Clemson University
Institutional Animal Care and Use Committee (IACUC)

Policy Number: 1.7

Policy Title: Addressing Noncompliance 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 noncompliance 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 noncompliance with applicable policies and regulations (federal, state, local, or University) is reported.

Section 3: Policy

Noncompliance
Noncompliance 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. Noncompliance 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.).

Initial Reporting requirements (Internal to the animal program)
The Principal Investigator (PI) is responsible for ensuring that reporting of noncompliance is prompt and complete. Other research personnel, facility managers or animal care personnel may also report information to the IACUC pertaining to noncompliance.

Once discovered, noncompliance events should be reported as soon as possible 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 noncompliance
- A detailed description of the event
- A description of observed impacts to animals.

Noncompliance 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.
Reporting in InfoEd
A formal report of the incident must be submitted in InfoEd via the Reportable Incident form. The report should include:

- A description of the noncompliance
- Immediate steps taken to address the outcome of the noncompliance
- Assessment/root cause of the noncompliance
- Corrective steps taken to prevent recurrence.

Examples of immediate actions a PI might take include, but are not limited to:

- Voluntarily suspending an activity
- Changing a formula or dosage
- Pausing an individual’s responsibilities until they are retrained
- Consulting with the AV

Examples of corrective actions to prevent recurrence might include, but are not limited to:

- Retraining
- Reviewing literature to confirm current practices
- Amending a protocol to modify, remove, or add procedures (including “flexibility” to prevent protocol deviation)
- Identifying a policy or resource need to better address
- Create or revise a standard operating procedure (SOP)
- Request review of a procedure by OAR staff or post-approval monitoring

Reviewing Noncompliance
1. Following a report of possible noncompliance, a preliminary assessment will be initiated by the Office of Research Compliance (ORC), the University (Attending) Veterinarian (AV), and/or the IACUC Chair. This initial assessment is to determine whether a more formal inquiry into the noncompliance is warranted.

   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.

   c. The PI will be notified of the outcome of the assessment.

2. If a more formal inquiry is warranted, it may include an animal facility inspection, interviews with the PI, students, or staff, and/or identification of funding sources or other resources. The IACUC Chair determines how the inquiry will be conducted.

   a. The inquiry may be conducted by staff in the ORC, or the chair may appoint a subcommittee consisting of IACUC members and other appointees deemed appropriate.

   b. The inquiry may be conducted prior to presenting the noncompliance to the IACUC, or it may be initiated following the IACUC’s review.
3. The IACUC chair, ORC, and AV will review the preliminary inquiry and determine if a noncompliance exists.
   a. If it is determined that noncompliance has not occurred, the PI will be notified, and no further actions will be taken.
   b. If noncompliance is identified, the noncompliance will be presented to the IACUC at the next convened meeting, along with any supporting information gathered during the inquiry (if applicable).

4. The IACUC will review the noncompliance at the next convened meeting and determine actions required to address the issue and prevent future noncompliance.
   a. The IACUC may request additional information before making a determination or identifying actions to be taken.
   b. The IACUC will vote on any actions in response to a finding of noncompliance. 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 an activity or an AUP
      • Suspension or termination of animal research privileges
   c. Because noncompliance discussions occur during a closed section of the IACUC meeting, public attendance is prohibited and records related to the noncompliance, including inquiry records, are not shared outside of the IACUC.

5. The PI will be informed of the IACUC’s findings and required corrective actions via a letter from the IACUC Chair. The PI is responsible for addressing these actions and reporting progress to the IACUC.
   a. If the corrective actions include a suspension of an activity or an AUP, the notification will include steps require to lift the suspension, the desired outcomes (e.g., verification of procedure training), and the timelines involved.

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1 If the IACUC votes to suspend part or all a protocol, the Institutional Official will be notified by a representative of the IACUC and discuss the reasons for the suspension. If a protocol is suspended and animals are impacted, the animals will be moved to a husbandry protocol and procedures will not resume until the suspension is lifted. Veterinary care will be provided in accordance with the welfare needs of the animals.

2 If the IACUC votes to suspend a researcher’s privileges, the Institutional Official and investigator’s supervisor will be notified, and review the reasons for the suspension with a representative of the IACUC. If the suspension results in active protocols being unable to progress, and the welfare of animals are impacted, the animals will be moved to a husbandry protocol and procedures will not resume until the suspension is lifted. Veterinary care will be provided in accordance with the welfare needs of the animals.
6. 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.
   b. Decisions will be reported to the PI by the IACUC Chair.
   c. 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.

“Recurring” or “Continuing” Noncompliance
Instances of repeat noncompliance can include the recurrence of the same noncompliance by the research team, or different but related noncompliance, indicating a failure of past corrective actions. While the IACUC has discretion in determining what frequency constitutes “repeated” noncompliance, communication to the PI referencing “repeated” noncompliance will include a citation of past events that led to this determination.

Repeated noncompliance will be reviewed on a case-by-case basis. Corrective actions required by the IACUC to address repeated noncompliance 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 noncompliance, 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, DoD, etc.), AAALAC International, and/or funding sources.

Research Misconduct
If the reported noncompliance 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
Noncompliance 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

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

Evidence of non-compliance

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

The PI is notified and no further actions are taken.

Further Investigation Needed

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

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