

UNIVERSITY OF TEXAS AT ARLINGTON

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

SOP: REPORTING ADVERSE EVENTS

Definition: An *adverse event* is an *unexpected incident* that leads to a significant injury or illness, unrelieved pain or distress, or the death of an animal. **Adverse events MUST be reported to the IACUC.** An *unexpected incident* is one that was not expected or anticipated during the planning of the research and is not addressed in the protocol.

Rationale: Experimental manipulation of animals in research, testing, or teaching may occasionally result in serious, unanticipated, or adverse clinical consequences. Adverse events can be a one-time occurrence or indicative of broader programmatic concerns. Reporting these events safeguards animal welfare and potential research outcomes, and contributes to our collective goal of optimizing animal care and use at UTA.

Examples of Adverse Events include, **but are not limited to:**

- Adverse abnormalities (phenotypes) such as early mortality or conditions that are not described in the animal protocol
- Adverse events related to the use of pharmaceutical or non-pharmaceutical grade substances
- Higher than expected mortality that is a direct result of protocol procedures
- Unexpected injury or death of an animal due to experimental manipulations, accidents, or equipment/power failure
- Unexpected clinical signs that develop as a result of an approved procedure and the signs are not described in the animal protocol
- Animal escape
- An animal dies or requires treatment or euthanasia due to human error

Reporting Deadline and Procedures: Adverse Events must be reported by the Principal Investigator (PI) to the IACUC promptly (within 5 business days for lab protocols and within 5 business days of returning from the field for field protocols) using the IACUC Adverse Event Report Form located on the [IACUC Forms](#) webpage. Completed Report Forms should be submitted to the Office of Regulatory Services (ORS) at regulatoryservices@uta.edu. Any questions about reporting requirements and whether a particular incident or event needs to be reported under this SOP should also be directed to ORS at regulatoryservices@uta.edu or 817-272-3723.

PLEASE NOTE: Any illness, pain, distress, or animal death must be separately and immediately reported to the Animal Care Facility (ACF) Manager according to the [IACUC Veterinarian Notification of Animal Welfare Issues SOP](#), acf@uta.edu or 817-272-5236/817-272-0743. This notification is separate from the Adverse Event Report in order to immediately address pending welfare issues and provide care or treatment if necessary.

IACUC Review of Adverse Events: Any immediate animal welfare issues will be addressed and overseen by the Attending Veterinarian. Once those are resolved, the IACUC will review the Adverse Event in accordance with the SOP: [Reporting and Processing Animal Care and Use Concerns and Incidents](#).