

University of Colorado at Boulder; Office of Research Integrity; Institutional Animal Care and Use Committee			
SOP # 3	Title: Unanticipated Adverse Events		
Date: 11/12/2008	Revision: initial	Effective Date: 11/30/2008	Pages: 3

1. PURPOSE

It is University policy that the procurement, housing, care, and use of animals should conform to the National Institutes of Health (NIH) Guide for the Care and Use of Laboratory Animals (the [Guide](#)) and other relevant federal policies and procedures. According to this policy, investigators are responsible for reporting events that adversely affect the health of animals used in research, and the University in turn may have a responsibility to report these events to the Office of Laboratory Animal Welfare (OLAW). This SOP describes the procedures to meet these requirements.

The first priority in responding to an adverse event is to ensure the safety and welfare of research animals and staff. If immediate action is required, the procedures described in section 5 of [SOP 1](#) (Complaints about Animal Care and Use) should be followed. The purpose of this SOP is to describe procedures involved in follow-up evaluation of adverse events.

2. DEFINITIONS

Unanticipated Adverse Events refer to outcomes that (a) adversely affect the health or well-being of animals used in research or teaching, (b) are a result of activities that were approved by the IACUC, but (c) were not anticipated in the IACUC's review of a protocol.

Reportable Events: According to the [PHS Policy](#) on Humane Care and Use of Laboratory Animals, "conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals" must be reported to OLAW. (Many other situations must be reported, but this is the statement most relevant to unanticipated adverse events." However, the Policy also notes that "there may be levels of morbidity and mortality in virtually any animal-related activity, including those associated with the care and use of animals in research, testing, and teaching that are not the result of violations of either the Policy or the *Guide*." Some examples of events that do not require reporting to OLAW include:

- death of animals that have reached the end of their natural life spans;
- death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;
- animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;

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- animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol; or
- *infrequent* incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding

3. Principal Investigator Responsibilities

- 3.1. The first priority is to protect the health and welfare of animals or staff that are, or may be, affected. As necessary, the PI should immediately contact the campus veterinarian for assistance.
- 3.2. Within 72 hours of learning about the event, the PI must inform the IACUC administrator of potential adverse events, using the Adverse Event Reporting Form.
- 3.3. If review suggests that modifications in the protocol are required to prevent future instances, the PI shall file an amended protocol for review by the IACUC.

4. Institutional Responsibilities

- 4.1 The IACUC is responsible for ensuring that PIs are aware of their responsibilities to report adverse events, by describing these requirements in application forms and approval letters.
- 4.2 Upon receipt of a report of a possible adverse event, the IACUC administrator will share the report with the IACUC chair, institutional veterinarian, and Director of the Office of Research Integrity.
 - 4.2.1 If the event requires an immediate response to protect the health of animals, the institutional veterinarian will follow the steps outlined in part 5.2 of [SOP 1](#) (Complaints about Animal Care and Use)
- 4.3 The institutional veterinarian will review the Adverse Event Reporting Form, as well as gather any additional information needed, and develop a summary report with recommendations for review with the IACUC chair and IACUC administrator.
- 4.4 If the event appears to require reporting to OLAW, the IACUC will promptly provide a preliminary report to OLAW via fax, email or a telephone call. The preliminary response will then be followed by a detailed report of the assessment.
 - 4.4.1 If the event constitutes noncompliance, as described in SOP 2, it will be treated in accordance with that SOP.

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4.4.2 Some events, particularly involving death of animals, may require reporting even though they do not represent noncompliance with an approved protocol.

4.5 Unanticipated adverse events will be reported to the IACUC at a regularly convened meeting. The IACUC may simply acknowledge the report, or may recommend additional actions. The IACUC will also review any protocol amendments that may result from an adverse event.

4.6 The IACUC Administrator will inform the PI of any decisions, corrective actions, or amendments required by the IACUC.