



Florida State University Animal Care and Use Committee

Policy - Reporting of Unexpected Outcomes

Federal laws, regulations and policies require the continuing oversight of animal activities by the Institutional Animal Care and Use Committee. This responsibility is considered by the 8th edition of the *Guide for the Care and Use of Laboratory Animals* as post-approval monitoring¹ (PAM). One facet of PAM is to recognize any unanticipated adverse consequences of planned procedures that affect animal well-being. As the nature of scientific inquiry is to explore new questions, the IACUC recognizes that along with this comes the potential for unexpected complications or adverse effects associated with the experiment(s). The greatest success of an animal research program occurs when there is a partnership between the IACUC, veterinary and animal care staff and investigators. Reporting unanticipated effects that affect animal well-being or assigned pain category to the IACUC allows for an informed discussion between the IACUC, the PI and the veterinary staff to address refinements to the protocol to avoid further incidents.

An unexpected outcome is any effect of an experimental or teaching procedure that negatively impacts animals. The effect is not described in the protocol, nor was it anticipated during the planning of the research.

Examples of unexpected outcomes which must be reported include, but are not limited to, the following:

- 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 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, unexpected infection).
- Study-related complications not expected as part of the research design; e.g. anesthetic specified in the protocol doesn't work as expected or anesthetic overdose results in death.

Policy: It is the responsibility of the Principle Investigator to promptly report any unanticipated and/or adverse experimental outcomes affecting animal wellbeing to the IACUC or Attending Veterinarian.

Procedure:

1. The Principal Investigator or their designees are to contact the IACUC or Attending Veterinarian as soon as an adverse outcome is identified or suspected. While the

principal investigator has primary responsibility for reporting such concerns, unexpected outcomes may also be reported by LAR animal care technician staff, breeding colony managers and other members of the research staff.

2. The Attending Veterinarian and the IACUC will work with the researcher to assess the situation, and develop a plan for revising the animal use protocol and/or experimental procedure (e.g. anesthesia, procedural method, monitoring interval, humane endpoints) as needed to ensure the well-being of the animals by circumventing or alleviating the impact of the unanticipated outcome.

Investigators and their staff are encouraged to be proactive in reporting animal health and well-being issues. Failure to report unexpected outcomes could be considered an issue of non-compliance.

References

- Guide for the Care and Use of Laboratory Animals (*Guide*), NRC, 2010.
- Animal Welfare Regulations, 9 CFR, chapter I, subchapter A.

¹ Guide for the Care and Use of Laboratory Animals, 8th edition, pp 33-34: *“Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies. A variety of mechanisms can be used to facilitate ongoing protocol assessment and regulatory compliance. Postapproval monitoring (PAM) is considered here in the broadest sense, consisting of all types of protocol monitoring after the IACUC’s initial protocol approval... PAM helps ensure the well-being of the animals and may also provide opportunities to refine research procedures...”* and *“Examples of effective monitoring strategies include: ... • regular review of adverse or unexpected experimental outcomes affecting the animals”*

² Guide for the Care and Use of Laboratory Animals, 8th edition, pp 5 and 28: *“Refinement refers to modifications of husbandry or experimental procedures to enhance animal well-being and minimize or eliminate pain and distress. While institutions and investigators should take all reasonable measures to eliminate pain and distress through refinement, IACUCs should understand that with some types of studies there may be either unforeseen or intended experimental outcomes that produce pain. These outcomes may or may not be eliminated based on the goals of the study.”* and *“Unexpected Outcomes Fundamental to scientific inquiry is the investigation of novel experimental variables. Because of the potential for unexpected outcomes that may affect animal well-being when highly novel variables are introduced, more frequent monitoring of animals may be required. “*

Approved by the FSU ACUC:
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