which conducts research using USDA regulated species is suspended it must be reported to the USDA through the Institutional Official, and any federal agency funding the activity.

4) Minor Non-Compliance

- a. **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. Minor non-compliance can often be corrected at the institutional level.
- b. Examples of minor non-compliance include, but are not limited to:
 1. Not informing the IACUC of the addition of personnel;
 2. Not maintaining surgical and post-operative care records per IACUC policy and/or protocol requirements;
 3. Failure to respond to a corrective health concern and address the problem or failure to monitor the animals adequately following invasive procedures;
 4. Use of an unapproved procedure area resulting in failure of the IACUC to inspect this area as required by law or policy;
 5. Personnel not attending training within the required time frame or not maintaining updated occupational health forms;
 6. Personnel accessing facilities without authorization;
 7. Inadequate controlled substance logs or controlled substance storage;
 8. Unapproved transfer of animals from one protocol to another;
 9. Improper or unapproved animal transportation;
 10. Not following safety procedures when working in BSL-2 or lower such as not wearing appropriate personal protective equipment;
 11. Housing animals in a lab without approval or over the time limit approved in the protocol;
 12. Inadequate housing conditions, e.g. overcrowded cages, weaning delays, or failure to separate aggressive animals as required;
 13. Minor protocol deviation which does not significantly compromise animal welfare.
- c. Consequences and Resolution of Minor Non-Compliance Incidents
 1. Resolution of minor issues may be achieved through communication between the ACS personnel, and the individual lab personnel without necessitating IACUC intervention.
 2. If an issue is not resolved or is deemed more serious, it will be reported to the IACUC. The following notification process may be used to obtain compliance or escalate the non-compliance.
 - **First notification:** The PI will be required to provide a written response regarding how the incident occurred, how it was corrected and how it will be prevented in the future. This response will be reviewed by the IACUC, and the IACUC may also require additional steps including retraining of investigative staff.
 - **Second notification:** Possible revocation of facility access privileges depending upon the circumstances and the response of the PI. The PI will be required to appear before the IACUC or a subcommittee of the IACUC.



- **Third notification:** The non-compliance may be reclassified as significant (see above). If reclassified, it may result in any potential consequences of significant non-compliance listed above. A third notification may require reporting to the appropriate federal authority and any suspension of animal activity must be reported (see above).

5. References

- Public Health Service (PHS). 2002. Public Health Service Policy on Humane Care and Use of Laboratory Animals. Washington, D.C.: U.S. Department of Health and Human Services.
- Animal Welfare Act of 1966 (P.L. 89-544) inclusive of amendments; 1970 (P.L. 91- 579; 1976 (P.L. 94-279); 1985 (P.L. 99-198).
- Animal Welfare Act Regulations, (9 C.F.R. 2.31) Institutional Animal Care and Use Committee.
- Office for Laboratory Animal Welfare. Requirements for prompt reporting of problems to OLAW. OPRR Reports, February 21, 2013.
- The Guide for the Care and Use of Laboratory Animals, Eighth Edition, National Academic Press, 2011.