



Subject:	Reporting Adverse Events (AE)
Source	Institutional Animal Care and Use Committee (IACUC)
Effective Date	08/10/2026
Replaces:	New
Applies to:	Personnel involved in Research or Teaching involving animals.
Reference:	Animal Welfare Act; PHS Policy on Humane Care & Use of Laboratory Animals. Guide for the Care & Use of Laboratory Animals

The Institutional Animal Care and Use Committee (IACUC) provides oversight of the institution's animal care and use program, ensuring compliance with federally mandated regulations, ethical standards, and institutional policies governing the humane use of animals in research and teaching at the University of Colorado Denver | Anschutz. The IACUC evaluates and reviews all activities related to the care and use of animals and determines if the proposed activities are in accordance with regulations.

Policy Statement

Purpose

This policy provides guidance on determining when and how events or outcomes impacting animal welfare should be reported.

Background

The use of animals in research or teaching may occasionally result in an adverse event (AE) or unexpected outcome, which may compromise animal welfare. The Institutional Animal Care and Use Committee (IACUC), in its oversight of animal care and use, must ensure there is a clear path for reporting these events in order to provide the highest quality animal care.

Definitions

Adverse Event:

Any undesirable or harmful occurrence in an animal participating in an approved activity that results in pain, distress, illness, injury, or death, whether expected or unexpected.

Unexpected Outcome:

Any unanticipated result, observation, or occurrence associated with approved animal activities that differ in nature, severity, frequency, or incidence from what was described in the approved protocol or reasonably anticipated based on prior experience.

Consider that many unexpected outcomes are adverse events because they negatively affect animal welfare.

Not all unexpected outcomes are adverse events. For example, an unexpected experimental finding that does not affect animal well-being but may still warrant reporting or protocol modification.

Not all adverse events are unexpected. For example, mild transient weight loss that is described in the approved protocol may be an expected outcome, although it is an adverse event. If they are described in the protocol, they probably do not need to be reported.

Policy

All unanticipated events or outcomes that pose an imminent risk to animal welfare should be reported immediately to veterinary staff and IACUC administration. If there is no imminent risk:

- Within 3 business days of discovery, an Adverse Event report (See Appendix A or complete the Adverse Event Form) should be submitted to the Attending Veterinarian (AV), IACUC Chair and/or IACUC office.
 - Note that if the event/outcome is initially reported to veterinary staff or IACUC administration, an AE report must still be completed and submitted for IACUC review. {Link to Form when available}
- The Principal Investigator is responsible for submitting the report within 3 business days of the event. (If the PI is unavailable, a senior scientist or laboratory manager may submit, but the PI must still be informed.)
- The AV, IACUC Chair, and/or IACUC office will contact the relevant parties for more information if needed and determine if further information should be submitted.

Reporting Concerns: Any concerns regarding animal welfare can also be reported anonymously via the CU Ethics Line ([CU Reporting Concerns and Suspected Misconduct - https://www.cu.edu/ethicsline](https://www.cu.edu/ethicsline)) or 800-677-5590



Appendix A:

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