FSU
ANIMAL CARE & USE COMMITTEE
DIVISION OF RESEARCH

Reporting Adverse Events and Unexpected Outcomes

The FSU ACUC **requires** principal investigators to report unexpected experimental outcomes that adversely affect animal or human well-being. An adverse event or unexpected outcome is any occurrence that has a negative impact on an animal that was not described in the approved ACUC protocol. Examples of adverse events or unexpected outcomes include, but are not limited to:

- The phenotype of a genetically modified or mutant animal is discovered to include an unexpected condition that negatively affects animal well-being.
- Physical restraint of an animal that results in lesions, illness, or behavioral changes.
- A surgical procedure that causes unexpected complications or death.
- A higher than expected morbidity or mortality rate occurs, related to the experiment or other unanticipated events (e.g. loss of power, equipment malfunction, human error)
- Study-related complications not expected as part of the research design (e.g. anesthetic failure, anesthetic deaths, post-procedural infections).

Adverse events and unexpected outcomes must be reported within 24 hours after their occurrence. Reports may be submitted online at https://lar.fsu.edu/forms/adverse-event-or-unexpected-outcome-report/. Reports may also be made by contacting an LAR veterinarian or any FSU ACUC member.

To comply with AAALAC accreditation standards, adverse events involving the following will be promptly reported to AAALAC:

- Inadequate veterinary care
- Conditions that resulted in unexpected animal harm or deaths
    - Accidents or errors
    - Equipment failure
    - Natural disaster
- Significant animal rights activities (e.g., protests, break-ins, property damage, FOIA and other public records requests that include AAALAC International documents)
- Inappropriate euthanasia techniques and/or failure to confirm euthanasia
- Substantiated complaints or reports regarding animal welfare concerns
- Internal or external reviews/inspections or other similar reports that document significant adverse events or noncompliance that resulted in animal harm or death; investigations by national oversight bodies; and other serious incidents or concerns that negatively impact animal well-being (e.g., failure to follow the approved protocol which resulted in compromised animal welfare; death during transport)
- Significant human health issue directly related to the animal care and use program

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