

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

Reporting and Investigating Animal Welfare Concerns, Noncompliance, Unexpected Findings, or Adverse Events

Policy: The humane care and use of animals is of paramount importance to the University of Louisville. Undesirable, unexpected outcomes and unanticipated events that result in significant negative impacts on animal health and well-being or animal use not approved by the IACUC must be reported to the IACUC by the principal investigator or their designee. A notification should be submitted within 48 hours of discovering the unexpected finding, adverse event, or noncompliant activity and a preliminary report submitted within one week of the event(s). Preferable notification should be via the [IACUC website form](#), but can also include emailing the IACUC office (iacuc@louisville.edu) or [CMRU veterinary faculty](#).

Additionally, individuals who may have specific concerns about animal care and treatment are strongly encouraged to report their observations of suspected deficiencies to the Institutional Animal Care and Use Committee (IACUC), Comparative Medicine Research Unit (CMRU), Institutional Official (Executive Vice President for Research and Innovation), or the University Integrity and Compliance Office. Individuals generating a report of concern shall not be discriminated against or be subject to any reprisal for generating the report per UofL Policy “[Duty to Report and Non-Retaliation](#).” Individuals who desire anonymity may be certain that the IACUC will handle a report of concern in confidence to the extent permitted by law. Signs alerting personnel to their opportunity to report concerns should be posted in all animal use areas, including laboratories where live animals are used.

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...” Additionally, oversight bodies, including funding sources, may require notification of unexpected findings, adverse events, or noncompliant activities.

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.*

Ethical mores, federal regulations, and accreditation standards dictate that perceived deficiencies and other concerns are investigated thoroughly. The Guide (2011) states, “Safeguarding animal welfare is the responsibility of every individual associated with the Program.” Institutional methods for reporting and investigating animal welfare concerns are mandatory. USDA Regulations place the responsibility for review and investigation with the Institutional Official and IACUC.

Procedures, Guidelines, and Exceptions:

1. Unexpected Outcomes, Adverse Events, or Self-reports of Noncompliance:
 - a. Reporting procedures:
 - i. Principal Investigators and CMRU leadership should provide reports to the IACUC via [the online form](#) or e-mail to the IACUC Service Account (IACUC@louisville.edu).
 - ii. Examples of circumstances that should be reported include (but are not limited to):
 1. Unexpected phenotypes affecting the health and well-being of animals, which may require additional monitoring or intervention (e.g., immunodeficiency, diabetes mellitus, muscle wasting)
 2. Unexpected morbidity or mortality (e.g., surgical complications, reactions to test articles, tumor metastasis, elevated levels of induced disease)
 3. Illness or injury from temporary or prolonged physical restraint
 4. Accidents or errors, equipment failure, or natural disaster leading to significant morbidity or mortality (e.g., water system malfunction, impeded access to food, drug overdose)
 5. Procedures performed that are not approved in an IACUC *Proposal*.
 6. Inappropriate euthanasia techniques and/or failure to confirm euthanasia.
 - iii. 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.
 - b. IACUC response to reports of unexpected outcomes, adverse events, or self-reports of noncompliance:
 - i. 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 and/or personnel in question.
 - ii. 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, DOD/ACURO, VA), 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 and/or personnel in question. IACUC and subcommittee members will remain honor-bound to respect report confidentiality.
 - iii. The IACUC will evaluate whether single incidents over time collectively indicate a more significant concern. This adverse event assessment will ensure that appropriate steps have

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been taken to determine whether the event/concern indicates changes are necessary to minimize further risks, if a single incident may or may not be an indicator of a larger issue and assure that appropriate actions have been taken and that key program personnel and oversight bodies are fully informed.

2. Animal Welfare Concerns:

- a. Reporting procedures:
 - i. Concerns regarding misconduct associated with the care and treatment of animals may be reported verbally or in writing to the IACUC chairperson, any committee member, or a CMRU veterinarian. A current roster of IACUC members may be obtained from the IACUC (502-852-6899).
 - ii. Concerns may also be reported to any of the CMRU management staff, including veterinarians, the facility manager, and facility supervisors or assistant supervisors (502-852-5268/[CMRU CONTACTS](#)).
 - iii. Concerns may also be submitted *anonymously* via the University's third-party Compliance Hotline (877-852-1167) or by using the link to the third-party vendor on their website(<http://louisville.edu/compliance/hotline>). A trained risk specialist will document your information and generate a written report to the University Integrity and Compliance Office for follow-up.
 - iv. Mechanisms for reporting concerns will be posted in prominent locations in the facility, animal procedure locations and applicable website(s) with instructions on how to report the concern and to whom.
 - v. Reports should be as specific as possible. I.e., date, time, species involved, animal/project identification number and the names of the UofL personnel involved, where possible.
- b. IACUC response to reports of animal welfare concerns:
 - i. The receipt of a written or verbal report of animal concern by the IACUC will be immediately brought to the attention of the Associate Vice President for Animal Welfare and/or the IACUC Chairperson, unless a conflict of interest exists. This(ese) individual(s) will select (an) additional committee member(s) to constitute a Subcommittee to investigate and, where concerns are substantiated, recommend the correction of the reported concern. Alternates for these individuals may also be selected such that the investigative subcommittee consists of at least three IACUC members, including one veterinarian.
 - ii. At the next regularly scheduled IACUC meeting, the Subcommittee will describe the reported concern and the corrective action that has been taken or recommended. Reports and corrective actions will conform to all applicable University policies.
 - iii. Items listed in 1.b.ii and 1.b.iii above.