#### University of California, Merced Institutional Animal Care and Use Committee Policy

## Version No. 2

Policy No. 104

# **Investigating Allegations of Mistreatment or Other Noncompliance Issues**

#### I. Purpose:

Both the Public Health Service Policy on Humane Care and Use of Laboratory Animals and the United States Department of Agriculture Animal Welfare Act require the Institutional Animal Care and Use Committee (IACUC) to review and investigate (if necessary) concerns involving the care and use of animals at the institution. This document describes the review and investigative process.

## II. Definition:

**Mistreatment**: Any action, physical or psychological, which results in wrongful or abusive treatment of an animal.

**Noncompliance**: Violation of University policy or noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (<u>PHS Policy</u>), the USDA Animal Welfare Act Regulations (<u>USDA AWAR</u>), and other applicable federal, state, and local laws or regulations governing animal care and use.

#### **III.** Policy:

It is the policy of UCM IACUC to review and investigate (if necessary) concerns involving the care and use of animals at the institution.

## **IV.** Responsibility:

## A. INITIAL EVALUATION AND ACTIONS

Upon receipt of a reported concern, the IACUC Chair, in consultation with the Attending Veterinarian, shall take immediate steps to ameliorate the problem and protect the animals. Such ameliorative steps may range from veterinary medical intervention, confiscation of the animals, and/or cessation of activities, to taking no action other than the investigation of the concern. In some cases, involvement by the Institutional Official (IO), legal counsel, and other University officials (e.g., Department Chair) may be required at the outset of the investigation.

In every investigation, the person(s) against whom the complaint has been raised shall be given notice of the concern and provided an opportunity to address the allegations in writing. In addition, if the identity of the reporting party is known, an acknowledgment of receipt shall be given, with an assurance that an investigation is underway.

Following the initial investigation, the IACUC Chair shall elect either to bring the matter as a whole immediately before the Committee or appoint a Sub-Committee to investigate the allegation. Information that is needed will be collected, which may entail review of documents, inspection of the facilities, and/or discussions with pertinent individuals.

## **B. IACUC EVALUATION**

Results of the initial evaluation, including all supporting documentation, will be provided to the Committee for consideration at a convened meeting. Based on the information, the IACUC will Revised (6-4-18) Page 1 of 3

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determine 1) the nature of the concern as it relates to the USDA AWAR, PHS Policy, and University policy; 2) the need for additional actions, such as further investigation or notification of other University officials as appropriate; and 3) corrective measures to address the concern and prevent recurrence. In all cases, the person(s) against whom the allegations have been directed will be notified of the IACUC's decisions in writing.

## C. INSTITUTIONAL RESPONSES

Institutional responses are influenced by legal requirements, institutional policy, and the nature of the investigative findings. If the violation is verified by the IACUC, the IACUC is authorized under the USDA AWAR and PHS Policy to suspend a previously approved activity. If the IACUC suspends an activity involving animals, the IO, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to the National Institutes of Health, Office of Laboratory Animal Welfare (OLAW) and, in cases involving USDA-regulated species, to the USDA and any federal agency funding the activity. Reinstatement of an activity may only be authorized by the IACUC and shall be made in writing to the investigator.

If an activity is not suspended but the IACUC determines that the violation constitutes serious or continuing noncompliance, the IACUC, through the IO, shall promptly provide NIH OLAW with a full explanation of the circumstances and actions taken with respect to such cases.

Serious noncompliance may include, but is not limited to, the following:

- Conducting procedures involving animal subjects without prior IACUC approval, including continuing ongoing research activities with animals beyond the expiration date of the protocol
- Switching from a non-survival to a survival surgery without prior IACUC approval
- Increasing the invasiveness of a procedure without prior IACUC approval
- Changing the animal species without prior IACUC approval
- Using additional animals beyond the number specified in the approved protocol
- Conduct of procedures by personnel not adequately trained and/or listed on the approved protocol
- Improper euthanasia techniques, or use of a method of euthanasia not approved for use by the IACUC and/or the *AVMA Guidelines for the Euthanasia of Animals*.
- Maintaining animals beyond the humane endpoints specified in the approved protocol
- Conducting survival surgeries or housing animals in facilities not approved by the IACUC for such use
- Failure to provide anesthesia or analgesia as described in the approved protocol
- Failure to perform adequate post-operative monitoring of animals
- Failure to provide adequate husbandry or veterinary care which seriously affects animals health or welfare

While the USDA AWAR and PHS Policy do not contain specific IACUC-imposed sanctions other than suspension, the IO, in consultation with the IACUC, has the authority to impose additional sanctions on an investigator found to be responsible for mistreatment or noncompliance.

If the identity of the complainant is known, he/she will be notified in writing at completion of the investigation, with an assurance that appropriate remedial action has been taken as applicable.

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## Version No. 2 D. CONFIDENTIALITY

Details pertaining to an investigation in progress remain confidential to the extent possible to protect all concerned; however, when the IACUC releases the final report of its findings to federal regulatory agencies, those reports may become accessible to the public under the Freedom of Information Act.

For information on reporting procedures, please refer to the IACUC Policy on Reporting Allegations of Mistreatment or Other Noncompliance Issues.

## E. STATUTORY AUTHORITY

USDA AWAR §2.31(d)(6) - (7) "The IACUC[3] 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. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to [USDA] APHIS and any Federal agency funding that activity."

PHS Policy IV.C.6-7 "The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or [the PHS Policy requirements for Review of PHS-Conducted or Supported Research Projects]. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW."

• PHS Policy IV.F.3 "The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to: a) any serious or continuing noncompliance with this Policy; b) any serious deviation from the provisions of the *Guide*; or c) any suspension of an activity by the IACUC.

## V. Related Policies:

- Research and Instruction Using Animal Subjects (Policy 100)
- Reporting Allegations of Mistreatment or Other Noncompliance Issues (Policy 103)

## VI. References:

- <u>*The Animal Welfare Act*</u> (Public Law 89-544, amended by Public Law 91-579, Public Law 94-279, and Public Law 99-198)
- Institutional Animal Care and Use Guidebook (OLAW 2<sup>nd</sup> edition)
- Guide for the Care and Use of Laboratory Animals (8<sup>th</sup> Edition)
- PHS Policy on Humane Care and Use of Laboratory Animals
- AVMA Guidelines on the Euthanasia of Animals (2013 Edition)