UNIVERSITY OF NEBRASKA–LINCOLN
Institutional Animal Care Program

Policy on Reporting

Adverse Events

During Animal Research, Teaching or Extension Activities

University of Nebraska
Institutional Animal Care Program
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http://research.unl.edu/orr/iacp.shtml

WHO to CONTACT
HOW TO REPORT

When an adverse event occurs, first take steps to ensure animal welfare.

1. In an emergency, contact the attending veterinarian at 402-472-6958 or the IACP office at 472-4486.

2. Establish contact with the animal facility manager to provide any necessary changes in animal care.

3. Communicate as soon as possible with IACP by phone or e-mail to inform them of the situation and receive further instruction if appropriate.

4. Fill out the AE Report Form from the IACP Web site and submit it by mail or fax within five to ten days of the event.

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What is an adverse event (AE)?

An adverse event is any occurrence, usually involving pain, distress or death of an animal, that was not described in the approved Application to Use Animals Form (AUAF) or its subsequent modifications and has a negative impact on animal welfare.

Why should AEs be reported?

Reporting AEs assists principal investigators, animal care staff and the attending veterinarian to find the cause and to prevent recurrence. Reporting also helps the Institutional Animal Care and Use Committee meet its federal requirement to monitor animal activities. Reports of AEs provide documentation of animals experiencing unexpected pain or distress for proper categorization on the Annual Report to the USDA.

Who should report AEs?

PIs and animal facility managers should report to the Institutional Animal Care Program (IACP) as soon as they become aware of an event that may impact animal welfare.

What qualifies as an AE?

When in doubt, call IACP to discuss the event. Unexpected events or problems are considered AEs if they affect greater numbers of animals than anticipated, have a negative impact on other animals or activities, or reflect a situation that could become more severe in the future.

A report is not required if the level of pain or distress does not exceed that which has been described in the AUAF and approved by the IACUC.

What types of events must be reported?

- *Deaths of animals not described in the AUAF*
  For example: mortality occurring during transport; an animal found dead following surgery.

- *Complications not described in the AUAF*
  For example: allergic reaction to a treatment; inadequate anesthesia; development of infection following surgery or treatment.

- *Greater mortalities or more severe responses than described in the AUAF*
  For example: 10% of animals die following surgery when a 5% fatality rate was expected; animals appear to be in more pain or distress than expected.

- *Facility or equipment failure that has a negative impact on animal welfare*
  For example: loss of electrical power impacting HVAC function or water supply; restraint equipment malfunction; biohazard containment failure.

- *Facility design, husbandry or postoperative care that has a negative impact on animal welfare*
  For example: entrapment; overexposure to heat source(s); inadequate analgesia or antibiotic use.

What events do not need to be reported?

- *Injury or illness unrelated to approved procedures and being treated by the attending veterinarian or a project veterinarian.*
- *Deaths of animals expected as described in the approved AUAF.*

What information needs to be reported?

The Adverse Event Form should be used to submit a report. The form is available at http://research.unl.edu/orr/qa.shtml. Information required includes the project title and IACUC protocol number; the principal investigator's name; the date, time, location and nature of the event; measures taken at the time to minimize impact on animal welfare; the actual or potential impact of the event on animal welfare and study outcomes; and immediate and long-term steps being taken or considered to prevent recurrence of the event. The name and signature of the person reporting the adverse event also are required.