

NCSU IACUC Policy on Animal Welfare Concerns and Noncompliance Situations

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1.0 Evaluation of Animal Care and Use Concerns

To help ensure that animals used in research and teaching activities receive humane care, use, and treatment in accordance with the highest ethical standards, laws, regulations, and policies, the Institutional Animal Care and Use Committee (IACUC) must review and, if warranted, address any animal-related concerns raised by the public, students, or institutional employees. This document establishes procedures to ensure that concerns are communicated to the IACUC. The Committee must review each concern in a timely and systematic manner and, when necessary, take prompt, appropriate corrective actions. The following sections outline the policies and procedures for reporting and evaluating animal welfare concerns and noncompliance situations at North Carolina State University.

Any suspected concerns of noncompliance related to animal care and use with regard to animal housing and use facilities, husbandry, animal use protocols, management, or security should be reported.

1.1 Methods for Reporting

To facilitate reporting, there are a number of avenues available to communicate concerns about animal care and use at North Carolina State University, or to report instances of suspected noncompliance with laws, rules, regulations, and policies. The phone numbers of contact persons including the IACUC Chair, University Attending Veterinarian, and the IACUC Administrator are posted:

- 1) in or near the entrance to animal holding, procedure, and treatment facilities and

- 2) on the NCSU IACUC website:
<http://www.ncsu.edu/iacuc/noncompliance.php>

It is helpful for the Institutional Animal Care and Use Committee to have as much information as possible in order to conduct a thorough investigation.

All complaints or concerns registered will be documented and investigated as thoroughly as possible. Reports may be made anonymously and, to the extent that it is possible, the University will preserve the anonymity of individuals reporting the complaint or concerns, as well as the anonymity of anyone against whom allegations are directed.

The USDA Animal Welfare Regulations and North Carolina law provide specific protection for employees, IACUC members, or laboratory personnel against discrimination or other reprisals for reporting violations of the Animal Welfare Act.

1.2 IACUC Procedures for the Investigation of Animal Care and Use Concerns

1.2.1 Initial Evaluation and Actions

The **first step** in the process of the evaluation of animal care and use concerns is to forward any allegation(s) to the IACUC Chair.

Potential situations and initial actions include:

- 1) Conditions outside those described in IACUC-approved protocols that reportedly jeopardize the health or well-being of animals will be evaluated immediately. To cope promptly with such situations, the University Attending Veterinarian is authorized to halt procedures which place animals in immediate danger until the IACUC can be convened and consider the matter formally.
- 2) Situations that may involve potential criminal activity or human safety should be reported promptly to the institution's law enforcement or occupational health and safety officials.
- 3) Allegations of other ongoing policy or procedural matters may not require such same-day attention, but should not be deferred merely as a matter of convenience. Emergency meetings may be necessary in these cases to ensure prompt consideration of concerns.

Whether the initial action required an immediate response, mandatory cessation of activities, or is ongoing in nature, upon receipt of a concern, the IACUC Chair will appoint a subcommittee to expeditiously conduct an initial evaluation of the concern and impose a completion date for the initial evaluation. After initial review of the complaint, a report will be made to the IACUC to determine whether the complaint requires:

- 1) further investigation and immediate action;
- 2) further investigation, but no immediate action; or
- 3) no action.

The IACUC Office must notify affected individuals or other institutional or non-institutional offices at this time (i.e. principal investigator, animal facility administration, department head, associate dean and dean, as applicable).

The IACUC Chair should immediately notify the Institutional Official (IO) if any of the following actions have been taken to protect animal or human welfare:

- 1) veterinary medical intervention;
- 2) suspension of a research activity; and/or
- 3) notification of appropriate safety, occupational health, or other officials.

In accordance with this Institution's Animal Welfare Assurance Statement (http://www.ncsu.edu/sparcs/iacuc/docs/Assurance_2007.pdf), if an activity is suspended by the IACUC, and if the activity is supported in any way by the Public Health Service (PHS), the IACUC, through the IO, must promptly notify the Office of Laboratory Animal Welfare (OLAW) and any federal agency funding the research. Prompt reporting guidance can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>. If the suspended activity involves the use of USDA-regulated species, the suspension must also be reported to the Animal and Plant Health Inspection Service (APHIS).

1.2.2 Investigation

If the IACUC determines that further investigation is required, the Chair, or another individual or the subcommittee appointed by the Chair, will conduct the investigation and report back to the IACUC. Members of the investigating subcommittee will be chosen to avoid actual or perceived conflicts of interest.

The IACUC Chair will charge the designated person or group with the IACUC's requirements for information gathering and impose a completion date. The assigned completion date will depend on the IACUC's determination of whether immediate remedial action may be required.

The nature of the information required will vary depending on the circumstances, but often involves:

- 1) interviewing complainants (if known), any persons against whom allegations were directed, and pertinent program officials;
- 2) observing the animals and their housing and experimental environment; and
- 3) reviewing any pertinent records, (e.g., animal health records, protocol, and

other documents).

The designated investigator(s) will provide a report to the IACUC, which includes:

- 1) the reported concern(s);
- 2) the results of interviews;
- 3) the condition of animals and their housing and experimental environment;
- 4) the results of records and other document reviews;
- 5) any supporting documentation such as correspondence, reports, and animal records;
- 6) conclusions regarding the substance of the concerns in relation to the requirements of the Animal Welfare Regulations, the *PHS Policy*, the *Guide*, and institutional policies and procedures;
- 7) if the complaint is related to an injury or illness, a statement on the condition of the individual(s), the circumstances related to the injury or illness, and the prognosis; and
- 8) recommended actions, if appropriate.

1.2.3 Outcomes and Final Actions

Upon receipt and evaluation of the report, the IACUC may:

- 1) request further information,
- 2) find that there was no evidence to support the concern or complaint,
- 3) find that the concern or complaint was not sustained, but
 - a) related aspects of the animal care and use program requires further review or
 - b) other institutional programs may require review, or
- 4) find that the concern or complaint was valid.

Following the final action(s) of the IACUC, the IACUC Chair will advise the person(s) who reported the concern that the investigation of the concern has concluded. All individuals previously notified (i.e. principal investigator, animal facility administration, department head, associate dean and dean, as applicable) shall also be notified of the outcome in separate correspondence in order to maintain the reporter's anonymity.

1.3 Noncompliance with IACUC Protocol, Policies, Procedures, or Decisions

Noncompliance may be verified following a complaint and investigation, as outlined in the previous sections, or also could be determined due to protocol noncompliance. Protocol noncompliance indicates that procedures or policies approved by the IACUC are not being followed.

When faced with protocol noncompliance, the IACUC's **first step**, if possible, will be to find a way to bring the protocol into compliance.

If allegations of animal mistreatment or protocol noncompliance are verified, the IACUC may apply sanctions.¹

1.4 Consequences of Noncompliance with IACUC Protocol, Policies, Procedures, or Decisions

- A. Actions of the IACUC that may be taken to resolve non-compliance matters include:
- 1) implementing institutional actions (explained, in Section B) to prevent recurrence;
 - 2) notifying relevant support departments impacted by the violations;
 - 3) notifying the Institutional Official and University Attending Veterinarian of its actions;
 - 4) notifying funding or regulatory agencies, as required; and
 - 5) notifying the complainant, any persons against whom allegations were directed, and pertinent program officials (appropriate supervisory and management staff, the public affairs office, institutional attorneys, etc.) of the non-compliance and directives to resolve.
- B. Some of the institutional actions that may be used to resolve and prevent future non-compliance and to revitalize the animal care and use compliance environment are:
- 1) require counseling in the proper use and care of animal subjects;
 - 2) require specific training aimed at preventing future incidents of protocol non-compliance;
 - 3) issue letters of admonishment outlining corrective actions, including but not limited to temporary or permanent revocation of rights to use animals in research, testing or training projects;
 - 4) monitoring by the IACUC (or designee(s)) of research, testing, or training that involves the care and use of animals;
 - 5) testing, or training that involves animals, pending compliance with specific, IACUC-mandated conditions;
 - 6) recommending to the Institutional Official that additional institutional sanctions be imposed (e.g., reassignment, termination of employment).

¹ If, in the opinion of the IACUC, sanctions are not appropriate, they need not be applied. A clearly minor and unintentional misinterpretation of an IACUC policy which has created no problem for an animal is an example of where a verified allegation of protocol noncompliance might lead to an explanation, not a sanction.

1.4.1 Suspension of Animal Activities

Suspension of Animal Activities

The IACUC is empowered to suspend a project if it finds violations of the PHS Policy (<http://grants.nih.gov/grants/olaw/references/phspol.htm>), Assurance (http://www.ncsu.edu/iacuc/docs/Assurance_2007.pdf), or Animal Welfare Regulations (http://www.aphis.usda.gov/animal_welfare/downloads/awr/awr.pdf). Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with the suspension vote of a majority of the quorum present. Further, the IACUC must inform the Institutional Official regarding the reasons for the suspension, the actions taken and any further recommended administrative actions. The Institutional Official will take the appropriate corrective action and promptly report the action and the circumstances surrounding the suspension to the federal Office of Laboratory Animal Welfare (OLAW), per the conditions of NCSU's Animal Welfare Assurance Statement.

1.4.2 Reporting Noncompliance, *Guide* Deviations, and Suspensions

Circumstances that must be reported to OLAW by the Institutional Official, without delay, are: serious or continuing noncompliance with the PHS Policy; serious deviations from the *Guide for the Care and Use of Laboratory Animals* (constituting violation of PHS Policy and noncompliance with our Assurance); and IACUC suspensions.

Examples of reportable situations can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>