

TITLE: Noncompliance Policy for Radford University IACUC	Effective Date: 27-February-2023
IACUC POLICY: 010 REVISION: 0	Last Revised:
SCOPE: This policy applies to all approved IACUC protocols and vertebrate animal researchers	Review Date:
PURPOSE: To guide how to report and investigate allegations of noncompliance in the animal research program according to IACUC protocols, policies, and regulatory guidelines.	
KEYWORDS: Protocol Deviation, Allegation, Report, Adverse Event, Serious Non-compliance, Institutional Animal Care and Use Committee (IACUC).	
Policy Owner: Research Compliance Office Radford University	
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BACKGROUND

Radford University’s Institutional Animal Care and Use Committee (IACUC) adheres to the Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals (PHS Policy), the USDA Animal Welfare Act Regulations (AWARs), the Guide for the Care and Use of Laboratory Animals (the Guide), and all other applicable standards.

According to the Guide, institutions “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” (p. 23). Section 2.31 of the U.S. Department of Agriculture (USDA) § 9 CFR 2.31(c)(4) requires that an IACUC “review, and, if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees” (para. 11).

This policy, which applies to all research faculty, staff, and students at Radford University who are using animals in research, testing, and demonstration, classifies non-compliance, informs members of the research community how to report allegations of noncompliance in Radford University’s animal research program, and serves as a systematic framework for the review of and responses to such allegations.

POLICY

Defining and Classifying Minor versus Major Noncompliance

Noncompliance with university policies or federal regulations can be classified as major or minor. **Minor noncompliance** includes instances of unintentional errors that do not threaten the health or welfare of animals.

Some examples of minor noncompliance are as follows:

- a. Modifying any element of an IACUC-approved protocol that does not pose a real or potential threat to the health and welfare of the animals without submitting and obtaining IACUC approval of a modification.
- b. Failure to respond to protocol, training, and semi-annual inspection deadlines established by the RCO and IACUC
- c. Allowing new personnel to work with animals without qualifications, training, or IACUC approval
- d. Failure to maintain sufficient record-keeping related to animal monitoring (e.g., disease condition, survival surgery, post-procedure care) and animal care (e.g., feeding, bedding changes, health checks)
- e. Performing an unapproved procedure that does not cause pain or distress
- f. Not securing controlled substances properly or maintaining proper dispensing logs
- g. Having bottles that are improperly labeled or used as secondary containers
- h. Relocating animals from a laboratory without properly notifying the IACUC and RCO or conducting research in areas not approved on the protocol.
- i. Exceeding the number of animals approved for the study (e.g., breeding colonies).
- j. Cage cards that fail to identify the IACUC protocol number, species, and any dangers or risks to people or to animals posed by the caged animals.
- k. Having cage cards that lack adequate information (e.g., date of surgery, chemical administration, tumor inoculation) for animals that are part of ongoing experiments
- l. Failure to maintain cleanliness, hygiene, and upkeep of lab or vivarium space where animal work or housing is conducted
- m. Failure to follow established IACUC policies and guidelines

Major noncompliance results from willful, intentional, and repeated activities in breach of federal, state, or university animal welfare regulations or policies, or violations that pose a real or potential threat to the health and welfare of animals.

Examples of **major noncompliance** include, but are not limited to, the following:

- a. Conducting animal-related activities without appropriate IACUC review and approval
- b. Implementation of any significant change to an IACUC-approved protocol that poses a real or potential threat to the health and welfare of animals without prior IACUC approval
- c. Performing a procedure so that animals endure distress, pain, or suffering not addressed in the approved protocol
- d. Breeding animals without IACUC approval
- e. Housing animals in a vivarium without IACUC approval
- f. Failure to ensure the death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂)
- g. Not following the aseptic technique described in the protocol when performing survival surgery
- h. Failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures)
- i. Housing animals over the recommended housing density
- j. Not administering analgesics as required in the approved IACUC protocol
- k. Failing to make personnel aware of hazards, training in safety procedures, not following safety procedures, or leaving personnel unknowingly exposed to hazards (e.g., dangerous chemicals, radioactivity, biohazards)
- l. Failing to adhere to veterinary-mandated instructions (e.g., evaluations, treatments)
- m. Conducting animal-related activities beyond the protocol expiration date
- n. Exceeding the number of animals approved on the study, where the protocol entails a real or potential threat to the animals
- o. Continuous and repeated failure to respond to protocol, training, and semi-annual facility and/or post-approval monitoring (PAM) inspection deadlines established by the RCO and IACUC
- p. Repeated failure on multiple occasions to maintain sufficient record-keeping related to animal monitoring (e.g., disease condition, survival surgery, post-procedure care) and animal care (e.g., feeding, bedding changes, health checks)
- q. Repeated failure to maintain cleanliness, hygiene, and upkeep of lab or vivarium space where animal work or housing is conducted

Semi-annual facility inspections as a means of identifying noncompliance

According to the PHS Policy and the AWARs, the IACUC must review the animal care program and inspect animal facilities and animal use areas at least every six months. This process allows for identifying deficiencies, potential issues, and incidents of noncompliance so they can be reported to the appropriate individuals and corrected by the principal investigators (PIs) on those protocols.

Deficiencies identified during the semi-annual inspection process are discussed during the subsequent IACUC meeting, and corrective actions are discussed and voted on by the IACUC.

When finalized, the deficiencies and corrective measures are forwarded to the Research Compliance Office (RCO), which sends official letters to the PI(s) listed on those protocols that include detailed descriptions of the deficiencies and a deadline for providing evidence to the RCO that they have been corrected. While it is understood that deficiencies denote circumstances in which a PI is out of compliance, deficiencies that are (a) identified during the semi-annual inspection and (b) corrected before the deadlines and extensions granted by the IACUC will not require an official IACUC investigation.

A **major (significant) deficiency** is “any deviation in policy, program, procedure, or facility condition from the standards described in the Guide, PHS Policy, or the AWARs, which is or may be a threat to the health and safety of the animals” (NIH Office of Animal Care and Use, 2022, p. 1). Significant deficiencies are determined to create an environment that is harmful to animals listed on a protocol. The severity of major deficiencies requires a practical, effective plan of remediation that is implemented immediately to “1) remove the condition causing the significant deficiency until a permanent correction can be implemented, or 2) minimize the negative impact of the deficiency as much as possible and for as brief a period as possible” (p. 1).

According to the NIH Office of Animal Care and Use, examples of **major deficiencies** that the Office of Laboratory Animal Welfare (OLAW) provides include “failure or malfunction of HVAC, electrical or watering systems sufficient to affect critical housing and operational areas, and broad circumstances, such as natural disaster, that cause injury, death, or severe distress to animals” (p. 1).

A **minor deficiency** is “any other deviation in policy, procedure, or facility condition from the standards described in the Guide, PHS Policy, the AWARs, or [IACUC policies and procedures], which is not a justified exception to those standards” These deficiencies require remediation but are not considered “serious breaches of policy or conditions endangering the health and safety of the animals” (NIH Office of Animal Care and Use, 2022, p. 2).

According to the NIH Office of Animal Care and Use, **minor deficiencies** in animal facilities include “infrequent findings of moderate environmental fluctuations that are generally well tolerated, even if auxiliary equipment (i.e., heaters or chillers) may be needed to help minimize fluctuations, peeling or chipped paint, burnt-out light bulbs, missing floor drain covers, chipped floor surfaces, and similar problems” (p. 2).

When a Major Deficiency becomes a Noncompliance Issue

If the date for correction of a **major deficiency** is exceeded, the RCO will report this information to the IACUC Chair, Vice-Chair, and Attending Veterinarian (AV) immediately, and a new date for correction will be discussed, approved, and communicated with the PI or staff member. The RCO and IACUC will communicate with the PI or staff member to determine why the original deadline was missed before setting a second deadline in case it is necessary to decide how to account for problems beyond the PI's or staff member's control, like supply chain issues. If the second deadline is exceeded without a reasonable excuse, the deficiency will be classified as an issue of noncompliance and initiate the inquiry procedures described in this document.

If **minor deficiencies** have not been resolved since the last semiannual report, the IACUC must review those items and reassess the timeline for correction. The PI or staff member must supply a written rationale to the RCO for not correcting the minor deficiency 1) within the timeline given after the semi-annual inspection and 2) within the entire period between semiannual inspections.

In some circumstances, minor deficiencies can be changed to major deficiencies after careful deliberation by the IACUC. In most circumstances, this **change from minor to major** alerts administrators and outside offices on campus (e.g., Facilities Management) about the need for resources to resolve the issue promptly since resolving the issue may stem from budgetary or resource restrictions.

Post-approval monitoring as a means of identifying noncompliance

Announced and unannounced inspections carried out by the AV or other individuals approved to carry out periodic post-approval monitoring (PAM) also allow opportunities to identify protocol deficiencies and deviations so they can be reported to the RCO and corrected by the principal investigator(s) before becoming major non-compliance issues.

A deficiency identified through PAM is reported to the RCO, who then notifies the PI of the deficiency. The IACUC Chair, Vice Chair, and AV should generate a plan of correction, which is then provided to the RCO and delivered to the PI. Depending on the severity of the noncompliance identified through the PAM process, the methods for correcting these deficiencies will typically follow a similar course for dealing with minor and major deficiencies identified through semi-annual inspections. Major deficiencies that fail to be corrected by the established deadlines will then be treated as major non-compliance violations and will require a full committee review and further investigation.

Self-Reporting of Protocol Deficiencies or Deviations

Any PI that finds themselves in noncompliance with their protocol **must** self-report by notifying the RCO and Attending Veterinarian via email immediately. This gives the RCO, AV, and IACUC proper notice and the opportunity to investigate further if needed, and the PI a chance to remedy the issue with self-corrective measures to prevent a recurrence. PIs should submit a report using the *Adverse Incident/Protocol Deviation* Form in IRB Manager and provide the following information:

- Date(s) of the protocol deviation
- A detailed description of the protocol deviation, and any relevant background as to why the deviation occurred
- An explanation of whether the protocol deviation also resulted in an Adverse Incident
- A description of documentable self-corrective measures that will be taken to prevent future protocol deviations as well as the date(s) for implementation.

The self-corrective measures and dates of implementation must be submitted to the RCO and reviewed and approved by the AV and IACUC Chair.

Additional monitoring, including announced or unannounced veterinary and semi-annual inspections may be used to ensure that the corrective measures are being followed. Failure to follow corrective measures or to follow remediations by established deadlines will be seen as major non-compliance and may result in the suspension of the protocol and require a full-committee review and investigation.

Confidential or Anonymous Noncompliance Reporting

Anyone concerned about the mistreatment or welfare of research animals at Radford University is strongly encouraged to report incidents involving perceived noncompliance through one of the following mechanisms. The university protects this reporting process by prohibiting retaliation against individuals who, in good faith, report alleged noncompliance.

Confidential reporting to the Research Compliance Office (RCO) Office

Phone: 540-831-5290

Email: irb-iacuc@radford.edu

Confidential reporting to Dr. Jeanne Mekolichick, Radford University's Institutional Official

Phone: 540-831-6504

Email: jmekolic@radford.edu

Confidential or anonymous reporting through Radford University's Online Whistleblower Reporting System

Whistleblowers can use [this link](#) to submit their complaint through Radford's online whistleblower reporting system, which allows them to choose whether they want to provide contact information, making this either a confidential or anonymous process depending on the whistleblower's preferences. This process enables whistleblowers to summarize their allegation(s) and provide supporting evidence.

Whistleblowers should attempt to provide as much detail about their allegation(s) and any supporting evidence as possible. This information could include, but is not limited to, names, locations, times and days the noncompliance was witnessed, and pictures of the suspected noncompliance. Any identifying information will be redacted before members of the IACUC review it. Whistleblowers who want to remain anonymous should use the online whistleblower reporting system and refrain from providing any identifying information when completing the form.

Initiation of the Major Noncompliance Inquiry

Once a report of major noncompliance is identified, through a whistleblower report or a PAM inspection, it will be processed by the RCO and immediately forwarded to the IACUC Chair, Vice-Chair, and the AV for an initial inquiry. These individuals will review all submitted materials and assess the concern to determine whether the complaint falls within the IACUC's jurisdiction. If any of these individuals have a potential conflict of interest, they should recuse themselves from this assessment, and if needed, another IACUC member can be designated by the IACUC chair or AV as a replacement.

If these individuals determine that the concern **does not** fall within the IACUC's jurisdiction, the matter shall be referred to the appropriate office/unit at Radford University for further investigation.

If these individuals determine that the concern **does** fall within the IACUC's jurisdiction, they shall determine whether the matter must be addressed immediately (as in the case of animals reported to be in immediate jeopardy) and take immediate actions to protect the welfare of the animals in question. The IO will also be informed about the alleged noncompliance issue and receive continued correspondence as the IACUC starts its investigation process.

Should an animal welfare matter require an immediate response, the AV, often in consultation with the IACUC Chair, RCO, and IO, is authorized to halt any activity to protect the well-being of the animal program until additional assessments can be made. These efforts could include a temporary suspension of animal research activities associated with the PI's protocol, the PI's animal research privileges, and/or a temporary suspension of a PI's access to the ACSAT or CHBS vivaria and field activities. If a PI's access to animals is suspended, the RCO will work with the AV and the IACUC Chair and Vice-Chair to ensure that appropriately trained researchers are assigned to care for the animals during the investigation process.

The report of noncompliance will be announced at the subsequent IACUC meeting, during which the **Animal Care and Use Compliance Committee (ACUCC)** will be charged with reviewing and investigating the concerns and reporting its finding to the IACUC at a later date. Depending on the nature and severity of the alleged noncompliance, a special IACUC meeting can be called to address the issue.

The PI and the IO will receive an official letter from the RCO that informs them that the IACUC has initiated an official investigation based on the report of alleged noncompliance. The letter will also provide details about the membership of the ACUCC, a copy of the noncompliance report, and supporting materials that initiated the investigation. The report and supporting evidence will be redacted, if needed, to protect the anonymity of the whistleblower or complainant. In certain circumstances determined by the IACUC Chair, AV, and IO, the PI's immediate supervisor (Department Chair) and College Dean may also be notified and provided with the same materials.

ACUCC Noncompliance Investigation

The ACUCC's investigation will continue until all necessary and relevant information has been gathered. The evidence obtained could include, but will not be limited to, email correspondence with the RCO and IACUC, whistleblower reports, pictures, door swipe access logs, and recorded interviews conducted with individuals with knowledge of alleged noncompliance. The ACUCC and the RCO will protect all whistleblowers who have brought forth reasonable belief charges and evidence of noncompliance and animal welfare from retaliation by redacting any information that reveals the identity of the whistleblowers from the final report drafted at the investigation's conclusion.

Once all evidence has been gathered and evaluated, a final report will be drafted by the ACUCC and sent to the PI and the IACUC for review. The PI and IACUC will be given **(5) five business days** to carefully review and prepare comments and responses to the allegations included in the report.

IACUC Noncompliance Review Meeting

A closed IACUC meeting will be convened after the **five (5) day period**, during which the PI will be invited to present a defense of the allegations to IACUC members. Once the PI has provided initial responses to the allegations in the report and answered follow-up questions from IACUC members, he or she will be asked to leave the meeting to allow the IACUC to make further deliberations.

The remainder of the noncompliance review meeting will be spent discussing the report's contents, the PI's testimony, and determining the IACUC's response to the report of noncompliance. This meeting can be in-person or virtual and will be recorded and transcribed by the RCO. The transcriptions from the meeting will be saved and become a part of the final draft of the report sent to the IO.

A primary goal of the IACUC during the latter half of this meeting will be to determine if “the evidentiary standard or burden of proof that most commonly applies to the IACUC and animal care settings” has been met and whether the noncompliance activity in question represents “a substantial deviation from accepted norms” (Hansen et al., 2017, p. 4221). The possible recommendations available to the IACUC are as follows:

1. There is no evidence to support the concern or complaint of animal welfare breaches or serious risks thereof.
2. Certain aspects of the animal care and use program should be further reviewed.
3. The allegations are valid; however, no additional action is needed after correcting the inadvertent error or issue.
4. The allegations are valid, and actions to prevent recurrence may include but are not limited to possible modification of the protocol or temporary or indefinite suspension of the respondent’s animal use privileges.

Suspension of a respondent’s animal use privileges requires a majority IACUC vote and will only be used for egregious acts, “including willful and significant noncompliance with federal animal welfare-related regulations or the failure of the respondent to cooperate in a manner that negatively affects animal welfare or that is a significant risk of doing so” (Hansen et al., 2017, p. 4222).

Other corrective actions that also require an IACUC vote could include “mandatory training, changes in administrative or management processes to prevent a recurrence, appropriate amendment to the animal use protocol, regular reports of the respondent to the IACUC, discussions (counseling) with the IO or other institutional management, official letters of reprimand, and direct veterinary or IACUC oversight or monitoring of animal procedures and record-keeping” (Hansen, et al., 2017, p. 4222).

Additional Review and Investigation Considerations

According to Hansen et al. (2017), “the IACUC may, as a result of its review, find evidence that violations of non–animal-related institutional policies and procedures, local, state, or federal statutes, regulations, or laws may have occurred—for example, scientific misconduct, misuse of monies, fraud, or theft. In such cases, those violations may be referred to the appropriate IO or committee” for further investigation (Hansen, et al., 2017, p. 4222).

Once the IACUC has reviewed the details of the respondent’s testimony and any evidence presented in the report from the ACUC subcommittee, it will make a final decision and recommendation, both of which will be supported by a majority vote.



Notification of Final Decision and Appeals Process

The IACUC's final decision and recommendations will be included in an official letter drafted by the RCO that will be sent to the respondent, AV, the IO, and, if needed, the respondent's Department Chair, and Dean.

The PI will be granted the right to an appeal to the IO within ten (10) business days of receiving the IACUC's final decision letter. The PI's request for an appeal process cannot challenge the IACUC's final ruling. The appeal can only present evidentiary challenges regarding the process followed by the IACUC and "whether the inquiry or investigation was conducted without bias and with respect for due process to the respondent, whether the process followed the rules, whether the regulations were correctly applied, whether the findings were accurate, and whether there were errors of interpretation or inappropriate corrective actions" (Hansen, et al., 2017, p. 4223).

If the IO determines that an investigation into the appeal is warranted, a separate committee with no connection to the IACUC will be charged by the IO to investigate and make a final determination of the appeal filed by the PI.

Appendix A – Definitions

Adverse Event

An unexpected incident that leads to harm or endangers the well-being of animals and/or humans.

Allegation

A reported concern that may potentially be an incident of noncompliance, an unanticipated adverse event, or a circumstance that may endanger the well-being of an animal and/or human. The report may be a written (i.e., using the Radford University Whistleblower Report form or email) or oral communication to any Radford University animal care and use program/IACUC member.

Animal Care and Use Compliance Committee (ACUCC)

A subcommittee of IACUC members comprised of the Attending Veterinarian, the IACUC Chair or Vice Chair, IACUC member (scientist), and another IACUC member (non-scientist or non-affiliated). This committee will be established at the beginning of each year and tasked with conducting the initial assessment of an allegation and, if needed, drafting a report for IACUC review.

Anonymous Reporting

A situation in which reporters or whistleblowers report alleged noncompliance through the online reporting system without providing their contact information or identifying information. While all reports submitted regarding noncompliance will remain confidential, it is up to the reporters or whistleblowers to determine if they want to remain anonymous to all university and IACUC officials.

Complainant

The individual who makes the complaint or allegation of noncompliance against a respondent.

Confidential Reporting

A situation in which reporters or whistleblowers report alleged noncompliance to a designated university and IACUC official, in person or by voluntarily providing contact information through the online reporting system. This implies that the official to whom the report is made will ensure that he or she protects their identity. All whistleblowers and reporters will remain confidential regardless of whether they make reports in person or through the online system.

Continuing Noncompliance

As defined by the *Guide for the Care and Use of Laboratory Animals*, an action of either minor or major noncompliance that repeatedly occurs without efforts to correct the noncompliance.

Inquiry

Inquiry is an official period to collect information about an allegation or report. The purpose of the *inquiry* is to decide if an allegation or report warrants an ACUC *investigation* (see below). If a determination is made to proceed to an investigation, all parties must be notified, including, when possible, the individual(s) who reported the allegation that initiated the inquiry.

Investigation

Process that begins after an inquiry determines that an allegation warrants a formal investigation. It initiates a charge for the ACUC to conduct a formal evaluation and examine of all relevant facts and evidence to determine, for example, whether noncompliance occurred and, if so, who is responsible, the incident's significance, and the appropriate corrective actions to be taken.

Major Noncompliance

Serious noncompliance is any noncompliant event that harms the welfare of an animal and/or human, and/or directly conflicts with federal standards governing animal activities, including provisions of the Occupational Health and Safety Program. In these cases, the IACUC and AV may request that all animal work be immediately halted pending a review.

Minor Noncompliance

As defined by the Guide for the Care and Use of Laboratory Animals, a deviation from approved procedures, regulations, or guidelines that do not pose a significant potential for causing harm to the health or safety of an animal or to personnel working with animals.

Report

Reports are verbal or written notices of concern relating to aspects of the Radford University Animal Care and Use Program. Reports are not limited to allegations of noncompliance and may be associated with, for example, an adverse event.

Respondent

Any persons against whom noncompliance allegations are directed.

Suspension

Both the AWRs and PHS Policy authorize the IACUC to suspend activity for cause, for example, to halt or prevent an imminent threat to animal welfare or continuing harm to an animal. The AV can temporarily suspend activities if warranted. However, an activity can only be permanently suspended by a majority of a quorum of the IACUC during a convened meeting; a quorum is one more than half of the total committee (a majority of the members of the IACUC). Activity refers to any action that involves animals, such as research, research training, monitoring, care and management, experimentation, teaching, biologic testing, holding, or quarantine. (Hansen et al., 2017)

References

Animal Welfare Regulations [9 CFR 2.31\(c\)\(4\)\(d\)\(\(6\)](#)

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REVISION HISTORY

Revision	Summary of Revisions	Revision Date