

## University of Nebraska Lincoln - Institutional Animal Care Program

### Policy on the Reporting of Unexpected Adverse Events During Animal Research, Teaching, or Extension Activities

#### **What is an unexpected adverse event (AE)?**

An AE is any occurrence that was not described in the approved AUF or subsequent modifications, and which has an impact on animal welfare.

#### **Why should AEs be reported?**

Reporting assists the IACUC in their federal requirement to monitor animal activities. It encourages PIs, animal care staff, and the attending veterinarian to investigate the cause of events and ways to prevent reoccurrence. Reports of AEs provide documentation of animals experiencing unexpected pain or distress for proper categorization on the mandatory Annual Report to the USDA.

#### **Who should report AEs?**

PIs and animal facility managers should report to the IACP as soon as they become aware of an event that may impact animal welfare. It is not necessary for both PI and manager to report the same event if they are aware that a report has already been made, but both are responsible for ensuring accurate and timely communication with IACP.

#### **What qualifies as an AE?**

When in doubt, report it. Events with mild impact may need investigation if they affect significant numbers of animals, will have an impact on other animals or activities, or reflect a situation that could be more severe in the future. This allows IACP to act proactively to prevent future problems. Even pain or distress that is appropriately and quickly relieved with analgesics may change the reporting category for an animal, so PIs should not fall to the misconception that animals must die to be reported.

#### **How do I avoid making many reports for things that normally happen?**

A report is not required if the IACUC is aware that an adverse event may occur and the event has happened as was expected and approved. When your experience causes you to expect certain complications in your research, indicate and explain the possible adverse events in your Animal Use Form. For example, list potential mortalities from induced infection, trapping, or surgery.

#### **What are examples of events that must be reported?**

- *Deaths of animals not described in AUF*  
e.g. 2 of 10 cattle die during shipping, pig found dead the day after surgery.
- *Study-related complications not described in the AUF*  
e.g. dog has an allergic reaction to a treatment, pig anesthetic doesn't work adequately, rabbits develop infection following surgery

- *More deaths or complications than described in AUF*  
e.g. 10% of cats die following surgery when a 5% fatality rate was expected and justified in the AUF, cattle appear to be in more pain or distress from a procedure than expected
- *Facility or equipment failure has or may have an impact on animal welfare*  
e.g. loss of electrical power temporarily alters HVAC function, cow is injured in a malfunctioning restraint chute
- *Poor facility, husbandry, or care has or may have an impact on animal welfare*  
e.g. pig burned by heat lamp, birds develop sore feet caused by cage flooring

**What are examples of events that do not need to be reported?**

- *Injury or illness unrelated to study procedures that are being treated by the attending veterinarian or a contract veterinarian.*  
e.g. a dog is diagnosed with coccidia, a calf is treated for bloat
- *Deaths of animals as expected and approved in the AUF.*  
e.g. up to 5% poultry mortality was expected from Newcastle's and 3% died

**What information needs to be reported?**

The report should include the nature of the event, how the event and animal welfare were monitored or addressed, the actual or potential impact of the event on animal welfare, the actual or potential impact of the event on the study outcomes, and what immediate and long-term steps are being taken or considered to prevent future reoccurrence of the event.