

Clemson University
Institutional Animal Care and Use Committee (IACUC)

Policy Number: 1.7

Policy Title: Addressing Non-Compliance with IACUC Policies or Procedures

Section 1: Purpose

Deviation from approved AUPs, policy or procedures may occur inadvertently or intentionally (such as in emergency situations). The following policy was developed to provide guidance for reporting and addressing non-compliance with applicable policies or procedures.

Section 2: Scope

This policy applies to situations occurring within the University's animal care and use program where suspected non-compliance with applicable policies and regulations (federal, state, local, or University) is reported.

Section 3: Policy

Non-compliance

Non-compliance with animal use regulations and policies, whether accidental or intentional, occur when procedures not approved by the IACUC are performed using animals overseen by the IACUC. Non-compliance ranges from minor protocol deviations (e.g., failure to notify IACUC of new personnel, minor changes in drug administration or sampling frequency, etc.) to serious animal welfare or human safety concerns (e.g., unapproved animal procedures that result in animal death or disease, failure to follow safety procedures, etc.).

Reporting requirements (Internal to the animal program)

The Principal Investigator (PI) is responsible for ensuring that reporting of non-compliance is prompt and complete. Other research personnel, facility managers or animal care personnel may also report information to the IACUC pertaining to non-compliance.

Non-compliance events should be reported to the Attending Veterinarian (AV), the IACUC Administrator, the IACUC Chair or the Director of Research Compliance either in writing or orally. Reports should include:

- The protocol(s) affected by the non-compliance
- A detailed description of the event
- A description of observed impacts to animals.

Non-compliance immediately affecting animal welfare

Any animal welfare issues should immediately be reported to the Attending Veterinarian. The AV has the authority to suspend the activity and treat animals, remove them from an experiment, institute appropriate measures to relieve pain or distress, or perform euthanasia if necessary.

Procedure

1. Following a report of possible non-compliance, a preliminary inquiry will be initiated by the Office of Research Compliance (ORC), the University (Attending) Veterinarian (AV), and/or the IACUC Chair. This inquiry may include an animal facility inspection, interviews with the PI, students, or staff, and/or identification of funding sources or other resources.
 - a. If an urgent animal safety or welfare concern is identified during the preliminary inquiry, the AV, or his/her designee, will expeditiously assess the concern. The AV has the authority delegated by the IO & the IACUC to assess animals, treat animals, remove them from an experiment, institute appropriate measures to relieve pain or distress, or perform euthanasia if necessary.
 - b. If an urgent human safety concern is identified in the preliminary inquiry, the ORC will notify appropriate safety personnel to mitigate risk and address the situation.
2. Findings of the preliminary inquiry will be discussed with the PI. The PI's response will be considered.
3. The IACUC chair, ORC, and AV will review the preliminary inquiry and determine if a non-compliance exists.
 - a. If it is determined that non-compliance has not occurred, the PI will be notified and no further actions will be taken.
 - b. If non-compliance is identified, the IACUC will determine actions required to address the issue and prevent future non-compliance. Actions may include but are not limited to the following:
 - Mandating training
 - Amending animal care and use protocols or standard operating procedures
 - Enhanced monitoring of records and/or procedures
 - Mentoring
 - Increased frequency of de novo protocol review
 - Protocol knowledge assessment (e.g. written or verbal test)
 - Suspension or termination of AUP
 - Suspension or termination of animal research privileges
4. The PI will be informed of required corrective actions by the IACUC. The PI is responsible for addressing these actions and reporting progress to the IACUC.
5. After the PI reports that all corrective actions are complete, the IACUC will determine if the issue has been fully addressed or if further investigation/corrective action is warranted.
 - a. If further investigation is necessary, the IACUC will determine the course of action on a case by case basis. Decisions will be reported to the PI by the IACUC Chair.
 - b. If all requirements have been met to the satisfaction of the IACUC and no further investigation is needed, the PI is informed and no further action is taken.

Repeated Non-Compliance

Repeated non-compliance will be reviewed on a case-by-case basis. Corrective actions required by the IACUC to address repeated non-compliance will escalate in severity and may result in the temporary or long-term loss of animal research and teaching privileges.

Reporting Requirements (External to the animal program)

At any point during the evaluation of a reported non-compliance, the IACUC/AV/ORC may report or may be required to and will report the event to relevant University offices, regulatory oversight agencies (OLAW and/or USDA), AAALAC International, and/or funding sources.

Research Misconduct

If the reported non-compliance involves fabrication or falsification of research data or an accusation of plagiarism, the incident will be reported to the Research Integrity Officer as an allegation of Research Misconduct.

Section 4: References

<https://media.clemson.edu/administration/compliance/whistleblowerpolicy.pdf>

Guide for the Care and Use of Laboratory Animals, Eighth Edition

AAALAC International reporting requirements, issued June 14, 2022

Animal Welfare Act Regulations, 9 CFR 2.31

IACUC Policy 1.5, Reporting and Investigating Animal Concerns

Non-Compliance Assessment Flow Chart

