

## Institutional Animal Care and Use Committee

### Managing Reports of Animal Welfare or Noncompliance Concerns

#### **Purpose:**

The Institutional Animal Care and Use Committee (IACUC) administers the vertebrate animal care and use program and facilities at Central Washington University (CWU). To ensure ethical and humane treatment of all live vertebrate animals, the IACUC oversees all policies and procedures involving animal welfare and approves all protocols for the use of live vertebrate animals in research and teaching. This document establishes guidelines to address instances of regulatory or policy noncompliance by individuals engaged in the care or use of animals used for research or teaching. This policy is intended to address compliance issues that may require action based on the determination of the IACUC and in some instances, the Institutional Official (IO).

#### **I. Policy**

- A. Research and Activity Requiring IACUC Oversight
  - 1. Federal laws and regulations require that all research, teaching, training, or testing involving live vertebrate animals have oversight by the IACUC at CWU.
  - 2. These animal-related activities are subject to oversight by the United States Department of Agriculture (USDA) and the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) and must meet the standards set forth by the *USDA Animal Welfare Act and Animal Welfare Regulations* and the *NIH Guide for the Care and Use of Laboratory Animals*.
  
- B. Reporting Suspected Noncompliance
  - 1. CWU is committed to the ethical and compliant care and use of animals in research, teaching, and testing.
  - 2. If anyone is aware of potential violations to existing animal care and use regulations or observes misuse or mistreatment of animals, they are strongly encouraged to report their concerns.
  - 3. Concerns may be reported to those responsible for animal care and use, to IACUC, or anonymously. Visit the following website for further reporting information: <http://www.cwu.edu/iacuc/report-animal-care-or-use-concern>.
  - 4. The phone numbers of all IACUC members, including the IACUC Chair, Attending Veterinarian, and Institutional Official are posted in areas where animal activities occur.
  - 5. All concerns will be treated as suspected noncompliance when initially reported, treated as confidential to protect all parties involved, and will be investigated promptly by IACUC.
  - 6. CWU will not tolerate retaliation against individuals who report suspected noncompliance violations in good faith.

C. Examples of Noncompliance

1. Noncompliance with university policies or federal regulations can be classified as major or minor.
2. Major noncompliance is the result of willful or repeated activities (intentional) in breach of federal, state, or university animal welfare regulations or policies, or violations that pose a real or potential threat to the health and welfare of animals.  
Examples of major noncompliance (this list is representative, not exhaustive):
  - a. Conducting animal-related activities that pose a real or potential threat to health and welfare of animals without appropriate IACUC review and approval.
  - b. Implementation of any significant change to an IACUC-approved protocol that poses a real or potential threat to health and welfare of animals without prior IACUC approval.
  - c. Performing a procedure in such a manner that animals endure distress, pain, or suffering that is not addressed in the approved protocol.
  - d. Breeding animals without IACUC approval.
  - e. Failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO<sub>2</sub>).
  - f. Not following aseptic technique as described in the protocol when performing survival surgery.
  - g. 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).
  - h. Extreme cage overcrowding.
  - i. Not administering analgesics as required in the approved IACUC protocol.
  - j. Not following safety procedures such that personnel are unknowingly exposed to hazards (e.g., dangerous chemicals, radioactivity, biohazards).
  - k. Failing to adhere with veterinary-mandated instructions (e.g., treatments).
  - l. Conducting animal-related activities beyond the expiration date established by the IACUC.
  - m. Exceeding the number of animals approved on the study, where the protocol entails real or potential threat to the animals.
3. Minor noncompliance includes instances of honest error (unintentional) that do not pose a threat to the health or welfare of animals.

Examples of minor noncompliance (this list is representative, not exhaustive):

- a. Conducting animal-related activities that do not pose a real or potential threat to the health and welfare of the animals, but without appropriate IACUC review and approval.
- b. Implementation of a change to an IACUC-approved protocol that does not pose a real or potential threat to the health and welfare of the animals without prior IACUC approval.
- c. Failure to respond to IACUC designated deadlines (e.g., annual renewal of multi-year protocol, annual renewal of medical clearance, renewal of CITI training).
- d. Housing animals in a laboratory or the vivarium without IACUC approval.
- e. Allowing new personnel to work with animals before they are qualified and

- trained.
- f. Insufficient records of monitoring animals (disease condition, survival surgery, post procedure care).
- g. Insufficient daily recording of animal care (e.g., feeding, bedding changes, health check).
- h. Personnel ignorant of IACUC-approved protocol content.
- i. Performing an unapproved procedure without causing pain or distress.
- j. Controlled substances not secured properly, or dispensing logs not kept.
- k. Improperly labeled bottles or secondary containers.
- l. Relocating animals from a laboratory without properly notifying the IACUC, or research conducted in areas not approved on the protocol.
- m. Improper waste disposal practices.
- n. Exceeding the number of animals approved on the study (e.g., breeding colonies).
- o. Cage cards that fail to identify IACUC protocol number, species, and any dangers or risks to people or to animals posed by the caged animals (e.g., rattlesnakes not labeled).
- p. For animals who are part of on-going experiments, cage cards lacking adequate information (e.g., date of surgery, chemical administration, tumor inoculation).
- q. Failure to maintain cleanliness, hygiene and upkeep of lab or vivarium space where animal work is done.
- r. Failure to follow established IACUC policy.

## **II. Procedures**

### **A. Initial Appraisal of Noncompliance Reports**

1. In response to internal tips or possible concerns, the IACUC Chair and IACUC Program Coordinator will immediately conduct an initial appraisal to determine if circumstances merit a full investigation.
2. The initial appraisal will consider in consultation with the Attending Veterinarian the nature and extent of the concern, whether the issue presents a potential immediate animal health or welfare risk, and if the concern involves noncompliance with university policy or federal regulations.
3. Formal allegations or concerns submitted anonymously will automatically receive a full investigation.
4. At this initial appraisal stage, the IACUC Chair will determine if a preliminary report must be submitted to the NIH Office of Laboratory Animal Welfare (OLAW). Reportable situations and guidance for the preliminary report are available at <https://olaw.nih.gov/guidance/reporting-noncompliance.htm>

### **B. Full Investigation of Noncompliance Reports**

1. The involved individual(s) will be informed of the suspected noncompliance investigation that is being conducted.
2. If the IACUC Chair concludes that the noncompliance merits a full evaluation, the

IACUC, at a convened meeting with quorum, will determine the appropriate course of the investigation. This may include formation of subcommittee and/or interviews with involved individual(s).

3. When the investigation deems that noncompliance with university policies or federal regulations has occurred, or that there is a past, present, or future threat to the health and well-being of animals, a noncompliance incident report will be filed with the IACUC office and provided to the Institutional Official. The report shall include:
  - a. A description of the noncompliance violation and whether the violation resulted in any adverse events, if known.
  - b. A summary of the records and evidence reviewed during the investigation.
  - c. Identification of university policies or federal violations under which noncompliance occurred.
  - d. Corrective actions (D below) that should be implemented to avoid noncompliance in the future and a timeline by which the corrective actions will be implemented.
  - e. A description of mandated noncompliance reporting to be submitted to federal entities (OLAW, USDA).

C. Formal Determination of Noncompliance

1. When determination that a violation of university policy or federal regulation has occurred, the IACUC Chair will formally notify the involved individual(s) in writing of the noncompliance violation and corrective actions.
2. In cases where the noncompliance is ongoing and presents risk to the health or well-being of the animal(s), the IACUC can suspend the research or teaching activity.
3. If corrective actions are required, a timeline will be established in which the individual(s) must implement corrective actions.
4. The individual(s) will have the opportunity to request, in writing, to modify the corrective actions. Such requests require approval of the IACUC during a convened meeting.
5. In addition to the IACUC and the Institutional Official, the Provost, Department Chair, College Dean, Research and Sponsored Programs (if externally funded), and Grant/Contract Accounting (if externally funded) may be notified of the noncompliance violation.

D. Examples of Corrective/Disciplinary Actions After Determination of Noncompliance

1. Most minor noncompliance violations that are not a result of willful intent and that do not pose a threat to animal health or welfare or violate federal regulations can be resolved administratively. However, continuing minor noncompliance events from an individual may be reclassified as major noncompliance.
2. For major 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 the individuals involved in the proper care and use of animals.

- b. Additional monitoring by the IACUC of the animal-related activities or regulations that pertain to the noncompliance violation.
  - c. Regular updates on the status of the corrective action plan.
  - d. Requiring submission and approval of an IACUC protocol or a modification to an already approved IACUC protocol prior to continuation of the research for which noncompliance was reported.
  - e. Restricting or limiting the scope of activities in which the individual(s) may engage.
  - f. Suspending approval of an IACUC protocol.
- E. Submission of reports to OLAW and USDA as a result of noncompliance
- 1. If it has been determined through the full investigation that there were or was serious or continuing noncompliance with *PHS policy*; any serious deviations from the provisions of *the Guide*; or any suspension of an activity by the IACUC, a final report will be submitted to OLAW. Guidance for the final report is available at <https://olaw.nih.gov/guidance/reporting-noncompliance.htm>
  - 2. If it has been determined through the full investigation that there were USDA regulated species and there was suspension of an activity by the IACUC, a report will be submitted to the USDA. Guidance for the USDA report is available at <https://www.nal.usda.gov/awic-faq-categories/protocol-noncompliance>