

Colorado State University Institutional Animal Care and Use Committee (IACUC)

Policy on Instances of Noncompliance

Requirement for IACUC Oversight

Federal and University policies require that all research, testing, and teaching activities conducted at Colorado State University (CSU) which include the use of animals be overseen by the CSU Institutional Animal Care and Use Committee (IACUC)¹.

An essential element in the required IACUC oversight of animal use activities is the review and approval of an IACUC protocol describing all proposed studies involving live vertebrate animals prior to initiation of the animal use activity.

An IACUC protocol is considered a contractual agreement between the investigator and the IACUC. Failure to obtain prior IACUC review and approval of a protocol describing animal use activities or changes to any element of an approved protocol without approval constitute noncompliance with the federal regulations and CSU IACUC policies. Depending on the nature and/or frequency of such violations, an investigator's ability to conduct research involving animals may be temporarily suspended or revoked entirely.

Reporting Noncompliance

To maintain the public trust in CSU's ethical and responsible use of animals and compliance with applicable regulations, instances of noncompliance should be reported whenever noted. Reports can be submitted by Principal Investigators (PIs), laboratory staff, animal care staff, or the general public. They can also be reported as a result of Post-Approval Monitoring of approved activities and IACUC review of the animal care and use program. Individuals, whether CSU employees, students, or members of the public, can report suspected noncompliance to the IACUC Chair², Attending Veterinarian³ (AV), IACUC staff within the Research Integrity and Compliance Review Office (RICRO), and the Vice President for Research, i.e. the Institutional Official (IO). The names and phone numbers of these individuals are listed on the [IACUC Reporting Animal Welfare Concerns](#) webpage. In addition, individuals may utilize the CSU System's [Compliance Reporting Hotline](#) (online reporting or phone reporting).

¹ [Animal Welfare Regulations, Public Health Service Policy on the Humane Care and Use of Laboratory Animals, Guide for the Care and Use of Laboratory Animals, CSU IACUC Policies and Guidelines, Guidance on Reporting Noncompliance \(NOT-OD-05-034\), AAALAC FAQs \(Reporting Requirements #H2\)](#)

² IACUC Chair = includes the Chair or their delegate, including but not limited to the IACUC Associate Chair, Attending Veterinarian (AV), or Associate Attending Veterinarians (AAVs), IACUC staff within RICRO.

³ Attending Veterinarian (AV) = includes their delegates, Associate Attending Veterinarians (AAVs).

Examples of Instances of Noncompliance

The following lists provide examples of common instances of noncompliance cited by the USDA Animal Care inspectors and NIH Office of Laboratory Animal Welfare (OLAW):

Examples of Noncompliance

- Conducting research, teaching, or testing using animals without prior IACUC approval
- Failure to communicate to the AV or LAR veterinary staff in a timely manner, that urgent care was provided for sick or injured animals
- Purchasing, collecting, or otherwise obtaining animals for use without prior IACUC approval
- Failure to ensure and document the provision of daily and veterinary care for animals under your care
- Failure to ensure and document that all personnel involved with the animal activities are adequately trained to perform the relevant procedures
- Failure to provide housing that is safe, clean, free of pests, and meets the animals' species-specific needs

Examples of Protocol-Specific Noncompliance

- Using more animals or different species than what is stated in the approved IACUC protocol
- Performing procedures not described in the protocol
- Performing more procedures than stated in the approved IACUC protocol
- Altering diet for experimental purposes without IACUC approval
- Collecting samples from live animals without IACUC approval, e.g. blood, tissue, etc.
- Collecting more samples than described in the protocol or using an altered collection schedule or method
- Changing the type or dose of drug administered (unless approved by the AV as prescribed for clinical reasons)
- Failure to adhere to endpoints defined in an approved protocol
- Failure to document post-surgical or post-anesthesia monitoring
- Failure to monitor animals or make observations as specified in an approved protocol
- Restraining an animal for periods exceeding those approved in the protocol
- Involving personnel not listed on the protocol

Investigation of Reported Noncompliance

When possible noncompliance is reported, the party receiving the report will immediately inform the IACUC Chair and the AV. The IACUC Chair will promptly assign a subcommittee of one or more IACUC members to gather information to allow determination of the following items:

1. Whether the actions resulted in harm to or mistreatment of animals or personnel;
2. Whether animals are still at risk;
3. Whether the actions constitute serious or continuing noncompliance with the regulations or CSU policies;

4. RICRO IACUC Staff will advise the principal investigator (PI) that a noncompliance review has been initiated by the IACUC.⁴

All cases in which the investigation leads to a conclusion that noncompliance with the requirements of applicable federal regulations or institutional policies is likely to have occurred, or that there is a past, present, or future threat to animal welfare, the Chair or subcommittee investigating will provide a report and make recommendations to the IACUC regarding the appropriate corrective action(s). The principal investigator (PI) may be asked to discuss the issue with the IACUC directly.

The IACUC will review the information gathered by the subcommittee and determine if noncompliance occurred, and whether corrective actions should be taken to avoid the noncompliance in the future, and an appropriate date by which the correction will be implemented. If the matter is deemed to not involve noncompliance, the matter will be considered closed by the IACUC and the PI will be notified.

Consultation with IO and Formal Determination of Noncompliance

Following review and determination of findings, the IACUC will forward its findings and recommendations regarding any corrective action to the IO for consultation. When the IACUC, in consultation with the IO, determines that the matter is noncompliance, the PI and the person(s) reporting the concern will be informed of this determination, when possible, depending on requests for anonymity. The PI will have the opportunity to work with the IACUC to modify the plan, if appropriate. Additional internal notifications may be made to the PI's Department Chair, College Dean, and the Office of Sponsored Programs, as appropriate. The notification will be in writing and will include any corrective actions being required and the timeline by which they must be implemented or official notification of suspension of the animal use activity.

Corrective Actions that May Arise from Determinations of Noncompliance

Most issues of noncompliance are minor and can be resolved administratively. For more significant issues, the IACUC may recommend remedial action including but may not be limited to:

- Specific training or retraining for the investigators and/or other personnel working on the study.
- Additional monitoring by the IACUC or IACUC-appointed individuals of animal use activities.
- Submission and approval of a protocol amendment, or placement of specific additional requirements of approval on the protocol.
- Notification of noncompliance forwarded to the Office of Sponsored Programs, which may result in cessation of funds for activities under an IACUC protocol.
- Restricting an investigator's research practice, the use of certain procedures, or conducting activities under supervision.

⁴ The Chair may also inform any of the following entities at this point in time, as deemed appropriate to the situation: PI's department chair, appropriate facility director (e.g. VTH, IDRC, ERL, EORC, AES, etc.) college dean, Office of Sponsored Programs, etc.

- Suspending approval or terminating one or more of the investigators' studies.

The IACUC's notification to the PI regarding noncompliance and any required corrective actions will be in writing.

Suspension of Animal Research Activities

The IACUC is empowered to formally suspend a protocol if it finds violations of the PHS Policy, the *Guide*, CSU's Animal Welfare Assurance, Animal Welfare Act Regulations, or for reasons of animal welfare arising from animal use activities conducted within the requirements of the regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with a vote for suspension by a majority of the quorum present. The AV is also authorized at any time to stop any animal use procedures or activities that do not comply with institutional policies, or that in their clinical judgment need to be discontinued to protect the welfare of the animal. The IACUC must consult with the IO regarding the reasons for the suspension. The IO is required to take appropriate corrective action and report the action and the circumstances surrounding action(s) to OLAW. In addition to this formal process, a PI may (and in appropriate cases will be encouraged) to agree to voluntarily suspend their protocol pending review by the IACUC.

Reporting Noncompliance to External Agencies

Federal regulations mandate that the determination by the IACUC of any serious or continuing noncompliance of Federal regulations or suspension of a protocol be promptly reported to the regulatory entities, as appropriate to the species, purpose, and source of funding for the animal use in question. Reporting can include notification to OLAW, USDA, and the federal funding agency, AAALAC, among others. The IACUC will inform the IO that any of the following has occurred, and that they therefore recommend reporting the noncompliance to external agencies:

- Serious or continuing noncompliance with PHS Policy on Humane Care and Use of Laboratory Animals
- Unauthorized and significant deviation from provisions of the *Guide for the Care and Use of Laboratory Animals*
- Suspension of activity (protocol) and/or personnel by the IACUC

Federal regulations specify that official reports of noncompliance originate with the Institutional Official (IO), rather than individuals involved in such cases, other than exceptional or emergency circumstances. The IO or the IO's delegate will seek the advice of the AV and IACUC when determining if an event constitutes a reportable noncompliance. In addition to deciding to file a formal written report, the IO or the IO's delegate may determine to contact relevant agencies informally.

Serious noncompliance may result in a determination by the Public Health Service or other Federal agencies that the University must return part or all of the funding for the project. Funding agencies may additionally impose future restrictions on CSU and the PI, impacting the ability to obtain Federal funding for animal research and teaching.

Institutional Endorsement

The “Policy on Instances of Noncompliance” approved by the IACUC on May 25, 2021 for recommendation to the Institutional Official supports the research, teaching, and service mission of Colorado State University, and ensures that the welfare of animal subjects used therein will be protected. Therefore, as the Institutional Official, I declare the IACUC-recommended policy to be the policy of the Colorado State University Animal Care and Use Program.



July 12, 2021

Institutional Official

Date