

POLICY ON REPORTING UNANTICIPATED OUTCOMES **IMPACTING ANIMAL WELFARE**

Background:

The University of Missouri – Kansas City (UMKC) Institutional Animal Care and Use Committee (IACUC), in alignment with the policies and procedures of the Office of Laboratory Animal Welfare (OLAW), is committed to ensuring the humane care and proper use of laboratory animals in research. As part of this commitment, the IACUC provides policies and training to inform personnel of the appropriate procedures for reporting unanticipated outcomes that may affect animal well-being.

This policy applies to all persons responsible for conducting research, teaching, training, breeding, and related activities, hereinafter referred to collectively as “activities” involving live vertebrate animals conducted at or under the auspices of UMKC.

Definitions:

Unexpected outcomes are any unanticipated effects resulting from research, teaching, training, breeding, or related activities that are not anticipated or described in the protocol that affect animal welfare.

Policy:

It is the responsibility of the Principal Investigator (PI) to promptly report any unanticipated outcomes that impact animal well-being to the Attending Veterinarian (AV) and Lab Animal Research Core (LARC) Director. An unexpected outcome is not described in the protocol and was not anticipated during the planning of the activities. Failure to report unexpected outcomes may be considered noncompliance.

Examples of unexpected outcomes include, but are not limited to:

- Unanticipated phenotype of genetically modified animals,
- Physical restraint resulting in lesions, illness, or behavioral changes,
- Increased postoperative mortality,
- Increased morbidity or mortality after administration of a hazardous agent,
- Equipment failure resulting in harm or death and
- Unexpected mortality.

Not all unanticipated problems involve direct harm to animals. Unexpected events may increase the risk of harm to animals without directly harming them or may not cause any detectable harm or adverse effect; however, both circumstances represent unanticipated outcomes and must be promptly reported.

Procedures:

In the event of unanticipated death, animals should be preserved by refrigeration as soon as possible to allow for necropsy.

The PI or their designee must notify the AV and LARC Director as soon as an unanticipated outcome is identified or suspected. While the PI has primary responsibility for reporting such concerns, unexpected outcomes should also be reported by LARC staff and other research staff.

Reports should be made to the AV (attendvet@umkc.edu) and the LARC Director (lac@umkc.edu). If the report should indicate:

- The event's severity in the subject line (e.g., Death Notice [Single] – Review Require, Death Notice [Multiple] – Immediate Review Required))
- The PI's name
- IACUC Protocol number
- Species
- Number of animals affected
- The location where the animals are housed

If the PI, LARC staff, LARC Director, or AV deem the event highly concerning, this information will be immediately forwarded to the IACUC Chair and IACUC coordinator for further review.

The AV and the IACUC will work with the researcher to assess the outcome and develop a plan, as needed, for revising the IACUC protocol to ensure the well-being of the animals. In the interval between notification of the unanticipated outcome and the IACUC's decision, the AV will assess the animal's health and consult with the PI to gather relevant information. During this interim period, the AV is authorized to make final decisions regarding care and the humane endpoints for the animal.

Applicable To:

All UMKC faculty, staff, employees, and students involved in the care or use of animals owned by the UMKC.

Revisions to the Policy:

This policy is intended to be flexible and readily adaptable to changes in regulatory requirements. The UMKC IACUC has the authority to amend this policy as needed. The UMKC IACUC has reviewed and approved this policy.