

The College of New Jersey
Institutional Animal Care and Use Committee

**Guidelines for Concerns Involving the Care and Use of Vertebrate Animals and
Noncompliance**

Regulatory authority:

- The Animal Welfare Act (7 U.S.C. 2142;Section 13)
- Animal Welfare Regulations (9 CFR Part 2, Subpart C, Section 2.32(c)(4)
- The USDA, Animal Plant and Health Inspection Services, 9 CFR Chapter 1, 1-1-92 Edition
- Public Health Services Section III, D.4. Assurance of Compliance Policy on Humane Care and Use of Laboratory Animals

A. Definitions

1. **Animals** – When used without qualification this term refers specifically (and only) to live vertebrate animals.
2. **Attending Veterinarian** – The veterinarian responsible for the health and welfare of all vertebrate animals used at the institution.
3. **Complainant** – An individual who expresses a concern about a perceived mistreatment of animals or noncompliance with College or IACUC policy related to the use of vertebrate animals in teaching or research at The College of New Jersey.
4. **Concern** – Any written or oral statement or other indication of possible mistreatment of animals and/or noncompliance made to a College official.
5. **IACUC** – The Institutional Animal Care and Use Committee.
6. **Institutional Official** – The individual who bears ultimate responsibility for the animal care and use program, for resource planning, and for ensuring alignment of program goals with the institution's mission.
7. **Mistreatment** – Abusive or wrongful physical or psychological treatment of an animal that may include, but is not limited to, striking the animal or otherwise inflicting physical pain or harm; performing a surgical procedure without adequate anesthesia or analgesia, not providing adequate food, water, or clean cages or bedding materials, overcrowding cages or unnecessarily restraining the animal without justification.
8. **Injurious Noncompliance** – Occurs when a Principal Investigator or others involved in animal husbandry or research conduct painful, distressful, or invasive procedures on an animal without IACUC approval, or when the investigator does not follow procedures approved by the IACUC that results in increased risk of pain, distress, morbidity or mortality. Examples of injurious noncompliance may include, but are not limited to:
 - a. Performing surgery or other painful procedures without proper anesthesia
 - b. Performing unauthorized surgery

- c. Use of excessive animal restraints
- d. Use of drugs not previously approved for the protocol
- e. Use of unapproved methods of euthanasia
- f. Permitting untrained or unauthorized personnel to perform invasive or potentially painful or distressing procedures
- g. Failure to provide habitable living conditions and/or adequate food and water to animals
- h. Failure to report to the Attending Veterinarian any unexpected adverse events that result in increased pain, distress, morbidity or mortality to an animal

9. Non-injurious Noncompliance – Occurs when a Principal Investigator or others involved in animal husbandry or research using vertebrate animals conduct this research without IACUC approval, even if the animals do not suffer pain, distress, morbidity or mortality. Non-injurious noncompliance also pertains when the investigator does not follow IACUC-approved procedures that have an impact on the animal with no increase in the risk of pain, distress, morbidity, or mortality. Examples of non-injurious noncompliance may include, but are not limited to the following activities if they do not increase the risk of animal pain, distress, morbidity or mortality:

- a. An unauthorized change in the purpose or specific aim of a study
- b. An unauthorized change in the Principal Investigator
- c. An unauthorized change in the animal species used
- d. A significant increase in the number of animals used without IACUC approval
- e. Modifications (even minor) to approved surgical procedures
- f. An unauthorized change in the type or dosage of drugs used
- g. An unauthorized additional behavioral or noninvasive sampling procedure
- h. Failure to submit a protocol modification for IACUC review and approval prior to implementing the modification

10. Administrative Noncompliance – Any act that does not directly impact the physical or psychological welfare of vertebrate animals but otherwise fails to comply with College or IACUC guidelines related to the care and use of these animals at The College of New Jersey. Administrative infractions are addressed directly by the IACUC as part of its regular business rather than through a preliminary hearing and investigative process. Examples of administrative noncompliance may include, but are not limited to:

- a. Failure to complete and submit reports and other paperwork in accordance with IACUC procedures and timelines
- b. Failure to follow administrative instructions given by the IACUC, the IACUC Chair, or the Attending Veterinarian, or the Office of Sponsored Research and Grants Administration
- c. Failure to comply with all terms and conditions of protocol approval
- d. Failure to consult with the Attending Veterinarian and the IACUC Chair before procuring animals
- e. Failure to submit a request in adequate time for continuing review of an active protocol prior to protocol expiration
- f. Failure to adhere to applicable environmental, health, and safety regulations and guidelines

11. Noncompliance Oversight Group – A group consisting of the IACUC Chair, the Attending Veterinarian, and at least one other designated member drawn from the IACUC. For individual

cases, *ad hoc* members drawn from either inside or outside the IACUC who have specific qualifications that are relevant to accurately assessing a reported concern may be appointed to the Noncompliance Oversight Group.

- 12. Principal Investigator** – The individual with overall responsibility for ensuring that the conduct of activities within their research or teaching protocols at The College of New Jersey adhere to all applicable College, local, state, and federal regulations related to the use of vertebrate animals in research or teaching.
- 13. Protocol** - A detailed description of the proposed use of vertebrate animals for research or teaching that must be approved by the IACUC prior to implementation.

B. The College of New Jersey Institutional Animal Care and Use Committee Policy

- 1. Introduction.** The College of New Jersey IACUC will review or look into all concerns relating to the care and use of vertebrate animals brought to their attention. Concerns can be those relating to any use of animals for research, teaching, or demonstration purposes and may include claims from the public, College faculty, students, or staff. Concerns may include but are not limited to allegations of mistreatment, violation of approved protocols, use of animals without an approved protocol, non-adherence to any applicable policy related to vertebrate animals, regulations or adopted guidelines, complaints regarding care provided to animals in College laboratory or animal facilities, or complaints regarding animals studied in the wild.
- 2. Confidentiality of Complainant**
 - a.** The College of New Jersey adheres to the regulatory authority of the Animal Welfare Act, Section 2.32(c)(4). This document states *“No employee (staff, faculty), IACUC member, or student shall be discriminated against or be subjected to any reprisal for reporting violations of the regulations or standards of the Animal Welfare Act, or expressing concerns they may have regarding mistreatment of animals used in research or teaching.”*
 - b.** In addition, under the College’s [Reporting and Non-retaliation Policy](#), members of the College community are encouraged to report good faith concerns about possible College-related violations of laws, regulations, or College policies. Under this policy, retaliation against members of the College community who make good faith reports regarding potential College-related violations of laws, regulations, or College policies is prohibited.
 - c. Confidentiality Policy:** When a complainant’s identity is known, the IACUC will acknowledge receipt of concerns. To the extent allowable under state and Federal law, and Institutional policy, details concerning any complainant, the identity of the complainant, the identity of the persons against whom allegations have been directed, and any investigations in progress, will generally be considered confidential. If the complainant specifically requests confidentiality, only the Noncompliance Oversight Group will know the identity of the complainant. In this case, the complainant’s name, and information identifying the complainant, will be redacted from all documentation forwarded to the IACUC as a whole or any subcommittee inquiring about the concern. All members of the investigation will strictly enforce the standards of the Animal Welfare Act Section 2.32(c)(4) above. However, when the Noncompliance Oversight Group or the IACUC releases the report of its findings, including any corrective actions that may have been taken, those reports may become accessible to the public under state “sunshine laws”, or, if reported to Federal regulatory agencies, under the Freedom of Information Act.

3. Conflict of Interest

- a. If a member of the full Committee is included in the concern, the person will not participate in the process in their role as an IACUC member. However, if the Committee member is the Principal Investigator included in the concern, then the person will be required to follow the same procedures noted below relating to Principal Investigators.
- b. If a member of the Noncompliance Oversight Group is included in the concern, then the person will not participate in the process in their role as part of the Noncompliance Oversight Group or the IACUC. However, if the Committee member is the Principal Investigator included in the concern, then the person will be required to follow the same procedures noted below relating to Principal Investigators. The Chair will appoint a Committee member to serve on the Noncompliance Oversight Group for the review of the concern.
- c. If the IACUC Chair is included in the concern, then another Committee member will be appointed by the Institutional Official to serve as an *ad hoc* Vice-chair to address this concern with the IACUC and the Noncompliance Oversight Group. If the IACUC Chair is the Principal Investigator included in the concern, then the person will be required to follow the same procedures noted below relating to Principal Investigators.

4. Steps in Reporting A Concern

- a. **Initial Step:** If an individual believes an activity is inappropriate, the most direct way to deal with the problem is to speak to the persons involved (e.g., Principal Investigator, technician, student, etc.). Those not familiar with animal research may misinterpret some procedures as painful or distressful when in fact it is not the case. If for any reason the individual does not wish to speak directly to those involved with the activity, or the question or concern is not adequately addressed by those involved in the activity, then it is appropriate to continue to pursue the question or concern as described below. However, concerns through the formal complaint process will not be considered unless those concerns are provided in writing, in accordance with the provisions set forth in B.4.c., below.
- b. **Point of First Contact:** An individual may elect to discuss the question or concern with any of the following IACUC personnel:
 1. The Chair of the IACUC
 2. A member of the Noncompliance Oversight Group
 3. An IACUC Committee member
 4. The Attending Veterinarian for TCNJ

The names and contact information for the IACUC Chair and the Attending Veterinarian may be obtained on-line at: <http://www.tcnj.edu/~iacuc/>

- c. **Registering a Formal Complaint:** A formal complaint should be sent to the IACUC Chair at: iacuc@tcnj.edu. The following information must be provided in the letter:
 1. The complainant's name
 2. The complainant's contact information
 3. The individual(s) or Principal Investigator's laboratory from which the concern arose
 4. A description of the event and date or time period of the incident
 5. The signature of the complainant
- d. **Alternative Method for registering a complaint:** Individuals who have concerns, but are unsure whether they want to file a formal written complaint may contact a member of the

Noncompliance Oversight Group. The Noncompliance Oversight Group may elect to follow up by means other than the formal complaint process if a written complaint is not submitted.

5. Inquiry

- a. The Chair of the IACUC will immediately forward all formal complaints to the Noncompliance Oversight Group. In conjunction with the Attending Veterinarian, the IACUC Chair may appoint *ad hoc* members to the Noncompliance Oversight Group with specific areas of expertise to look into the concern, and impose a specific completion date for an initial review of the concern. The initial review will take no more than sixty (60) days to complete.
- b. The Noncompliance Oversight Group will investigate the concern. In most cases, the complainant (if known) will be interviewed, the Principal Investigator will be asked to meet with the Noncompliance Oversight Group, the animals in question and their environment will be observed in light of the reported concern, and any relevant documents or records (e.g. health records, approved protocols, etc.) will be reviewed. A written report will be prepared within sixty (60) days by the Noncompliance Oversight Group and sent to the IACUC Chair for distribution to the Committee for consideration and further action, if necessary. The report to the IACUC will include a summary of the concern, the results of any interviews, a description of the animals and their environment, and the results of any record and document review. During the preparation and subsequent dissemination of this report, the confidentiality policy outlined in section B.2 will be followed. The IACUC Chair will maintain detailed minutes of all meetings relevant to the discussion and resolution of the concern.

6. IACUC Actions

- a. The concern will be reviewed within thirty days of submission of the Noncompliance Oversight Group report. However, where significant concerns warrant immediate action to protect the welfare of animals, the Chair will convene an emergency meeting at the earliest possible date. If it is not possible to convene an emergency meeting within a reasonable timeframe, the Attending Veterinarian may stop the research activities until the IACUC can meet to review the concern.
- b. The Noncompliance Oversight Group will inform the IACUC of its investigation and provide the Committee with a written summary of its findings. The Principal Investigator will be invited to attend the IACUC meeting to discuss the concern. This will provide an opportunity for the Principal Investigator and the Committee to resolve any misunderstandings and work together to find solutions to the alleged concern.
- c. After discussing the matter and hearing any input from the Principal Investigator, the IACUC may take action or it may request additional information before taking action. The IACUC will vote on the actions that are to be taken. A quorum must be present for a valid vote and a majority of the quorum must be in favor for the proposed action to be pursued. All minority viewpoints will be recorded. Actions may include, but are not limited to the following:
 1. Dismissing the complaint.
 2. Mandating specific training aimed at preventing future incidents.
 3. Requiring an amendment to the IACUC approved protocol.

4. Requiring a change in procedures previously approved by the IACUC in an animal protocol or facility standard operating procedure.
 5. Requiring a previously approved protocol to be re-submitted.
 6. Requiring increased oversight via unannounced inspections of laboratory or animal facility work areas. Additional conditions, training, monitoring or restrictions may also be required.
 7. Suspension of all or parts of the research activity within approved protocols.
- d. If the investigation determines that facts exist that warrant the referral to another appropriate College process (e.g., Research Misconduct), the Noncompliance Oversight Group shall refer the allegation to the appropriate College personnel (e.g., Sponsored Research Compliance Committee).
- e. Actions will be documented as follows:
1. The Chair of the IACUC will ensure that the Principal Investigator submits any needed amendments or protocol revisions, and that any additional conditions are fulfilled in the stipulated timeframe, as designated by the IACUC. The Chair will inform the IACUC of the progress of the Principal Investigator toward addressing the concern.
 2. The IACUC Chair will provide the Principal Investigator with a letter stating the outcome of the IACUC's deliberations on the situation, and noting what agencies, if any, would be notified.
 3. The IACUC Chair will provide the complainant, if known, with a summary of the actions taken by the IACUC, but any confidential information concerning protocols will not be included.
 4. The Institutional Official will receive a summary of the reported concerns, the Noncompliance Oversight Group and IACUC response to those concerns, as well as any IACUC actions taken.
 5. The Institutional Official, in consultation with the Office of General Counsel and the Office of Grants and Sponsored Research, will provide OLAW with a full explanation and actions taken with respect to: 1) any serious or continuing noncompliance with PHS Policy; 2) any serious deviations from the provisions of the *Guide for the Care and Use of Laboratory Animals*; or 3) any suspension of an activity by the IACUC. A report to OLAW will be made regardless of funding source for the research. Relevant granting agencies (e.g. NIH, NSF, USDA, private foundation, etc.) will also be informed, as appropriate.
 6. The IACUC Chair will maintain the documentation regarding the matter in a secure location.

Approved by The College of New Jersey Institutional Animal Care and Use Committee on [insert date]