

REPORTING CONCERNS ABOUT ANIMAL CARE AND USE POLICY

Background:

The University of Missouri – Kansas City (UMKC) intends for all aspects of animal care and use in research and teaching to fully comply with applicable Federal animal welfare policies, regulations, and with the standards of the *Guide for the Care and Use of Laboratory Animals*. The UMKC Institutional Animal Care and Use Committee (IACUC) is responsible for oversight of all UMKC animal care and use activities for compliance with Federal mandates and standards, and with protocols and procedures approved by the IACUC for animal care and use. In addition, the University maintains accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), an external peer review process that helps assure adherence to high standards.

The investigation of concerns about animal care and use is an important function of the IACUC in assuring compliance with standards. UMKC and the IACUC encourage reporting of concerns. It is UMKC's policy to prohibit discrimination or reprisal against anyone for reporting violations of standards or deviations from policies or approved protocols and procedures for animal care and use.

Functions of the IACUC specified by the Federal Animal Welfare Act Regulations, 9 CFR Part 2 and Subpart C include:

"Review and, if warranted, investigate concerns involving the care and use of animals at the facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees". In addition, institutions are required to train personnel in the "methods whereby deficiencies in animal care and treatment are reported including deficiencies in animal care and treatment reported by any employee of the facility."

Procedure for Reporting Concerns:

The UMKC IACUC investigates all concerns regarding the care, treatment, and use of animals for research at the university. Reports can be made to the IACUC e-mail, umkciacuc@umkc.edu or to any member of the IACUC or to the Attending Veterinarian, attendvet@umkc.edu.

Report concerns to the following:

UMKC Research Compliance Office
5211 Rockhill Rd.
Kansas City, MO.
umkciacuc@umkc.edu
816-235-5929

UMKC IACUC Anonymous Reporting
[Website Link](#)

Anonymous reports can be submitted through the web address above.

The IACUC would prefer the reports of concerns to be in writing, by either e-mail or memo to ensure accuracy and facilitate investigation. If possible, indicate times, dates, place, and procedures of concern. The more specific information provided, the more effective the IACUC's evaluation.

Initial Evaluation and Actions:

A concern involving the care and use of animals submitted to any IACUC member or the IACUC Coordinator is immediately distributed to the IACUC Chair or the Vice Chair if the Chair is not available or if the Chair is involved with the protocol or animals to which the concern is related. If appropriate to the particular concern, or if the Chair and Vice Chair are both not available, other IACUC members will be notified and charged with acting on behalf of the Chair in implementing this policy. The Chair, or the Vice Chair or other IACUC members acting on behalf of the Chair, will promptly initiate an investigation of the circumstances underlying the concern.

Investigation:

A subcommittee appointed by the Chair, will investigate the circumstances underlying the concern and report findings to the IACUC. It is important to avoid actual or perceived conflicts of interest in this process. The IACUC should charge the subcommittee to gather information and should impose a deadline for reporting to the IACUC. The time allowed will depend on the initial determination of whether immediate action may be required.

If, at any point during the investigation, the health and well-being of animals is an immediate concern, the Attending Veterinarian, or a designee, will be notified and will assess the health status of the animals involved to ensure that animal health and welfare issues are resolved as soon as possible.

The nature and sources of the information required will vary depending on the circumstances, but may involve:

- interviewing complainants (if known), any persons against whom allegations were directed, and pertinent program officials,
- observing the animals and their environment, and
- reviewing any pertinent records, (e.g., animal health records, protocol, and other documents).

The subcommittee investigator(s) should provide a report to the IACUC that summarizes:

- the concern(s) as reported to the IACUC, the results of interviews, the condition of animals and their environment,
- the results of records and other document reviews,
- any supporting documentation such as correspondence, reports, and animal records, conclusions regarding the substance of the concerns *vis-a-vis* requirements of the AWRs, the *PHS Policy*, the *Guide*, and institutional policies, procedures, and protocols, and
- recommended corrective actions and deadlines, if appropriate.

IACUC consideration of the concern and determination of corrective actions:

- The report of the subcommittee investigation should be provided to all IACUC members. The IACUC may vote to accept the recommendations of the investigating

subcommittee, offer further suggestions or comments, or request convened meeting to discuss the concern and/or the report; and

- Any member request for a convened meeting to consider a concern must result in a convened meeting.

Based upon the report of the investigation, the IACUC will determine required actions, if any.

IACUC determinations may include, but are not limited to:

- investigation did not reveal either adverse animal welfare or non-compliance,
- investigation revealed adverse animal welfare or non-compliance, related aspects of the animal care and use program require further review, and
- other related institutional programs may require review.

For any noncompliance with standards accepted by the IACUC, the IACUC must approve corrective actions along with appropriate deadlines and reporting requirements. The IACUC must also determine whether the noncompliance meets the criteria "serious or continuing noncompliance" or "serious deviation" to require reporting to PHS and/or USDA as discussed below.

Notification in Writing:

IACUC Chair will communicate, in writing, the results of the IACUC evaluation of a reported concern to the person(s) responsible for the situation reported, the Institutional Official (IO) and, except in anonymously reported concerns, the person reporting the concern. The communication will contain a summary of the concern, the findings of the investigation, determinations of the IACUC, and the recommended corrective actions/sanctions. The letter will also inform the person(s) responsible for the situation reported of his or her option to appeal the decision by writing the IACUC Chair within 10 days of receipt of this letter detailing the basis of the appeal and requesting a meeting with the IACUC.

Examples of IACUC actions that may be appropriate in response to situations that constitute adverse animal welfare states not approved by the IACUC or non-compliance are:

- terminate IACUC approval of the respective research study,
- suspend IACUC approval of the respective research study pending completion and acceptance by the IACUC of an independent audit of the study and/or the submission, by the principal investigator, of a written plan for the correction and/or prevention of the problem,
- suspend further animal orders for the research study pending completion, and acceptance by the IACUC, of an independent audit of the study and/or the submission of a written plan for the correction and/or *prevention* of the problem,
- institute an IACUC-mandated corrective action plan and independent audit of the study,
- levy a monetary fine that must be paid by the principal investigator and take such other action as the IACUC deems appropriate.

The IACUC is obligated to report, through the IO, to the NIH OLAW, and/or USDA, and/or AAALAC, and/or funding agency if investigation reveals:

- a) any serious or continuing noncompliance with the PHS Policy,
- b) any serious deviation from the provisions of the Guide for the Care and Use of Laboratory Animals or AWA,

- c) any deviation from activities in an IACUC approved protocol, and
- d) any suspension of an activity by the IACUC (PHS Policy, Section IV.F, paragraph 3).

To assist IACUCs in making such judgments, OLAW offers the following examples of occurrences that they have determined meet these reporting criteria:

- a) Serious or continuing noncompliance with the PHS Policy, such as failure to correct situations identified in previous semiannual evaluations as significant deficiencies conducting animal-related activities without appropriate IACUC review and approval failure of animal care and use personnel to adhere to IACUC - reviewed and approved institutional policies and procedures,
- b) Serious deviation from the provisions of the Guide, such as conditions that jeopardize the health or well-being of animals, including accidents, natural disasters and mechanical failures resulting in actual harm or death to animals' shortcomings in programs of veterinary care, occupational health or training, identified during semiannual program review and not corrected within the institutionally determined time frame, and
 - i. NOTE to (a) and (b): SERIOUS NONCOMPLIANCE WITH THE PHS POLICY AND DEVIATIONS FROM THE GUIDE MUST BE REPORTED TO OLAW, EVEN IF IDENTIFIED INITIALLY BY OTHER AGENCIES, SITE VISITORS OR CONSULTANTS.
- c) Suspension of an activity by the IACUC any IACUC intervention that results in the temporary or permanent interruption of an activity involving animals.

The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. If the IACUC decides to suspend or terminate the approval of a research study or to replace the principal investigator, this decision and the reason(s) for this decision will be reported, within one week of the IACUC decision, to the IO, the NIH OLAW, and if applicable the USDA Animal and Plant Health Inspection Service, AAALAC, and any Federal agency funding the study.

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. It is reviewed as part of the semiannual program review to ensure regulatory compliance. The UMKC IACUC has the authority to amend this policy as needed. The UMKC Institutional Animal Care and Use Committee has reviewed and approved this policy.