

University of Louisville
Institutional Animal Care and Use Committee
Policies and Procedures

Unexpected Findings and Adverse Events

Policy: Undesirable, unexpected outcomes and unanticipated events that result in significant negative impacts on animal health and well-being must be reported to the IACUC. A notification should be submitted within 48 hours and a preliminary report submitted within one week of the event(s).

Rationale: The Guide of the Care and Use of Laboratory Animals (Guide) acknowledges that “fundamental to scientific inquiry is the investigation of novel experimental variables,” but includes additional emphasis on responding to unexpected outcomes and adverse events. A primary example is the use of genetically modified animals (GMAs), in which unexpected phenotypes are often manifested. While individual animal welfare could be impacted, even an unexpected reduction in fertility may result in Principal Investigators’ need for more animals than originally approved by the IACUC. The Guide also states that examples “of effective monitoring strategies include... regular review of adverse or unexpected experimental outcomes affecting the animals...”

Monitoring for such outcomes has and will always depend on careful observation by research staff, augmented by daily care provided by the Comparative Medicine Research Unit (CMRU). Historically, adverse events have been resolved by the laboratory in consultation with CMRU veterinary staff. While such a routine is entirely appropriate, the Guide suggests that the IACUC should also be made aware of such events. *Please note: as always, animal health-related issues should be reported to CMRU veterinary care staff immediately.*

Procedures, Guidelines, and Exceptions:

1. Principal Investigators and CMRU leadership should provide reports to the IACUC via e-mail to the IACUC Service Account (IACUC@louisville.edu).
2. Examples of circumstances that should be reported include (but are not limited to):
 - a. Unexpected phenotypes affecting the health and well-being of animals, which may require additional monitoring or intervention (*e.g.*, immunodeficiency, diabetes mellitus, muscle wasting)
 - b. Unexpected morbidity or mortality (*e.g.*, surgical complications, reactions to test articles, tumor metastasis, elevated levels of induced disease)
 - c. Illness or injury from temporary or prolonged physical restraint
 - d. Accidents leading to significant morbidity or mortality (*e.g.*, water system malfunction, impeded access to food, drug overdose)
 - e. Procedures performed that are not approved in an IACUC *Proposal*.
3. Reports should summarize the events (to include the # of animals affected and any adverse consequences to animal welfare) and outline means of avoiding their recurrence, if possible. The reports should also ensure “veterinary consultation when pain or distress is beyond the level anticipated in the protocol description or when interventional control is not possible” (Guide 2011). The IACUC may or may not require *Proposal* modifications to describe newly-discovered outcomes and consideration of alternatives and indications for intervention.

Original Adoption: 17 November 2016

Revised: 13 August 2024

Latest Approval: 15 August 2024

4. The reports will be discussed at the next monthly convened IACUC meeting and determine whether any additional means of avoiding recurrence or any corrective action is necessary. The IACUC will also determine whether any of the events meet the requirements for external reporting. The outcome of IACUC deliberations will be communicated to the PI and the department chair affiliated with the project in question.
5. If the IACUC determines that the events meet the requirements for external reporting, a letter reporting a deficiency is forwarded to the appropriate outside regulatory agency/agencies (*i.e.*, OLAW, AAALAC, USDA), funding agency (through the Office of Sponsored Programs Administration), or in other instances where notification seems appropriate as determined by the committee. A letter will also be forwarded to the department chair affiliated with the project in question. IACUC and subcommittee members will remain honor-bound to respect report confidentiality.

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