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

The following policy was developed to provide guidance for 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 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.).

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.

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

Repeted 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.
Non-Compliance Assessment Flow Chart

Suspected Non-Compliance is Reported

A preliminary inquiry is conducted by the IACUC Chair/AV/ORC

*If an urgent animal safety or welfare concern is identified, the AV, or his/her designee, will assess the concern and act as necessary to protect animal safety and wellbeing.

*If an urgent human safety concern is identified, the ORC will notify appropriate safety personnel to mitigate risk and address the situation.

Findings are discussed with the PI. The PI is given the opportunity to respond and provide clarification.

The IACUC Chair/AV/ORC will determine if a non-compliance occurred.

- Non-compliance did not occur
- Evidence of non-compliance

The PI is notified of the findings and no further actions are taken.

The event is presented to the IACUC and the Committee determines corrective actions.

The PI is informed of required corrective actions. The PI is responsible for addressing these actions and reporting progress to the IACUC.

The PI reports to the IACUC that all corrective actions are complete.

The IACUC will determine if the issue has been fully addressed or if further investigation is warranted.

- Issue Adequately Addressed
- Further Investigation Needed

The PI is notified and no further actions are taken.

the IACUC will determine the course of action on a case by case basis. The PI is notified of the decision.

*At any point during the process of evaluating a reported non-compliance, the funding agencies, I/O, department heads/chairs, or other administrative/regulatory bodies may be informed of the event and actions being taken to address the issue.