

Institutional Animal Care and Use Committee		UNTHSC
Title: IACUC Guidelines for Reporting to OLAW, USDA, and AAALAC		
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A. BACKGROUND INFORMATION

Events or outcomes occur which requires reporting to the appropriate agency, especially when impacting the animal welfare.

According to the Animal Welfare Act, the IACUC, in consultation with the Institutional Official, shall report any suspensions involving animal activities, including a full explanation of the reason for suspension, along with the appropriate corrective actions to APHIS and any Federal agency funding that activity.

The PHS Policy requires the IACUC, through the Institutional Official, to provide the Office of Laboratory Animal Welfare (OLAW) with a full explanation of serious or continuation noncompliance, deviations from the Guide, or any suspension of animal activity by the IACUC.

The Association for Assessment and Accreditation for Laboratory Animal Care (AAALAC) International indicates that an adverse event report must be submitted to AAALAC International promptly.

This SOP is to provide guidance on determining when and how events are to be reported, and when to report to which agency.

B. RESPONSIBILITIES

- a. It is the responsibility of all personnel (students, staff, faculty) to report or self-report issues of non-compliance.
- b. It is the responsibility of the IACUC to investigate any reports of non-compliance, and report instances of serious non-compliance to the IO (Institutional Official).
- c. It is the responsibility of the IACUC Office to work with the IACUC Chair, the Attending Veterinarian, and Institutional Official in reporting to the appropriate agencies.

C. DEFINITIONS:

- a. **Administrative Events:** Events of an administrative nature that do not directly impact the welfare of an animal. Examples of Administrative Events include:
 - i. Change in Institutional Ownership
 - ii. Change in Unit Contact
 - iii. Change in Facilities
 - iv. Change in Location, Size, or Name of the Facilities
 - v. Withdraw from AAALAC accreditation
- b. **Adverse Event:** An event, usually unanticipated, that impacts the welfare of an animal, leading to pain/ distress, morbidity, and/or death of an animal. Examples of adverse events include, but are not limited to:
 - i. Serious Animal Welfare Concerns, such as conditions that jeopardize the health or well-being of animals.
 - ii. Animal Rights Activity
 - iii. Inadequate Veterinary Care
 - iv. Conditions that Result in an Unexpected Animal Death caused by:
 - 1. Errors
 - 2. Equipment Failure
 - 3. Natural Disaster
 - 4. Inappropriate Euthanasia Technique
- c. **Noncompliance:** A violation of federal, state, or university procedures and policies. Examples include, but not limited to, the following:
 - i. Conduct of animal-related activities without appropriate IACUC review and approval;
 - ii. Failure to adhere to IACUC-approved protocols;
 - iii. Implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;
 - iv. Conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
 - v. Conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;
 - vi. Conduct of official IACUC business during a period of time that the Committee is improperly constituted;
 - vii. Failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
 - viii. Chronic failure to provide space for animals in accordance with recommendations of the Guide unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification;
 - ix. Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;
 - x. Failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);

- xi. Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
 - xii. Failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂);
 - xiii. Failure of animal care and use personnel to carry out veterinary orders (e.g., treatments)
- d. **IACUC Suspension:** An institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the PHS Policy, Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance. Any instance of non-compliance will be brought to the attention of the IACUC and the procedures in IACUC SOP 031: Reporting and Investigation of Concerns Involving the Care and Use of Animals will be followed.

D. PROCEDURES:

- a. Methods for Reporting to USDA: Annual Reports are submitted between October 1st through December 31st through the animal usage reporting system. Questions regarding other reportable events to the USDA, may be done through contacting the VMO officer assigned to our institution.
- b. Methods of reporting to OLAW:
 - i. Preliminary Report: Institutions should promptly report situations to OLAW. Preliminary Reports may be submitted via phone call to the Division of Compliance Oversight. The following information should be included in the Preliminary Report:
 1. Name and contact information of person reporting
 2. Name of Institution
 3. Assurance Number
 4. Funding Component, and if contact (for situations related to PHS-supported activities)
 5. Brief description of incident (e.g., species, category of personnel involved, dates, times, animal deaths)
 6. Plan and schedule for correction and prevention (if known)
 7. Timeframe for final report from the Institutional Official
 - ii. Final Report: Institutions must provide a Final Report of reportable situations. A Final Report must be in writing, and signed by the Institutional Official. Final Reports are to be submitted as a PDF document via email to the Division of Compliance Oversight. Final Reports must include, the following:
 1. Name of Institution
 2. Assurance Number
 3. Reporting requirement (i.e., serious or continuing noncompliance with the PHS Policy, serious deviation from the *Guide*, or suspension of an activity by the IACUC).
 4. Preliminary Report information, when, and to whom the preliminary report was made.
 5. Explanation of incident
 6. Corrective Actions

7. Grant/ contract number
 8. Impact on PHS-supported activities
 9. Compliance with terms and conditions
- iii. Annual Reports are a way to communicate program changes or administrative changes. This is submitted using the Annual Report Template in PDF format to the Division of Assurances, Annual Reports. . This report is due by December 1st.
- c. Methods for Reporting to AAALAC:
 - i. Adverse or Administrative Events requiring reporting to AAALAC, may be performed via phone call to AAALAC Point of Contact. The contact information for reporting is maintained in the IACUC Office.
 - ii. Annual Reports may be used to communicate changes in key personnel, physical areas, Actions taken in response to Suggestions for Improvement (SFIs), Organizational Structure, Animal Usage, Protocol Violations, Animal Use not approved by IACUC, or Significant adverse events. Annual Reports are submitted through the AAALAC Unit Login Section of the website. Annual Reports are available each year in mid-December. While there are no specific due dates for submitting the Annual Report, AAALAC requires annual reports to be submitted in order to maintain accreditation.

E. REFERENCES

- a. [Animal Welfare Act, Public Law 89-544 as amended; codified at 7 U.S.C. 2131-5159.](#)
- b. [PHS Policy on Humane Care and Use of Laboratory Animals, NIH, Office of the Director, revised 2015](#)
- c. OLAW Guidance Reporting Noncompliance website:
<https://olaw.nih.gov/guidance/reporting-noncompliance.htm>
- d. [Institute of Laboratory Animal Resources \(2011\). Guide for the Care and Use of Laboratory Animals. National Academies Press, Washington, D.C.](#)
- e. AAALAC FAQs, I. Maintaining Accreditation, #2. Managing and Reporting Adverse Events, Website: <https://www.aaalac.org/accreditation-program/faqs/#H2>
- f. [IACUC SOP 031: Reporting and Investigation of Concerns Involving the Care and Use of Animals](#)