

 <p>Institutional Animal Care and Use Committee Guiding Principles and Procedures</p>	<p>Effective: 3/16/2017</p> <p>Revised: 8/24/2017, 1/17/2019, 5/13/2021, 5/19/22</p>
<p>Title: Adverse Event and Protocol Deviation Reporting</p>	<p>Page 1 of 4</p>

GUIDING PRINCIPLE

The use of animals in research and teaching is a privilege granted to institutions, investigators, staff, and students that commit to meeting high ethical and regulatory standards. The IACUC is under federal mandate to provide continual monitoring and oversight of all research activities related to animal use. To assist the IACUC in fulfilling this requirement, all adverse events or protocol deviations must be reported to the IACUC.

Timely reporting allows the institution to provide the highest quality animal care by engaging all available resources.

Definitions

- 1. Adverse Events**-outcomes that adversely affect the health or well-being of animals used in research, teaching, or testing; incidents related to experimental procedures that resulted in an increased level of pain or distress in an animal or death of an animal that was not anticipated and described in the approved protocol; OR any occurrence of an unforeseen event that negatively impacted the welfare of animals; usually involving pain, distress, or death of an animal.
- 2. Protocol Deviation**-any departure from methods approved in an IACUC protocol or the conduct of animal related activities without appropriate IACUC review and approval.
- 3. Noncompliance**-Failure to adhere to IACUC protocol, policies, procedures, or decisions. Protocol noncompliance can occur in a variety of ways, either intentionally or unintentionally. ([USDA Protocol Noncompliance: Overview](#))

REQUIREMENTS

Animal Welfare Act in accordance with, (9 CFR Ch. 1), Part 2 – Subpart C, 2.31(d)(5), The IACUC shall conduct continuing review of activities covered by this subchapter at intervals as determined by the IACUC but not less than annually.

The Public Health Service (PHS) Policy in accordance with IV.C.5-The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this

Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C.1.-4. at least once every three years.

The Guide Eighth Edition, page 28, “Because of the potential for unexpected outcomes that may affect animal well-being when highly novel variables are introduced, more frequent monitoring of animals may be required.”

The Guide for the Care and Use of Agricultural Animals in Research and Teaching, Third Edition, page 2, investigate concerns, complaints, or reports of noncompliance, involving agricultural animals at the facility.

PROCEDURE

1. Principal Investigator/Animal Care Staff Responsibilities

- 1.1. The first priority is to protect the health and welfare of staff or animals that are or may be affected.
- 1.2. Within 48 hours of learning of the adverse event, protocol deviation, or noncompliance the Principal Investigator (PI) and/or animal care staff must report the event to the IACUC Office. [Protocols in Novelution contain a panel for reporting either an Adverse Event or Protocol Deviation](#). For Legacy protocols, AEs and Protocol Deviations are reported via the Report an Incident form on the IACUC website.
- 1.3. If IACUC review suggests that modifications in the protocol are required to prevent further instances, the PI shall file a [change in protocol request](#).
- 1.4. Animals that die unexpectedly or are unexpectedly euthanized in a research study must be submitted to a Veterinary Diagnostic Laboratory for Necropsy. Submission of an animal to a diagnostic laboratory should be done in consultation with the Attending Veterinarian.

2. Institutional Responsibilities

- 2.1. The IACUC is responsible for ensuring that PIs are aware of their responsibilities to report adverse events and protocol deviations.
- 2.2. Upon receipt of an adverse event or protocol deviation the IACUC Office forwards the report to the IACUC Chair, Attending Veterinarian and if necessary, the Institutional Official.
 - 2.2.1. The Attending Veterinarian investigates the adverse event or protocol deviation.
- 2.3. The IACUC Administrator and Attending Veterinarian review the Adverse Event/Protocol Deviation Report, gather additional information, and develop a summary report for the IACUC.
 - 2.3.1. The reports are provided to the IACUC at regularly convened meetings. The IACUC reviews the report and determines whether any further action is required. Further action may include but is not limited to:
 - Additional training

- Cessation of specific animal-related activities
- Protocol suspension
- It should be noted that any action taken by the IACUC that stops research on a protocol may have an effect on the granting agency involved. PIs should be prepared to make appropriate adjustments in funding.

2.4. The IACUC Office informs the PI in writing of any decisions, corrective actions, or amendments required by the IACUC.

Examples of adverse events:

- Unexpected clinical signs, either related or unrelated to a protocol procedure
- Unexpected euthanasia that is not part of the approved animal activities
- Increased or unexpected moribundity or mortality.
- Failure to recover from anesthesia.
- Surgical complications such as infection or wound dehiscence (wound opens up)
- Phenotypes associated with transgenic animals that negatively impact the welfare of the animal.
- Facility or equipment failure that has a negative impact on animal welfare.

Examples of protocol deviations:

- Any intentional or unintentional use of animals that was not described in the approved IACUC protocol;
- Failure to adhere to procedures within an IACUC approved protocol;
- Implementing protocol amendments prior to obtaining IACUC approval.

Examples of situations that DO NOT need to be reported:

- Injury/Illness unrelated to approved procedures and being treated by a clinical veterinarian.
- Death or morbidity of animals as expected and described in approved IACUC protocol.
- Death of animals that have reached the end of their natural life spans

Examples of noncompliance:

- Conduct of animal-related activities without appropriate IACUC review and approval;
- Failure to adhere to IACUC-approved protocols;
- implementation of any significant change to IACUC-approved protocols without prior IACUC approval;
- conduct of animal-related activities beyond the expiration date established by the IACUC:
- participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained;
- 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);

- failure to maintain appropriate animal-related records (e.g.; identification, medical, husbandry);
- failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂);
- failure of animal care and use personnel to carry out veterinary orders (e.g., treatments).

References

[Reporting Noncompliance | OLAW \(nih.gov\)](#)

[Protocol Noncompliance: Overview | Animal Welfare Information Center | NAL | USDA](#)