

University of Notre Dame Institutional Animal Care and Use Committee (IACUC) Policy	
Title: Noncompliance	
Effective Date: 7/20/24	Last Revised Date: 7/20/24

I. Purpose

Appropriate care and use of animals in research requires adherence to federal law, institutional policy, and with an approved IACUC protocol. The IACUC is tasked with ensuring that animal use follows these requirements through review of any reports of noncompliance.

II. Definitions

Noncompliance: Activities that depart from an approved IACUC protocol, institutional policy, or federal regulation.

Minor noncompliance: Noncompliance that does not adversely affect or pose a significant potential for causing harm to the health and safety of an animal or to personnel working with animals or does not adversely affect the scientific integrity of the study.

Major noncompliance: Noncompliance that adversely affects the safety or welfare of animals, personnel working with the animals, or the scientific integrity of the study.

Corrective Action: Remediation steps proposed by the IACUC or the PI describing how the lab will resolve noncompliance concerns and prevent the issue(s) from reoccurring.

Post Approval Monitoring (PAM): Protocol-specific review of activities by IACUC staff in cooperation with investigators outside the IACUC protocol review process.

III. Policy

1. Minor noncompliance
 - a. Examples of minor noncompliance include, but are not limited to:
 - i. Not informing the IACUC of the addition of personnel

- ii. Inadequate training of personnel in animal care and laboratory safety procedures
 - iii. Use of an unapproved procedure area resulting in failure of the IACUC to inspect this area
 - iv. Personnel accessing facilities, or allowing others to access facilities, without authorization
 - v. Inadequate controlled substance logs or controlled substance storage
 - vi. Improperly labeled bottles or secondary containers
 - vii. Keeping expired drugs in the laboratory
 - viii. Cage cards not containing required information (e.g., surgery date, chemical administration, tumor inoculation, etc.)
 - ix. Unapproved transfer of animals without exceeding the approved number or performing procedures
 - x. Improper or unapproved animal transportation
 - xi. Not following safety procedures when working in BSL-2 or lower facilities (e.g., not wearing appropriate PPE)
 - xii. Inadequate housing conditions (e.g., overcrowded cages, weaning delays, or failure to separate aggressive animals as required)
 - xiii. Failure to participate in the semi-annual inspection at the request of the IACUC
 - xiv. Minor protocol deviation which does not compromise animal welfare
- b. Potential minor noncompliance may be resolved through communication between veterinary staff, the Attending Veterinarian (AV), the Principal Investigator (PI), and the individual research personnel.
- i. First notification: Activities resulting in minor noncompliance will only be allowed to continue following correction through consultation with veterinary staff or an individual designated by the IACUC or AV. The consultation may include re-training of personnel.
 - ii. Second notification: Minor noncompliance that has not been adequately addressed (as determined by the AV or IACUC designee) or a repeat of activities that initiated a first notification will result in a written second notification to the PI. The PI must respond to the second written notification, explaining any identifiable causes for the noncompliance and corrective and preventative actions. This response will be reviewed by the IACUC, which will determine if additional action will be required of the PI. The PI may be asked for more information, to submit a full noncompliance report, or to appear in person at an IACUC meeting. Failure to cooperate with the AV, the IACUC, or any IACUC designee may result in additional actions, such as revocation of facility access privileges.
 - iii. Third notification: Activities resulting in repeated minor noncompliance following a second notification will require submitting a noncompliance report in eProtocol. A third notification will be sent to the PI, requesting a detailed description of previous corrective actions and the circumstances resulting in repeated noncompliance. Repeated incidents may be

reclassified as major noncompliance based on the potential for impact on animal welfare, lab personnel safety, and research integrity. The PI may also be required to meet with the IACUC Chair, Attending Veterinarian, FLSC personnel, and/or the Institutional Official.

- c. If an issue remains unresolved or is deemed more serious, it will be reported to the IACUC.

2. Major noncompliance

- a. Examples of major noncompliance may include, but are not limited to:
 - i. Acquiring a species of animal for research or performing procedures without IACUC approval
 - ii. Performing a procedure in such a manner that animals endure pain or suffering that is not addressed by the approved protocol
 - iii. Willful acts of abuse
 - iv. Performing a procedure with improper technique or safeguards that puts either the staff or animals at risk
 - v. Failure to adhere to proper aseptic technique for survival surgery
 - vi. Repeated or willful incidents of minor noncompliance
 - vii. Failure to provide adequate anesthesia or analgesia according to the approved protocol
 - viii. Failure to monitor animals adequately following an invasive procedure
 - ix. Not following safety procedures such that personnel are unknowingly exposed to hazards (e.g., dangerous chemicals, biohazards)
 - x. Exceeding the number of animals approved on the study (e.g., breeding colonies, transferring animals from another protocol without prior approval)
 - xi. Lack of sufficient information in surgical and post-operative records to demonstrate adequate care
 - xii. Failure to follow safety procedures while using biohazardous materials in a manner that substantially increases the risk of harm to laboratory staff
 - xiii. Repeated failure to adhere to Freimann Life Sciences Center and IACUC Policies and SOP's
 - xiv. Conducting experiments or use of animals not described in approved protocol
- b. When potential major noncompliance is identified, the AV will determine if any immediate action is necessary to ensure the welfare of animals, lab personnel, and veterinary staff. Immediate action may include prohibiting additional procedures, limiting access to animal facilities, moving animals, and more. The PI will be required to provide information to the IACUC about the potential noncompliance in order to address animal welfare, and allow the IACUC to review the matter. A noncompliance report must be submitted to the IACUC for review at a convened meeting. The report shall include all relevant information about the circumstances, including any corrective and preventative actions taken. Consultation with IACUC staff may occur while a noncompliance report is drafted or submitted for review.

- c. Incidents will vary in their degree of seriousness. An IACUC subcommittee may recommend corrective action, and a majority vote (during a convened meeting) by a quorum of IACUC members will decide on corrective action and may vote on any or all of the following possible actions:
 - i. Protocol suspension
 - ii. Revocation of research privileges
 - iii. Communication to the PI from the IO or IACUC Chair outlining the problem and requesting a detailed plan of corrective action
 - iv. Notification to the PI's department chair
 - v. Reporting to appropriate internal and external authorities
 - vi. Retraining of personnel
 - vii. Unannounced inspections of the lab by IACUC member(s) or PAM personnel
- d. If the IACUC suspends any research:
 - i. all procedures under the protocol and animal ordering must cease
 - ii. the PI, his/her department chair, and the IO will be notified promptly
 - iii. the IACUC will require that the PI develop a detailed corrective action plan
 - iv. The PI will be required to meet with the IACUC, the IACUC Chair, and/or the Institutional Official as a condition of reinstatement.
 - v. Suspension may only be removed by the IACUC at a convened meeting and after it has been determined that the activities under the protocol can be accomplished in full compliance with the relevant rules and regulations and that adequate corrective and preventative actions have been taken.
 - vi. Suspension will be communicated to the appropriate regulatory authorities.

IV. References

1. Public Health Service (PHS) Policy.
2. Office of Laboratory Animal Welfare. Requirements for prompt reporting of problems to OLAW. OPRR Reports, February 21, 2013.
3. The Guide for the Care and Use of Laboratory Animals, 8th ed.