

IACUC Policy for Handling Issues of Noncompliance

Introduction:

University at Buffalo (UB) Institutional Animal Care and Use Committee (IACUC) ensures that animals used for research, teaching, training, or testing are treated humanely. Research is performed with the highest scientific and ethical standards. UB maintains standards to comply with Federal Law of the United States Department of Agriculture (USDA), the Office of Laboratory Animal Welfare (OLAW), and voluntary accrediting bodies such as the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). All individuals using animals at UB must follow standards set forth by internal policy, accreditation agencies guidelines, and regulatory agencies.

Noncompliance, whether accidental or intentional, occurs when procedures not approved by the IACUC are applied to animals in research or teaching and when there are deviations from the IACUC approved policies. Principal Investigators (PI) are responsible for the actions of those who work under their supervision. Noncompliance can range from minor protocol deviations to a significant infraction. The IACUC is responsible for identifying noncompliance issues and ensuring appropriate corrective actions to prevent recurrences. In compliance with federal requirements, any individual with concerns involving the care and use of animals at UB may have those concerns addressed by the IACUC. Any concerned party may remain anonymous and protected from discrimination and reprisal. Based on OLAW guidelines examples of reportable situations include, but not limited to:

- Conduct of animal-related activities beyond the expiration date established by the IACUC
- Failure to correct deficiencies identified during the semiannual inspection in a timely manner
- Conducting animal-related activities without appropriate IACUC review and approval
- Failure to adhere to IACUC approved protocols
- Participation in animal-related activities by an individual(s) who are not listed on the approved protocol and have not been determined by the IACUC to be appropriately qualified and trained
- Failure to monitor animals post procedurally as outlined in the protocol
- Any condition that jeopardizes the health or well-being of an animal(s)
- Failure to ensure the death of an animal after euthanasia procedures
- Failure to follow safety procedures such that personnel are unknowingly exposed to hazards (e.g., hazards chemicals, radioactivity, and biohazards)

Definitions:

Serious noncompliance: Any non-compliant event that has a demonstrated or potentially severe negative impact on the welfare of the animal(s) and/or is in direct violation of a federal standard regulating animal activities. Serious noncompliance issues will require reporting to federal agencies and accreditation bodies.

Minor noncompliance: Any noncompliant event where policy has been violated, but there is no immediate impact to the animal(s). Examples may include incidental or unintentional breaks in aseptic technique, delayed submission of animal records, or cleanliness issues that are easily addressed.

Continuing noncompliance: Repeated episodes of noncompliance (serious or minor) involving the same PI. Continuing noncompliance issues may require reporting to federal agencies and accreditation bodies. The committee will consider all noncompliance events over a 3 year period when evaluating the PI's protocol *de novo* (triennial review).

Corrective Action: Remediation steps proposed by the IACUC committee or by a PI describing how the lab will resolve noncompliance concerns and prevent the issue from recurring.

Adverse Outcome: An unforeseen clinical outcome during a research study reported to the IACUC by the veterinary staff but is not treated as a noncompliance concern (unless it is determined that a noncompliance event was directly involved in the adverse event outcome). The veterinary staff and investigators work together to resolve adverse outcomes concerns.

Post-Approval Monitoring (PAM): A visit with the PAM Officer to review the protocol and observe ongoing procedures in a laboratory. The goal is to prevent noncompliance and protocol drift from occurring. Visits can be random, unannounced, or scheduled.

Reporting Noncompliance:

Self-reporting is encouraged. Allowing the PI to self-identify areas of potential noncompliance, develop a plan to remedy the issue, and implement self-corrective measures taken to prevent a recurrence. Noncompliance can also be reported to the IACUC Chair or the IACUC Administrative Office. "Mechanism for Reporting Issue of Noncompliance or Misuse of Animals" is posted at every Animal Facility.

Procedures:

1. Submission of a noncompliance or animal welfare Noncompliance concern.
2. In response to the possible noncompliance or animal welfare concern, the IACUC Chair will assess the concern and determine if circumstances merit a full investigation.
3. During the initial appraisal, the IACUC Chair will consider a consultation with the Attending Veterinarian (AV) or designee regarding the nature and extent of the concern and whether the issue presents a potential immediate animal health or welfare risk.
 - a. In the event that there is an urgent safety or welfare concern identified, the AV or designee will assess the concern and has the authority delegated by the Institutional Official (IO) and the IACUC to assess and treat the animal(s), remove the animal(s) for the experiment, institute appropriate measures to relieve pain or distress or perform euthanasia if necessary.
4. Within two business days, the IACUC Chair will decide the best course of action based on the information obtained from the initial submission. This may include one or more of the following:
 - a. Dismissal of the allegation (unsubstantiated)
 - b. Referral to the appropriate university process
 - c. Immediate corrective action required (implemented by the AV and/or IACUC Chair)
 - d. Review at a convened IACUC meeting

- e. Further investigation required by the PAM Officer
- 5. The PI will be informed of any recommended actions based on the inquiry findings.

IACUC Investigation Processes:

1. Prior to the next IACUC meeting, information regarding the noncompliance or animal welfare concern will be distributed to the IACUC committee. Committee members will review the provided information and associated protocol. The PI may be invited to join the meeting if they wish to provide information relevant to the IACUC review of the issue. The IACUC may discuss the incident with the PI during this time, but any deliberations regarding the incident by the IACUC will only occur in the absence of the PI.
2. Following IACUC deliberations, members may vote on the following outcomes:
 - a. Is the concern a noncompliance or animal welfare concern (Yes/No)?
 - i. Further information is required to vote on the issue (tabled until the next meet, more information needs to be gathered)
 1. A subcommittee of IACUC members or PAM Officer may gather additional information.
 - ii. If the committee votes no, no further action is needed.
 - iii. If the committee votes yes, the committee will deliberate and determine if the issue is a serious or minor noncompliance/ animal welfare concern or continuing noncompliance.
 - iv. Based on the severity of the noncompliance, the committee will determine if a report must be sent to regulatory and accrediting agencies.
 - v. Has the issue been satisfactorily resolved? If not, what corrective actions will be required of the PI?
3. Once the investigation is complete, the IACUC Administrative Office will provide the PI with a formal written notification regarding the IACUC's decisions.
4. If applicable, the IACUC Administrative Office will draft official correspondence(s) to regulatory and accrediting agencies. The correspondence(s) will be sent to the Vice President's office and directly to the IO for distribution.

Submission of reports to OLAW and USDA as a result of a noncompliance:

If it has been determined that there was or is a serious or continuing noncompliance with PHS policy, any serious deviations from the provisions of *the Guide*, or any suspension of activity by the IACUC; or animal welfare concern, a final report will be submitted to OLAW. If a USDA regulated species was part of the noncompliance or animal welfare concern a report will also be sent to USDA within 15 days of the committee's determination.

Examples of Corrective/ Disciplinary Actions after Determination of Noncompliance:

1. Minor violations: Noncompliance violations that are not the result of willful intent and do not pose an immediate threat to animal health or welfare or violate Federal regulations may be resolved administratively. However, continuing minor noncompliance events from an individual may be reclassified as major noncompliance.

2. Serious noncompliance violations: The IACUC may mandate remedial corrective actions. Such corrective actions may include, but are not limited to:
 - a. Requiring specific training or retraining of individuals involved in noncompliance or animal welfare incidents.
 - b. Additional monitoring by the IACUC of the animal related activities or regulations that pertain to the violation.
 - c. Regular updates on the status of the corrective action plan.
 - d. Requiring submission and approval of an IACUC protocol or modification to an already approved IACUC protocol prior to continuing the research for which the noncompliance was reported.
 - e. Restricting or limiting the scope of activities the individual(s) may engage.
 - f. Suspension of PI's privileges to continue animal research
 - g. Suspension of an approved protocol or a specific procedure defined in the protocol for a definite or indefinite period
 - i. Suspensions must be reviewed with the IO.
 - ii. Appropriate corrective action taken is reported to OLAW, USDA (APHIS) and any Federal Agency finding the activity, and the Chair of the PI's Department.
 - h. A probationary period during which IACUC may arrange for unannounced visits to PI's laboratory