

**University of Cincinnati
Animal Care and Use Program**

Reporting and Investigating Concerns

Non-compliant conduct (also known as a deficiency) is categorized as either minor or significant¹. Significant deficiencies are those which are determined by the IACUC and the Institutional Official (IO) to have been a threat to the health or safety of the animals¹, and must be reported promptly to the Office of Laboratory Animal Welfare (OLAW) if federally funded, the Association for Assessment and Accreditation of Laboratory Animal Care Inc. (AAALAC)³ in an annual report, and the United States Department of Agriculture (USDA)⁴ if applicable.

Serious or continuing noncompliance with the PHS Policy and/or the *Guide for the Care and Use of Laboratory Animals* (the *Guide*)², and any suspension of an activity by the IACUC may also constitute a significant deficiency even though the health and safety of the animals may not have been threatened. The IACUC, through the IO, is responsible for reporting deficiencies.

Reporting Concerns

All suspected or observed animal abuse, mistreatment, neglect, or other non-compliance with federal, state, or local regulations or an approved protocol (“concerns”) are required to be investigated by the IACUC. Any personnel who are informed of a concern should contact the IACUC Office to make a report within 48 hours. **Report urgent concerns to the Attending Veterinarian (AV) or designee for immediate action.**

Personnel have an ethical and legal responsibility to report concerns to the IACUC using good judgment. In all cases, anonymity and confidentiality will be maintained to the limits allowed by law, including no discrimination or reprisal for reporting violations.⁷ You may confidentially report concerns to:

1. **IACUC Office/IACUC Chair** 513-558-5106, IACUC@uc.edu
2. **Attending Veterinarian** 513-558-5518
3. **RAP Research Administration Portal**⁶ to create and submit electronic concern
4. **Compliance Hotline** 1-800-889-1547 (if anonymity concerns are important)

Investigating Concerns

The IACUC Office will notify the investigating team of each reported concern. The investigating team (“team”) consists of the IACUC Director, AV, and IACUC Chair; appropriate alternates will be chosen by the IACUC if team members are unavailable or have a conflict of interest. The team will meet with involved parties to determine concern details and validity, and may request appointment of additional IACUC members or consultation of subject matter experts to ensure a thorough review. Upon completion of the investigation, the team will summarize findings and include suggestions for corrective actions in a written concern report for IACUC review.

The IACUC will review the concern report at either a regularly scheduled or emergency IACUC meeting (depending on the severity of the allegation) consisting of a quorum of the voting members.

The objectives of this review are to:

1. Discuss the allegations in the concern report and ask questions of the investigating team,
2. Determine which allegations are substantiated,

3. Decide whether each substantiated allegation represents a serious and/or continuing non-compliance, and
4. Establish suggested corrective actions and related resolution timelines.

Determining Corrective Actions for Non-Compliance

When determining appropriate corrective action(s), the IACUC may consider these factors:

1. Extent to which the incident(s) were self-reported by the Principal Investigator (PI) or staff,
2. Proactive corrective action(s) taken in response to the incident(s),
3. Extent to which the incident(s) represent a continuing or repeated violation,
4. Extent to which the incident(s) represent a minor or significant deficiency,
5. Extent to which animal welfare was jeopardized as a result from the incident(s) and/or
6. The length of time between incidents of non-compliance.

Corrective Actions for Significant Non-Compliance

The IACUC may impose corrective actions separately or in combination to ensure compliance. A list of potential corrective actions is below. *The list is not comprehensive and examples are not ranked in any particular order of severity.*

1. Retraining
2. A letter to the PI from the IO or Chair outlining the problem and requesting a detailed corrective action plan
3. PI required to appear before the IACUC to present corrective action plan
4. Notification to the PI's department chair or division director
5. Require specific care of animals (e.g. additional analgesics, additional monitoring)
6. Require amending or rewriting a protocol
7. Require oversight of protocol activities by an IACUC member, AV, or other designee
8. Suspension or revocation of specific personnel from performing animal work
9. Suspension of some or all activities in the protocol

Notification of IACUC Decision, the Appeal Process, and Completion of Actions

The IACUC Office will notify the PI or designee ("responsible party") of their investigation review and resulting decision. If the resulting decision includes a corrective action plan, the IACUC will assign a due date by which the responsible party must complete the action(s). If the responsible party disagrees with any part of the IACUC's decision, they may appeal the decision in writing to the IACUC within 10 days of the letter. The responsible party may be asked to appear at an IACUC meeting to discuss their appeal. A discussion summary and the IACUC's reconsideration will be sent to the IO.

The responsible party must submit a letter to the IACUC detailing the completion of action(s) in the corrective action plan by the due date. If the responsible party does not complete the action(s) before the due date, the IACUC Chair and IO will discuss and may request escalation of consequences.

Reporting Non-Compliance to OLAW⁵

OLAW considers the following incidents as reportable, significant non-compliances:

1. Any serious or continuing noncompliance with PHS policy.¹
2. Any serious deviation from the provisions of the *Guide*.²
3. Any suspension of an activity by the IACUC.

If the IACUC determines any incident qualifies as a major non-compliance, the IACUC Office will submit a preliminary report to OLAW via phone or email. When the responsible party completes the corrective action plan, the IACUC Office will draft a final report to OLAW including:

1. Institution name and assurance number,
2. Reporting requirement: identify the reporting requirement of the PHS Policy IV.F.3. under which the incident qualifies,
3. Explanation of the incident: Detailed explanation of what happened, when and where, the species of animals involved, and the category (but not the names) of the individuals involved (e.g. PI, researcher),
4. Description of the corrective and preventative actions issued, including IACUC review and acceptance of the completion of action(s) letter submitted by the responsible party and any ongoing action(s),
5. Grant/contract number (if PHS-supported activities),
6. Impact on PHS-supported activities: Description of potential or actual effect on PHS-supported activities and
7. Compliance with terms and conditions of grant award, including confirmation that the situation was reported to the funding component.

The final report will be sent to the IO for approval and signature, and the final signed report will be sent electronically to [OLAW](#). **All documents will be retained by the IACUC Office per UC Retention Policy.**

Reporting Non-Compliance to USDA⁴

The IACUC must report any suspensions of USDA-covered animal activities to the USDA.

References

1. [PHS Policy on Humane Care and Use of Laboratory Animals](#)
2. *Guide for the Care and Use of Laboratory Animals* (8th ed)
3. AAALAC
4. AWA/AWAR
5. NOT-OD-05-034-Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals-defines what is and what is not required to be reported to OLAW
6. [Research Administration Portal \(RAP\)](#)
7. Personnel qualifications, 9 C.F.R. § 2.32(c)(4)