Clemson University
Institutional Animal Care and Use Committee (IACUC)

Policy Number: 1.6

Policy Title: Reporting and Investigating Unexpected Outcomes or Adverse Events

Section 1: Purpose

A comprehensive animal care program includes the acknowledgment that unexpected events happen; but investigators, animal care personnel, and anyone who is affiliated with the program is able to identify and promptly report these events as part of their commitment to promoting animal welfare. The IACUC is required to conduct "continuing protocol review" which includes the receipt and review of "adverse or unanticipated events." (*Guide*, p. 33-34)

This policy is intended to assist researchers, facility managers, and animal care personnel in defining adverse events or unexpected outcomes and provides guidance on reporting these events to the IACUC. This policy also provides the IACUC with a basic framework for evaluating those events.

Section 2: Scope

This policy applies to all IACUC approved animal activities, all personnel working within Clemson's animal program, and all facilities inspected by the IACUC on a semiannual basis.

Section 3: Policy

Adverse Events

An adverse event is an unexpected incident that endangers the well-being or leads to the harm of animals utilized by the University's animal program. Examples of adverse events may include:

- Natural disasters
- Mechanical failures
- Animal husbandry issues
- Accidents or human error

Unexpected Outcomes

A well-planned AUP identifies potential outcomes that may reasonably occur within the parameters of the experimental procedures. Unexpected outcomes are undesirable effects that occur during or result from a research procedure or teaching activity. These undesirable effects negatively impact animal welfare and were not anticipated during the planning of the research or teaching activities. Examples of an unexpected outcomes may include:

- Higher than expected mortality associated with the administration of a test substance
- Device/implant failure

- Unexpected phenotypes of genetically modified animals that are detrimental (malocclusion, impaired immunity, unexpectedly high mortality of offspring)

Veterinary Authority
Immediately after an adverse event or unexpected outcome, the Attending Veterinarian has the authority to pause a study until the IACUC has reviewed information pertaining to the issue especially if animal welfare is a concern.

Reporting Requirements (Internal to the animal program)
The Principal Investigator (PI) of the involved protocol(s) is responsible for ensuring that reporting of adverse events or unexpected outcomes is prompt and complete. Facility managers or personnel may also report information to the IACUC pertaining to adverse events or unexpected outcomes.

All adverse events or unexpected outcomes should be reported to the Attending Veterinarian (AV) and the IACUC Administrator in writing within 72 hours of the occurrence. This written statement should include:

- The identification of the animal(s) involved
- The protocol(s) affected by the event or outcome
- A detailed description of the event
- A description of actions taken to eliminate, modify, or mitigate repetition of the event or outcome
- A description of any efforts to increase monitoring of animals.

In the event of a major disaster or emergency that precludes prompt communication, the 72-hour reporting requirements may be extended. In these situations, reporting should occur as soon as circumstances allow.

IACUC Evaluation of an Adverse Event or Unexpected Outcome
The general procedure for the review of adverse events or unexpected outcomes is illustrated in the matrix below. The procedure may vary depending on the situation and severity/extent of the event.

Reporting Requirements (External to the animal program)
At any point during the evaluation of adverse events or unexpected outcomes, the IACUC/AV/ORC may report or may be required to and will report the event to relevant University offices, regulatory oversight agencies (OLAW and/or USDA), AAALAC International, and/or funding sources.

Research Misconduct
If the reported incident involves fabrication or falsification of research data or an accusation of plagiarism, the incident will be reported to the Research Integrity Officer as an allegation of Research Misconduct.

Section 4: References

Clemson's Whistleblower policy:
https://media.clemson.edu/administration/compliance/whistleblowerpolicy.pdf
Guide for the Care and Use of Laboratory Animals, Eighth Edition

Adverse Event or Unexpected Outcome Evaluation Flow Chart

Completed By:_____ Date: _____ Accession #:_____

Associate AUP:_____ PI:_____