

IACUC Policy for Handling Protocol Noncompliance

Introduction:

The University at Buffalo (UB) Institutional Animal Care and Use Committee (IACUC) ensures that animals used for research, teaching, training, or testing are treated humanely. Animal research and teaching protocols are approved in accordance with the ethical standards, laws, regulations and accreditation standards pertaining to animal research which include the:

- Animal Welfare Act (enforced by the United States Department of Agriculture, USDA),
- Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals/Health Research Extension Act of 1985 (through which PHS-funded animal activities are overseen by NIH's Office of Laboratory Animal Welfare, OLAW),
- U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training,
- New York State Department of Health (NYS DOH)
- Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC).

Noncompliance, whether accidental or intentional, can occur when an IACUC protocol, policies, procedures, or decisions are not followed. Principal Investigators (PIs) are responsible for the actions of those who work under their supervision. Noncompliance can range from minor protocol deviations to a significant infraction impacting animal welfare. 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 noncompliance include, but are not limited to:

- Conduct of animal-related activities beyond the protocol's expiration date.
- 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.
- 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).

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Definitions:

Serious noncompliance: Any noncompliance event that has a demonstrated or potentially severe negative impact on animal or human welfare and/or is a serious deviation from The Guide. This includes conduct of any activity that is not approved by the IACUC. Procedures being performed must be attached to an experiment in an active approved protocol.

Minor noncompliance: Any noncompliance event where the protocol 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. - The committee will consider all noncompliance events over a 3-year period when evaluating the PI's protocol *de novo* (triennial review).

Corrective and Preventive Action (CAPA): 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.

Post-Approval Monitoring (PAM): A visit from the PAM Liaison to review the protocol and observe ongoing procedures in a laboratory may be scheduled. The goal is to prevent noncompliance and protocol drift from occurring.

Reporting Noncompliance to the IACUC:

Self-reporting of noncompliance by PIs is encouraged, though anyone may report noncompliance. Self-reporting allows the PI to explain the incident and describe their corrective and preventive action plan to remedy the issue and prevent a recurrence. IACUC's document, "Mechanism for Reporting Noncompliance or Misuse of Animals" is posted at every animal facility to provide directions and contact information.

No individual will be discriminated against or subject to any reprisal for reporting a concern or animal protocol violation. The reporter's anonymity will be protected when reporting an animal welfare concern or noncompliance. However, providing contact information will allow the IACUC to follow up with the reporter.

Reporting Procedures:

1. Submission of a noncompliance concern:
 - a. If an emergency exists:
 - i. The Director of the Laboratory Animal Facilities should be contacted immediately by calling (716) 829-2919 (LAF Administrative Offices) or

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- (716) 803-5985 (cell phone). The Director will then take any necessary action and report the incident to the IACUC Chair.
- ii. If the Director is unavailable, please contact a Clinical Veterinarian to act in their place by calling the LAF Admin. Offices or (716) 536-4933 or (716) 339-5387 (cell phones).
- b. If the situation is not an emergency, the concern or complaint can be submitted with anonymity to the IACUC Office:
 - i. Via Mail: UB-IACUC Office, 1021 Main St., Room 106, Buffalo, NY, 14203
 - ii. Via Phone: (716) 829-3977
 - iii. Via Email: iacuc@research.buffalo.edu
 - c. Other methods of reporting situations that are not emergencies include:
 - i. Contacting the Institutional Official (IO): (716) 645-1019
 - ii. Contacting the IACUC Chair: (716) 829-3827
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. This initial appraisal is made in consultation with the Attending Veterinarian (AV) or a Clinical Veterinarian to determine potential animal health or welfare risks.
 - a. If there is an urgent animal 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) from the experiment, institute appropriate measures to relieve pain or distress or perform euthanasia if necessary.
 3. 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 and preventive 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
 4. The PI will be informed of any recommended actions based on the inquiry findings.

IACUC Investigation Process for Reported Noncompliance:

1. Prior to the next IACUC meeting, information regarding the noncompliance or animal welfare concern will be distributed to the IACUC members. Committee members will

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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 will vote to determine whether the incident was a noncompliance. Outcomes of voting include:
 - a. Defer voting until a subsequent meeting to allow more information to be gathered. A subcommittee of IACUC members and/or the PAM Liaison may gather this information.
 - b. Incident is NOT noncompliance. No further action is needed.
 - c. Incident IS noncompliance. Follow subsequent voting decisions:
 - i. Vote to decide if the noncompliance is serious or minor.
 - ii. Review historical data to vote to classify this as a continuing noncompliance (versus initial event).
 - iii. This policy will be used to determine to which agencies the noncompliance must be reported.
 - iv. Vote to decide if the issue has been satisfactorily resolved. If not, determine the required CAPA by the PI (and vote to finalize the actions required).
3. Once the investigation is complete, the IACUC Administrative Office will provide the PI with a formal written notification regarding the IACUC's decisions. If applicable, the IACUC Administrative Office will draft official correspondence(s) to regulatory and accrediting agencies. All correspondence will be sent to the IO for final review and distribution to these agencies.

Reporting Noncompliance to Outside Agencies:

There are four main agencies to which noncompliance reporting may be required.

- 1) **Office of Laboratory Animal Welfare (OLAW)**
 - a) Reporting is required for **PHS-funded animal activities**. This includes animal activities funded through: NIH, NSF, NASA, DOD and VA.
 - b) Reporting is also required if noncompliance involves functional, programmatic, or physical areas that could affect animal studies funded by these agencies.
 - c) Reporting to OLAW is required for these types of noncompliance:
 - i) **Serious** or **Continuing** Noncompliance with PHS Policy
 - ii) **Serious** deviation from The Guide.
 - iii) **Suspension** of an activity by the IACUC
 - d) A prompt preliminary report may be made via phone, fax or email.
 - e) A final written report should be submitted by the IO to include:
 - i) Animal Welfare Assurance number (D16-00231)

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- ii) Relevant grant/contract number of funded activity if directly funded by PHS
- iii) Description of potential/actual effect to PHS supported activities
- iv) Full description of situation:
 - What happened
 - When/where it happened
 - Species/number of animals
 - Category of individual personnel involved
 - Actions taken to address the situation
 - Corrective and preventive action (CAPA) plans for the future

2) United States Department of Agriculture (USDA)

- a) Reporting is only required if animal activities involve species covered by the Animal Welfare Act (hamster, rabbit, pig, sheep, dog, chinchilla, ferret, etc.)
- b) Reporting to USDA is required for these types of noncompliance:
 - i) **Suspension** of a protocol by the IACUC
 - ii) Noncompliance involves the **failure to adhere to a plan to correct a significant deficiency**.
- c) Note: OLAW has an MOU with USDA. Noncompliance events reported to OLAW will be shared with USDA.

3) Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC)

- a) Reporting to AAALAC is required for these types of noncompliance:
 - i) Noncompliance **had the potential to compromise animal welfare**
 - ii) Noncompliance had an impact on **human welfare (safety)**
 - iii) Animal use was **not approved** by the IACUC
- b) Reports may be made using the online Adverse Event Report available through the Unit Login.

4) Department of Defense (DOD)

- a) Reporting to DOD's Animal Care and Use Resource Office (ACURO) is required for **DOD-funded animal activities**.
- b) All noncompliance must be reported to ACURO within 5 business days. See IACUC's Policy on DOD Funded Protocols for further information.

Examples of Corrective/ Disciplinary Actions after Determination of Noncompliance:

1. Minor noncompliance that neither poses an immediate threat to animal welfare nor violates federal regulations may be resolved administratively. However, continuing minor noncompliance events from an individual may be reclassified as major noncompliance.

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2. Serious noncompliance: 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 noncompliant animal activity.
 - c. Requests for regular updates on the status of the CAPA.
 - 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 with which an individual may participate.
 - 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 when outside agency reporting is required.
 - h. A probationary period during which IACUC may arrange for unannounced visits to a PI's laboratory.

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