



Policy on Reporting Unexpected Outcomes Affecting Animal Well-Being

The University of Georgia is committed to the humane care of the animals used in its research and instructional activities. Federal laws, regulations, and policies require continued institutional oversight of animal use activities after IACUC approval. Principal Investigators participate centrally in this oversight by reporting any unexpected outcomes to the IACUC.

Policy

It is the responsibility of the Principal Investigator to promptly report any unexpected outcomes that negatively affect animal well-being to a Laboratory Animal Veterinarian, the Office of Animal Care & Use or the IACUC.

The UGA IACUC's interpretation of an "unexpected" outcome:

The UGA IACUC recognizes that in the course of scientific inquiry there is the potential for unexpected outcomes that may affect animal well-being. Most procedures, even when performed appropriately and according to the IACUC protocol and veterinary standards, are expected to have some level of morbidity, and possibly mortality, due to expected complications (e.g., anesthesia sensitivities, failure to recover from the procedure, post-operative infection, or unexpectedly rapid disease progression). For any model, this level is based on historical data within the lab and/or the model's known success rate. These expected levels should be defined in the IACUC protocol.

What does NOT need to be reported to the IACUC:

Morbidity/mortality is within the expected level as described in the protocol, and the procedure was performed according to the protocol and veterinary standards.

What does need to be reported to the IACUC:

Morbidity or mortality in excess of the expected level as described in the IACUC protocol.

Any outcome that negatively affects animal well-being due to the IACUC protocol or veterinary standards not being followed.

Examples of unanticipated 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 results in lesions, illness, or behavioral changes.
- A procedure causes an unexpected complication that negatively affects animal well-being.

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- A higher than expected incidence of complications, illness, or morbidity that negatively affects animal well-being, due to the experimental (e.g., infection, treatment) or instructional procedures.
- Morbidity or mortality due to unanticipated events (e.g., power loss).

Procedure

The Principal Investigator or their designee should contact a URAR veterinarian (for URAR-managed animals) or the Attending Veterinarian (for other animals), the Office of Animal Care & Use or the IACUC promptly when an unexpected adverse outcome is identified or suspected. Initial communication in person or via phone is encouraged. The veterinarians and IACUC will work with the PI to assess the situation, and develop a plan for improving the well-being of the affected animals and revising the AUP (e.g., anesthesia, procedural method, monitoring interval, humane endpoints) as needed to ensure the well-being of the animals in ongoing and future studies or courses.

In the event of unexpected death, death from unknown causes or euthanasia due to unanticipated morbidity, the cadaver should be preserved by refrigeration (NOT freezing) ASAP to allow for necropsy. The URAR veterinarians (for animals managed by URAR) or the Attending Veterinarian (for other animals) should be notified promptly. In accordance with the USDA Animal Welfare Inspection Guide standards, this policy requires necropsy for USDA regulated animals when cause of death is not clear. By default, the necropsy is usually to be performed by a veterinary pathologist; however, the mechanism for necropsy is at the discretion of the URAR veterinarians or the Attending Veterinarian.

References

- Guide for the Care and Use of Laboratory Animals (*Guide*), NRC, 2011.
- Guide for the Care and Use of Agricultural Animals in Research and Teaching (*Ag Guide*), American Dairy Association, the American Society of Animal Science, and the Poultry Science Association, 2020. Animal Welfare Regulations, 9 CFR, chapter I, subchapter A.
- Animal Welfare Inspection Guide, USDA APHIS, 2021