

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 # 6.0

Title	Reporting Animal Welfare Concerns and Noncompliance		
Date of Last Revision	04-10-23	Version	2.0

In order to ensure that laboratory animals receive humane care, use, and treatment in accordance with the highest ethical standards, laws, regulations, and policies governing animal research, the IACUC must review and if verified appropriately address any animal-related concerns raised. Each concern will be investigated in a timely and systematic manner. Prompt appropriate actions will be implemented when necessary, including notification of governmental oversight offices.

Protocol noncompliance will be reviewed via the eProtocol IACUC Adverse Event Form. Allegations of animal mistreatment and animal welfare complaints or noncompliant events that cannot be resolved between the IACUC and investigator will be reviewed using the method described in Policy 6.2 - The Complaint Assessment Subcommittee (CAS).

6.0.1 – Definitions

Animal welfare complaint, concern, or allegation – Any concern regarding the care, use, or treatment of animals. Concerns may be raised by individuals at the institution, individuals in the community, or members of the IACUC. If a concern or allegation is brought forward, a Complaint Assessment Subcommittee can be appointed to review the concern. See Policy 6.2.

Protocol noncompliance – Protocol noncompliance occurs when procedures or policies approved by the IACUC are not being followed. Examples include performing unauthorized surgery, unauthorized persons participating in a research project, or injecting drugs that the IACUC has not approved. When faced with protocol noncompliance, the IACUC's first step, if possible, should be to find a way to bring the protocol into compliance.

6.0.2 – Institutional Sanctions and Institutional Reporting

The IACUC will investigate all complaints, allegations, or noncompliant events reported. If after investigation these occurrences are verified, the IACUC can apply sanctions. If, in the opinion of the IACUC, sanctions are not appropriate, they need not be applied. A clearly minor and unintentional misinterpretation of an IACUC policy that has created no problem for an animal is an example of where a verified allegation of protocol noncompliance might lead to an explanation, not a sanction. Failure by research personnel to follow Federal and/or University regulations, guidelines, policies and/or procedures may require reporting to the appropriate institutional, local, state and/or Federal agencies. Violations may include, but are not limited to serious or continuing noncompliance with the [PHS Policy](#), serious deviations from the [Guide for the Care and Use of Laboratory Animals](#), and IACUC suspensions.

Subsequent actions of the IACUC may include:

- Implementing measures to prevent recurrence;
- Notifying the IO and the AV of its actions;
- Notifying funding or regulatory agencies, as required; and/or
- Notifying the complainant, any persons against whom allegations were directed, and pertinent program officials (appropriate supervisory and management staff, the public affairs office, institutional attorneys, etc.).

Examples of institutional sanctions that have been previously devised include:

- counseling;
- issuing letters of reprimand;
- mandating specific training aimed at preventing future incidents;
- monitoring by the IACUC or IACUC-appointed individuals of research, testing, or training that involving animals;
- temporary revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals, pending compliance with specific, IACUC-mandated conditions;
- permanent revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals; and
- recommending to the IO that institutional (e.g., reassignment, termination of employment) sanctions be imposed.

The IACUC is empowered to suspend a project if it finds violations of University policy, PHS Policy, the Guide, OLAW Assurance, or Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and a vote for suspension by a majority of the quorum present. Further, the IACUC must consult with the Institutional Official regarding the reasons for the suspension.

The Institutional Official is required to take appropriate corrective action, and promptly report the action and the circumstances surrounding the suspension as applicable to federal regulatory or funding agencies (i.e. OLAW, APHIS, DOD, VA, etc.) as required.

6.0.3 - Reporting Noncompliance

The Principal Investigator and/or protocol personnel must report any serious or continuing noncompliance with an IACUC protocol, policies, procedures, decisions, or deviations from the Guide. The report should be submitted in eProtocol IACUC by completing and submitting the Adverse Event Form. The self-report of noncompliance should include the following information:

- relevant grant or contract number(s);
- full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., principal or co-principal investigator, technician, animal caretaker, student, veterinarian, etc.);
- description of actions taken by PI to address the situation; and description of short- or long-term corrective plans and implementation schedule(s).

6.0.4 – Reporting Animal Welfare Complaints and Concerns

Concerns about animal care and use should be reported to the IACUC, Attending Veterinarian, or University Compliance Services. Individuals reporting concerns do not have to identify themselves, and the University will protect the privacy of those who report concerns to the maximum extent possible. The policy of the University is to prohibit unlawful retaliation against employees as a consequence of good faith actions in the reporting of, or the participation in an investigation pertaining to, allegations of wrongdoing. For more information, click here: <https://research.utexas.edu/ors/animal-research/report-animal-welfare-concerns/>

Approval Date	Major Change(s) Approved
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