



University of Michigan Policy on Investigating Noncompliance and Animal Welfare Concerns

Background Information

The University of Michigan's Animal Care and Use Program (ACUP) adheres to the Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals (PHS Policy)*, the federal Animal Welfare Act and Regulations (AWAR), the *Guide for the Care and Use of Laboratory Animals (the Guide)*, and all other applicable standards. Individuals utilizing vertebrate animals under the auspices of the University of Michigan (U-M) must adhere to these standards any time vertebrate animals are used for research, teaching, or testing activities. Violations of these standards have the potential to jeopardize U-M's privilege of using animals in research, teaching, or testing activities.

In accordance with federal policy and law (i.e., PHS *Policy* and AWAR), organizations with ACUPs must establish an Institutional Animal Care and Use Committee (IACUC), and authorize it to oversee the ACUP. The same standards require the IACUC to provide ongoing oversight for animal activities conducted at the institution.

This policy describes the process that the U-M IACUC will follow when investigating reports and allegations of noncompliance or welfare concerns relating to the care and/or use of vertebrate animals.

Definitions

Inquiry is an official period of time used to collect information associated with a report or allegation. It is also used to determine whether an allegation or incident warrants IACUC investigation.

Investigation is the formal IACUC review of information gathered during the inquiry process. It includes the discussion and evaluation of the relevant facts to determine, for example, whether noncompliance occurred. During this process, the IACUC also quantifies the significance of the incident and identifies the appropriate corrective actions to be taken.

Reports are verbal or written notices of concern relating to aspects of the U-M ACUP. The reports may be associated with, for example, animal wellbeing, compliance with federal regulations, and/or program safety.

Serious noncompliance is any noncompliant event that has a negative impact on the welfare of an animal and/or is in direct violation of a federal standard regulating animal activities, including provisions of the Occupational Health and Safety program (Appendix 1).



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Policy

1. Reports:

Individual reports submitted to the IACUC for investigation through, for example, the Attending Veterinarian (AV), the IACUC Chair, or the Animal Care and Use Office (ACUO) are routed to the ACUO where the inquiry is initiated.

2. Inquiry Process:

- a) Upon receipt, a preliminary assessment of each report is immediately completed by ACUO staff. If the report alleges serious noncompliance as defined, a formal inquiry is initiated. For any other reports, the details of the allegation are formalized and reported to the IACUC during the next scheduled meeting as a matter of information.
- b) To initiate the formal inquiry, the details of the report are immediately summarized by ACUO staff and emailed to the IACUC Chair, AV and ACUO Director.
- c) The formal inquiry may include, for example, a series of email communications and/or an emergency teleconference to determine if the health and welfare of any animal is being compromised. The IACUC, through the Chair, the AV and the ACUO Director, will take immediate action to ensure the welfare of any animal associated with the report. If animals are determined to be at risk, Unit for Laboratory Animal Medicine (ULAM) staff (in conjunction with ACUO staff) will immediately resolve issues affecting the welfare of animals, which may include confiscating or removing animals from the control of the principal investigator (PI). Certain situations may also necessitate the AV and/or the Vice President for Research, or designees, to suspend animal activities until an inquiry/investigation is conducted.
- d) During the inquiry, the IACUC Chair, AV and ACUO Director will determine if additional information must be gathered before the IACUC investigation is initiated. A final summary of the relevant information will be prepared through the ACUO and provided to the IACUC to support the investigation process.
- e) The inquiry group (i.e., Chair, AV, and ACUO Director, or their designees) will decide if the PI will be required to attend the IACUC meeting to explain the circumstances and/or discuss possible resolutions to the problem. In addition, the inquiry group may ask others (e.g., faculty, research technicians, animal care staff, and/or students) to attend the meeting to provide information.



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- f) In preparation for the investigation, the ACUO staff will:
 - i. notify the PI of the allegation and the details of the investigation process;
 - ii. provide a copy of the allegation summary to the IACUC members and the PI;
 - iii. notify the PI if he or she will be required to attend the IACUC meeting to discuss the allegation, or if attendance is not mandatory give the PI the opportunity to attend the meeting and participate in the investigation process, which may include providing supplemental written information;
 - iv. provide a copy of the allegation to the PI's Department Chair; and
 - v. upon completion of the inquiry process, the ACUO will file preliminary reports with relevant agencies (e.g., the Office of Laboratory Animal Welfare (OLAW), USDA, AAALAC).
3. Investigation Process (occurs during a convened meeting of a majority of IACUC voting members):
 - a) ACUO staff initiate the investigation by summarizing the allegation and distributing the information to IACUC members in advance of the meeting;
 - b) IACUC members discuss the allegation as a committee;
 - c) If the PI or any others participate, they are then invited to discuss their concerns and answer committee member questions;
 - d) Once the PI and his/her associates depart the meeting, the IACUC deliberates and determines if the allegation is noncompliance and/or a program deficiency (Appendix 1); and
 - e) The IACUC will impose corrective actions as defined in Appendix 2, Corrective Action Escalation.
 - f) Once the investigation is completed, the ACUO will provide formal notification to the PI. The correspondence will summarize the findings of the IACUC and, when applicable, provide IACUC-implemented corrective actions. A copy of the notice will be provided to the Institutional Official (IO) and the PI's Department Chair or Research Dean.
 - g) The IACUC, through the IO, will promptly (i.e., within 30 days) provide a full explanation of the circumstances and actions as a written report to AAALAC, OLAW and, if applicable, the USDA. The report will be prepared by the ACUO.



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Appendix 1: Guidance on Serious (Reportable) Incidents of Noncompliance

Through Notice ([NOT-OD-05-034](#)), *Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals*, OLAW provides the following guidance to institutions on how to determine if an incident requires a formal report to OLAW:

“A comprehensive list of definitive examples of reportable situations is impractical. Therefore, the examples below do not cover all instances but demonstrate the threshold at which OLAW expects to receive a report. Institutions should use rational judgment in determining what situations meet the provisions of IV.F.3 and fall within the scope of the examples below, and consult with OLAW if in doubt.

Examples of reportable situations:

- 1. conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;*
- 2. conduct of animal-related activities without appropriate IACUC review and approval;*
- 3. failure to adhere to IACUC-approved protocols;*
- 4. implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;*
- 5. conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);*
- 6. conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;*
- 7. conduct of official IACUC business during a period of time that the Committee is improperly constituted;*
- 8. failure to correct deficiencies identified during the semiannual evaluation in a timely manner;*
- 9. chronic failure to provide space for animals in accordance with recommendations of the Guide unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification;*
- 10. participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;*
- 11. failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);*



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12. *failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);*
13. *failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂);*
14. *failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance.*

OLAW recognizes that there may be levels of morbidity and mortality in virtually any animal-related activity, including those associated with the care and use of animals in research, testing, and teaching that are not the result of violations of either the Policy or the Guide. OLAW offers the following examples of situations which may not meet the threshold for reporting, based on consideration of the circumstances by the IACUC.

Examples of situations not normally required to be reported:

1. *death of animals that have reached the end of their natural life spans;*
2. *death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;*
3. *animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;*
4. *animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol; or infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, must be reported promptly along with corrective plans and schedules)."*

Appendix 2: Corrective Action Escalation

Ensuring animal welfare and maintaining program compliance is a shared responsibility, and U-M depends on everyone to do his or her part. For example, animal researchers must adhere to their approved protocols, maintain required records, and help to ensure the health and wellbeing of their animals.



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The institution has taken action to minimize or eliminate incidents of noncompliance. U-M will use, for example, a combination of formal notices, training, and when necessary, punitive measures to mitigate incidents of noncompliance with governing standards. Actions taken to minimize occurrences of noncompliance will be based on the seriousness of the incident and/or the number of incidents that occur on all protocols under the direction of a PI.

The following mitigation measures will be employed when incidents of noncompliance are confirmed. Since PIs are ultimately responsible for ensuring their animal activities are conducted in accordance with governing standards and their IACUC approved protocols, the IACUC will direct any relevant correspondence and actions directly to the PI.

1. Single incident of serious noncompliance:

- a) A single incident of serious noncompliance with the PI having no additional serious noncompliant incidents associated with his/her research program over the past 3 years, and that incident having no direct negative impact on animal welfare.

The PI receives a formal notice from the IACUC that identifies the importance of maintaining a compliant research program and the impact incidents of serious noncompliance can have on U-M's overall ACUP.

- b) A single incident of serious noncompliance with the PI having no additional serious noncompliant incidents associated with his/her research program over the past 3 years, and that incident having a direct negative impact on animal welfare.

The PI receives a formal notice from the IACUC that identifies the importance of maintaining a compliant research program and the impact incidents of serious noncompliance can have on U-M's overall ACUP. In addition, the PI is required to provide an action plan to prevent reoccurrences.



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2. Second incident of serious noncompliance:

All individuals listed as animal handlers on the protocol are required to retake the *Orientation to Animal Care and Use* online module within thirty days of the notice. In addition, at least one or more of the following corrective actions will be imposed:

- a) The PI and/or other individuals will prepare a training module that will be presented at an appropriate forum such as an ethics class or town hall meeting, or the training may be included in a newsletter.
- b) Select procedures or an individual's activities on a protocol can only be conducted under the supervision of an IACUC-identified individual (e.g., a veterinarian or an ACUO member).
- c) The PI's research program may be placed on probation, during which the IACUC may mandate "for cause" post-approval monitoring (PAM) visits by ACUO staff members, with the stipulation that any additional serious noncompliant incidents identified during the probation period would result in additional corrective actions.
- d) Requirement for the PI to be physically present for select animal activities (e.g., survival surgery), and for he/she to conduct post-procedure observations and sign the relevant records to ensure he/she is overseeing the animal activities associated with his/her research.
- e) Requirement for the PI to submit scheduled reports to the IACUC on the status of his/her research program.

3. Three or more incidents of noncompliance or failure to satisfy previously imposed corrective actions:

All individuals listed as animal handlers on the protocol are required to retake the *Orientation to Animal Care and Use* online module within thirty days of the notice. In addition, at least one or more of the following corrective actions will be imposed:

- a) An individual's access to the animal facilities is restricted (e.g., loss of access or supervised access only).
- b) Suspension (indefinitely or for a defined time period) of an individual's privilege to conduct animal activities.
- c) The suspension of a procedure within a protocol.
- d) Suspension (for a defined time period) of an approved protocol.



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Resources

Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals*:
<https://grants.nih.gov/grants/olaw/references/phspol.htm>

USDA Animal Welfare Act and Regulations (AWAR):
<https://www.nal.usda.gov/awic/animal-welfare-act>

Guide for the Care and Use of Laboratory Animals (eighth edition):
<http://www.aaalac.org/resources/theguide.cfm>