

**University of Cincinnati  
Animal Care and Use Program**

## **Reporting Adverse Events and Protocol Deviations**

The IACUC is under federal mandate to monitor all research activities related to animal use. To assist the IACUC in fulfilling this requirement, all unanticipated outcomes, protocol deviations, and adverse events must be reported to the IACUC. Reporting helps assist the Principal Investigators and animal care/veterinary staff to find the cause and to prevent recurrence. Reporting is intended to be an interactive process with the PI, the Veterinarian and IACUC. The purpose of reporting is to provide a collaborative means of facilitating research effectiveness and to improve animal care.

### **Responsibilities**

1. Reporting is the responsibility of the Principal Investigator, all animal users, staff, and technicians.
2. Research staff is expected to seek assistance from veterinary staff and to report the adverse event to the IACUC office within 48 hours. Veterinarian consultation **MUST** occur when pain or distress is beyond the level anticipated in the protocol description or when interventional control (such as analgesics) is not possible.
3. Veterinary staff can assess the situation, assist in seeking resolutions, and helping with the report.
4. The IACUC office will notify the PI, study contacts and veterinary staff when the report has been received.

### **Definitions**

1. Adverse event (AE) - an instance of unfavorable or unanticipated signs or outcomes. Adverse events include suboptimal well-being, animal death, disease, distress, or trauma that was not the anticipated result of approved protocol activity.
2. Protocol deviations - departures, omissions or mistakes made by the research team inconsistent with the intent of the approved protocol.

Events that **MUST** be reported include, but are not limited to the following:

- Unexpected animal death or study related complications associated with approved animal activities in a cohort of animals (e.g., allergic reaction to treatment, broken limbs, complications during or recovering from surgery, anesthetic/analgesic approved in protocol that appears ineffective, sudden death).
- Mortality greater than 10% of that predicted in the IACUC protocol or greater than 10% of the animal subjects in a study group if no mortality is expected.
- Unanticipated phenotype from genetic manipulation that may negatively affect animal well-being (e.g. unforeseen immunodeficiency).
- Death due to equipment failure (e.g. anesthetic machine malfunction, HVAC failure, loss of electrical power) or natural disaster. Note: In the case of a serious facility issue that affects multiple projects, a single adverse event report or incident report would be initiated by appropriate facility staff.
- Unforeseen events that lead to the harm of animal(s) or that cause pain or distress not justified and approved in the protocol.
- Protocol deviations (e.g. unclear or missing procedures in protocol, refinements not clearly defined in protocol).

Examples of events that are not required to be reported as AEs:

- Death or morbidity of animals described as expected in the approved IACUC protocol.
- Injury or illness unrelated to study procedures which are considered normal species related health issues being treated by veterinary staff (e.g. animal is treated for bloat, fight wounds, etc.).

## **References**

1. Animal and Plant Health Inspection Service, USDA. [Animal Welfare Act and Animal Welfare Regulations](#). July 2023. CFR Title 9, Subchapter A - Animal Welfare. U.S. Government Printing Office, Washington DC.
2. National Research Council. Institute for Laboratory Animal Research. 2011. [Guide for the Care and Use of Laboratory Animals](#). Public Health Service, Bethesda, MD.
3. Office of Laboratory Animal Welfare, National Institutes of Health, US Department of Health and Human Services. [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#). 2015. Public Health Service, Bethesda, MD.
4. AAALAC International. [Managing and reporting adverse events](#). Accessed 8 February 2024.