

University of Cincinnati
Animal Care and Use Program

Reporting and Investigating Concerns

In compliance with the Animal Welfare Act (9 CFR, Part 2, Subpart C, Section 2.31(c)(4)) the IACUC is required to "review and if warranted, investigate concerns involving the care and use of animals at the research facility."

Furthermore, "the institution must develop methods for reporting and investigating animal welfare concerns, and employees should be aware of the importance of and mechanisms for reporting animal welfare concerns". The IACUC and the IO are responsible for assuring that all laboratory animals at the University, are treated and used humanely, in accordance with the highest ethical standards, and in accordance with all regulations, laws, policies and guidelines governing animal welfare.

Reporting Concerns

Anyone who has engaged in or observed noncompliance (even if unintentional); or who has concerns about inappropriate care and use of live animals is obligated to self-report or report the incident to the IACUC within 48 hours. All non-compliance with regulations, policies, and/or of an approved protocol are required to be investigated by the IACUC. **Immediately report any animal welfare concerns that require prompt attention to prevent serious health consequences or suffering, such as severe pain or distress, rapid health deterioration, or acute medical conditions to the Attending Veterinarian (AV) or designee.**

You may confidentially report concerns to:

1. **IACUC Office/IACUC Chair** 513-558-5103, IACUC@uc.edu
2. **Attending Veterinarian** 513-558-5518
3. **Compliance Hotline** 1-800-889-1547 (if anonymity is important) or [Anonymous Reporting Hotline](#)

Reports should include (if known): names of personnel involved, principal investigator, who else witnessed the incident, protocol number, location of incident, date, and time the incident occurred, number of animals and species involved and description of what was observed with as much detail as possible, and any subsequent corrective actions.

Confidentiality and Whistleblower Protections

In all cases, anonymity and confidentiality will be maintained to the limits allowed by law, including no discrimination or reprisal for reporting violations.⁶ Any violation of this section should report the incident(s) to the IACUC. Any reports of reprisals should be made to Human Resources/Labor Relations emplabor@uc.edu.

Investigating Concerns

All reports of animal welfare concerns or suspected noncompliance must be submitted to the IACUC. On behalf of the IACUC an investigating team ("team") consisting of the IACUC Director, AV, and IACUC Chair or designees or appropriate alternates will do a preliminary assessment to determine if an allegation is credible and an investigation is warranted. The team will meet with involved parties to collect information and assess validity and may request appointment of additional IACUC members or consultation of subject matter experts to ensure

appropriate review. Upon completion of the investigation, the team will provide the IACUC with a reports that summarizes findings and, as appropriate, includes suggestions for corrective actions. The IACUC will review the report an IACUC meeting consisting of a quorum of the voting members.

The objectives of this review are to:

1. Discuss the allegations and review,
2. Determine which, if any, 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,
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 to facilitate 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 IACUC Chair outlining the problem and requesting a detailed corrective action plan
3. Requiring the PI to appear before the IACUC
4. Notifying the PI's unit head
5. Requiring specific care of animals (e.g. additional analgesics, additional monitoring)
6. Requiring modification of a protocol
7. Requiring oversight of protocol activities
8. Suspending or revoking of specific personnel from performing animal work
9. Suspending 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 the 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. Failure to comply may result in increasingly severe consequences (including suspension of all animal activities, up to and including disciplinary action).

Reporting Non-Compliance to OLAW⁵

If the IACUC determines any incident qualifies as a significant 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 providing the required information and summarizing the incident, findings, and resolution.

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 AAALAC³

It is AAALAC's expectation that they should be informed of the results of animal welfare concern investigations and any subsequent corrective measures.

Reporting Non-Compliance to USDA⁴

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

References

1. Office of Laboratory Animal Welfare, National Institutes of Health, US Department of Health and Human Services. [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#). 2015. Public Health Service, Bethesda, MD.
2. National Research Council. Institute for Laboratory Animal Research. 2011. [Guide for the Care and Use of Laboratory Animals](#). Public Health Service, Bethesda, MD.
3. [AAALAC International](#)
4. Animal and Plant Health Inspection Service, USDA. [Animal Welfare Act and Animal Welfare Regulations](#). July 2023. CFR Title 9, Subchapter A - Animal Welfare. U.S. Government Printing Office, Washington DC.
5. Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research. [NOT-OD-05-034: Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals](#). 24 February 2005.
6. Ohio Revised Code, Section 124.341. [Violation or misuse - whistleblower protection](#). 29 September 2013.