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

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
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)

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)**

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.

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

**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), and/or funding sources.
Adverse Event or Unexpected Outcome Evaluation Flow Chart

Completed By: ________________________ Date: _________________ Accession #: __________________

Associate AUP: ________________________ PI: ________________________

A report of an adverse event or unexpected outcome is received.

The report will be communicated to the IACUC Administrator, AV, IACUC Chair, and the Director of Research Compliance. An initial review of the event will occur. This review will determine if the event/outcome has been sufficiently addressed, if additional information is needed, or if immediate IACUC action is required.

If the event/outcome has been sufficiently addressed, the occurrence will be communicated to the IACUC either in the veterinary report or as a separate agenda item at the next convened meeting.

If additional information is needed, the PI, research personnel, or facility personnel may be contacted. This information will be reviewed by the IACUC Administrator, AV, IACUC Chair, and the Director of Research Compliance. Repeated communications may be made until sufficient information is obtained.

If immediate action by the IACUC is warranted, the IACUC Administrator will schedule an emergency meeting of a quorum of members. If needed, animals may be placed under emergency care of the veterinarian.

If the committee has no concerns regarding the event, the incident is closed and no further actions are taken.

If the committee has concerns regarding the event, additional corrective actions may be assigned.

Depending on findings, the event will either be presented to the Committee at the next planned meeting or immediate IACUC action may be required.

At the convened meeting, the IACUC will determine the appropriate course of action. Requirements will be communicated to the PI by the IACUC Administrator or ORC Director.

The PI must fulfill all requirements determined by the committee and is required to provide updates to the IACUC Office. Updates will be provided to the Committee during subsequent planned meetings or through email.

The PI will be notified when the Committee agrees that all concerns have been addressed. Failure to adhere to the corrective actions assigned by the committee will be handled as a non-compliance.

Approved: November 12, 2014
Revised: February 2021

(Adapted from Former Policy #15)