

IACUC Policy #:	110
Policy Title:	<i>Managing Reports of Animal Welfare or Noncompliance Concerns</i>
Date Approved:	November 20, 2017
Date Reviewed:	

Purpose:

The Institutional Animal Care and Use Committee (IACUC) administers the vertebrate animal care and use program and facilities at Southern Illinois University Carbondale. To ensure ethical and humane treatment of all vertebrate animals, the IACUC oversees all policies and procedures involving animal welfare and approves all protocols for the use of vertebrate animals in research, teaching, and testing. This policy establishes guidelines to address instances of regulatory or policy noncompliance by individuals engaged in the care or use of animals used for research, testing, training, or teaching. This policy is intended to address compliance issues that in the determination of the IACUC and in some instances, the Institutional Official (IO), go beyond a minor oversight.

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 SIUC.
 - 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. SIUC 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. Members of the university community are encouraged to report their concerns through normal lines of communication. Concerns may be reported anonymously to members of the IACUC or through its web-based form found at iacuc.siu.edu.
 - 4. The phone numbers of all IACUC members, including the IACUC Chair and Attending Veterinarian 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.
 6. SIUC 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 serious or moderate.
 2. Serious violations are the result of willful or repeated activities 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.
 3. Moderate violations include instances of honest error that do not pose a threat to the health or welfare of animals.
 4. Examples of violations include:
 - a. Conduct animal-related activities without appropriate IACUC review and approval;
 - b. Conditions that jeopardize the health or welfare of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
 - c. Failure to adhere to the standards set forth by the *USDA Animal Welfare Act and Animal Welfare Regulation* and the *NIH Guide for the Care and Use of Laboratory Animals*.

II. Procedures

- A. Evaluation of Noncompliance Reports
1. In response to internal tips or possible concerns, the SIUC IACUC Chair, Attending Veterinarian and Research Compliance Coordinator will immediately conduct an initial appraisal to determine if circumstances merit a full evaluation.
 2. The initial appraisal will consider 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 left anonymously will automatically receive a full evaluation.
 4. At this initial stage, the SIUC IACUC Chair will determine if a preliminary report must be filed to the Office of Laboratory Animal Welfare.

B. Investigation of Suspected Noncompliance

1. The involved individual(s) will be informed of the noncompliance investigation that is being conducted.
2. If the IACUC Chair concludes that the noncompliance merits a full investigation, the IACUC, at a convened meeting, will determine the appropriate course of the investigation. This may include formation of subcommittee and/or interviews with involved individual(s).
3. When the evaluation deems that noncompliance has occurred with university policies or federal regulations, or that there is a past, present, or future threat to the health and well-being of animals, the 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 that should be implemented to avoid noncompliance in the future and an appropriate date by which the corrective actions will be implemented.
 - e. A description of reporting requirement, such as OLAW, USDA, and AAALAC

C. Formal Determination of Noncompliance

1. When determination that a violation of university policy or federal regulation has occurred, the IACUC Chair will 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 activity. If corrective actions are required, a timeline will be established in which the individual(s) must implement corrective actions.
3. The individual(s) will have the opportunity to request, in writing, to modify the corrective actions. Such request require approval of the IACUC during a convened meeting. The Provost, Department Chair, College Dean, and the Office of Sponsored Programs may be notified of the noncompliance violation.

- D. Examples of Corrective Actions After Determination of Noncompliance
1. Most moderate 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.
 2. For 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 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. 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;
 - d. Restricting or limiting the scope of activities in which the individual(s) may engage;
 - e. Suspending approval or terminating an approved IACUC protocol.
- E. If any animal-related noncompliance is identified associated with an activity supported by the Public Health Service (PHS), the IACUC, through the IO, must promptly notify OLAW and the PHS funding agency, per PHS Policy, IV.F.3. Reporting guidelines can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>.