

IACUC Policy on Noncompliance	Policy No. IACUC-019
	Effective Date: 11/13/2023

1. Reference(s):

Guide for the Care and Use of Laboratory Animals, NRC, 2011, pp. 23-35

Applied Research Ethics National Association/Office of Laboratory Animal Welfare.
Institutional Animal Care and Use Committee Guidebook. 2nd edition, reprinted 2008, pg. 164-165

The IACUC Handbook, 3rd edition, CRC Press, 2014, pg. 685-718

2. Purpose:

The Oklahoma State University (OSU) Institutional Animal Care and Use Committee (IACUC) works to ensure that all research and instructional activities involving the use of animals, and the facilities to conduct such work, are in compliance with all external federal, state and local regulations, laws, required guidelines, as well as applicable university policies. Reports of noncompliance will be directed to the appropriate IACUC staff and to the IACUC for investigation and corrective action. This document outlines the procedures that will be used for reporting and investigating any noncompliance with pertinent government regulations, laws, required guidelines, OSU policies, and/or IACUC policy, procedures, and decisions.

3. Policy:

3.1. Reporting Allegations of Noncompliance

3.1.1. Allegations of noncompliance may be submitted to the IACUC Chair, IACUC members, IACUC office personnel, or University Research Compliance (URC) either verbally or in writing. In addition, reports of noncompliance may be submitted via the EthicsPoint confidential reporting system used by OSU. The identity of the individual making the report will be kept confidential if requested.

3.2. Processing the Allegation of Noncompliance

3.2.2. Screening the initial review of the allegation: The IACUC Manager screens the allegation to determine if it involves an active protocol. If an active protocol is involved, the IACUC Manager determines the source of funding, if any, and if there are any issues pertinent to other research review committees (e.g., IBC, IRB, RSC, Laser Safety). The IACUC Manager, IACUC Chair and University Attending Veterinarian (UAV) will serve as the designated Compliance Subcommittee and will review the allegation to allow an initial determination of the nature and severity of the alleged noncompliance. This may involve discussion with the research team and the complainant (if not anonymous), and others as needed. The IACUC Manager will document and compile the information into a summary report. Investigator noncompliance may often be the result of communication difficulties; therefore, the IACUC will attempt to resolve apparent instances of noncompliance without interrupting the conduct of the study.

3.2.3. Determinations: After the initial review, the Compliance Subcommittee will determine whether:

- The allegation was demonstrably false or alleges actions that would not constitute noncompliance.
- The allegation, if true, is of minor noncompliance.
- The allegation, if true, is of major noncompliance.

False allegation: If it is determined that the allegation of noncompliance is false, then the matter will be documented for the protocol file, if appropriate, the Compliance Subcommittee will communicate the decision to the complainant (if his/her identity is known) and to the investigator. The IACUC will be informed at the next convened meeting.

Minor noncompliance: If it is determined by the Compliance Subcommittee that the allegation is a minor noncompliance, the investigator will be notified in writing. In addition, the Compliance Subcommittee will discuss the issue and develop an action plan with the investigator. The final action plan will be forwarded to the investigator via letter or e-mail and the IACUC will be informed at the next convened meeting.

Major noncompliance: If the allegation is a major noncompliance and involves an active protocol, the IACUC, UAV, and/or the IO will determine if immediate suspension of study procedures and/or enrollment is required for the protocol in question as well as for other protocols being conducted by the same investigator. The investigator(s) involved in the allegations, associated research staff, appropriate school or department heads, college research deans and the IO are notified in writing about any suspension. The IACUC, UAV, and IO will discuss the reasons for the suspension, and will determine what corrective actions must be taken. The IO will report to the USDA and any federal agency funding the research activity. Once the appropriate corrective actions have been taken, the IACUC and IO will meet to discuss reinstatement of the IACUC protocol.

If, after initial screening, the allegation is considered to be a noncompliance, the IACUC will initiate an inquiry. The purpose of the inquiry is fact-finding and may involve examination of study records, discussion with the research team, personnel, witnesses, the complainant (if not anonymous), and others as needed. The IACUC Chair may appoint one or more additional committee members to assist the Compliance Subcommittee in the gathering of information pertaining to the nature of the allegation. The investigator will be notified of the inquiry by the IACUC Manager or the IACUC Chair and asked to respond in writing to the allegation within 3 workdays. If the investigator needs more time, an extension may be granted by the IACUC Chair. The IACUC Manager will document and compile the information, including the investigator's response, into a summary report. The summary report will be presented to the IACUC at a convened meeting for review. The investigator

may be asked by the IACUC Manager or the IACUC Chair to attend the next convened IACUC meeting.

3.2.4. Review Procedures for Noncompliance: The allegation and inquiry results will be presented at the next scheduled IACUC meeting. For urgent issues, the IACUC Chair may convene an emergency meeting of the IACUC. At the convened IACUC Meeting, the IACUC Manager will present the allegation(s) to the IACUC. All IACUC members will receive the investigation report, synopses of any communication with the investigator, the last approved IACUC protocol, and any other pertinent information. All members attending the IACUC meeting will review all the documents and determine whether:

- There is an isolated or continuing major noncompliance.
- More information is needed and determination is deferred to future meeting pending receipt of additional information.
- There is no major noncompliance.

3.2.5. Review Outcomes/IACUC Actions: The convened IACUC makes the final determination whether the alleged noncompliance is major based on the materials compiled during the inquiry. The convened IACUC may take a variety of actions depending on the outcome of the review, including, but not limited to the following:

- Approve continuation of research without changes
- Request minor or major changes in the research procedures.
- Require audits of other active protocols of the researcher.
- Suspend the use of animals in research and/or instructional activities.
 - Consultation between the IACUC and IO will review the findings and determine appropriate corrective actions. The IO will then report the suspension to the USDA and other federal funding agencies.
- Terminate the use of animals in research and/or instructional activities.
- Recommend further administrative action to the University administration.

The IACUC resolves questions or concerns raised by a PI regarding the outcome of a specific IACUC noncompliance review through direct communication with the PI. The PI may submit concerns in writing to the IACUC within thirty days of the date the IACUC issues the final decision and may request to attend a convened meeting of the IACUC to discuss the concerns. The IACUC limits concerns to a review of the procedures employed to reach the decision (i.e., claims that the process was faulty in a way that creates a considerable risk that the outcome was incorrect) or grievances against sanctions imposed as a result of a finding of noncompliance. The PI specifies the nature of any claimed procedural error, or the perceived unfairness of sanctions issued.

3.2.6. Reporting: The IACUC informs the following individuals internal to the university of the allegation, the review process, and the findings of the review in writing:

- Investigator(s)
- Complainant via blind carbon copy (if the identity is known)

- Associate Dean(s) for Research
- IO, UAV and Assistant Vice President for Research
- Other administrative personnel as appropriate

If the research is supported by an external sponsor, they will also be notified. If the IACUC determines that the incident is serious or continuing noncompliance, the findings will be reported to the appropriate agency (i.e., USDA, NIH-OLAW, DoD, NSF, AAALAC, etc.) as applicable.