

IACUC Policy on Noncompliance Investigation Procedures

Purpose

The following is the University of Alaska Anchorage (UAA) Institutional Animal Care and Use Committee (IACUC) policy on noncompliance investigation procedures, in accordance with the [Animal Welfare Act](#), the *Guide for the Care and Use of Laboratory Animals*, the IACUC's Federal Wide Assurance, and [Public Health Service \(PHS\) Policy](#). Noncompliance is a deficiency, either major or minor, in a research activity which is not in accordance with the policies and regulations previously cited. The committee is mandated to review allegations of animal welfare misconduct and research protocol noncompliance. All allegations of noncompliance are treated as a noncompliance unless determined otherwise. In the event of an investigation, the Institutional Official works collaboratively with the IACUC to ensure that PHS Policy is being followed.

Policy Definitions

1. *Noncompliance*: The term "noncompliance" means the failure to comply with accepted standards and regulations set forth by institutional, local, state, and federal policies.
2. *Complaint*: The term "complaint" means a written or verbal statement in which a person or persons are not satisfied with a situation.
3. *Allegation*: The term "allegation" means an assertion that must be supported and proved with evidence of noncompliance unless determined otherwise.
4. *Suspension*: The term "suspension" means that any suspended research activity must be stopped. Furthermore, the activity does not have approval until further notified by the IACUC. A suspension may be temporary or final, depending on the outcome of the suspension.

General Principles

1. *Lines of Authority*

Per PHS Policy (section IV.C.6-7), the IACUC is authorized to suspend animal research during a convened meeting with a quorum of voting members. Additionally, the attending veterinarian may suspend a research project if, in their professional opinion: an eminent threat to animal welfare or public safety exists, or if a principal investigator is not following approved procedures. If research activity is suspended, the Institutional Official does not have the authority to override sanctions imposed by the IACUC and only the IACUC can repeal a suspension.

2. *Confidentiality*

The IACUC will ensure that confidentiality is maintained throughout an investigation. Under the Animal Welfare Act, any person(s), who submits the complaint, will *not* receive reprisals for submitting the complaint to the IACUC (AWRs section 9 CFR Part 2, Subpart C, Section 2.32(c)(4)). Details regarding the progress of the investigation, including the complaint and the complainant, are considered confidential. The IACUC acknowledges that false allegations can jeopardize the integrity of the institution, employees, and research.

3. *Reporting Timeline*

In general, the complaint should be submitted to the IACUC Chair but a person, who wishes to report an allegation of noncompliance, should notify any appropriate individual (see “Reporting Allegations of Noncompliance”) promptly. If the complaint rises to the level of possible noncompliance, the IACUC Chair will convene an emergency meeting of the UAA IACUC as soon as possible. The IACUC will work to ensure a timely response to an allegation. The researcher against whom the allegation is made will be contacted. If the researcher does not respond in a timely manner or does not acknowledge the IACUC’s concerns, the appointed subcommittee may contact the researcher’s superiors (e.g., Department Chair, Director, or Dean about the allegation and may request their assistance to resolve the matter).

Reporting Allegations of Noncompliance - Whistleblowing

The general public, institutional employees or students should report allegations of noncompliance to any of the following individuals: the Attending Veterinarian, IACUC Chair, Institutional Official, or IACUC member (see the IACUC web site: <http://www.uaa.alaska.edu/research/ric/iacuc/index.cfm>). Allegations can be issued verbally or as a written document. Whistleblowers are not required to be identified for an allegation to be submitted; however, it is the responsibility of the person(s) receiving the complaint to fully document all communication regarding the allegation in order to prevent miscommunication. Documentation should include the time and date of the complaint, description of the complaint (including time and date of any observations that raise concern), and why the complaint is being made.

Investigation Procedures

1. Initial Evaluation and Action

- A. Once the IACUC is notified of alleged noncompliance, the IACUC will hold a meeting to determine one of the following actions:
 - a) further investigation with immediate action (e.g. suspension),
 - b) further investigation but no immediate action (e.g. inquiry),
 - c) or no action.

The IACUC must report suspended activity to the Institutional Official, who then contacts [Office of Laboratory Animal Welfare](#) (OLAW) with the corrective action (PHS Policy, IV.F.3.).

- B. If the IACUC Chair is perceived to have a conflict of interest, the Institutional Official will delegate the responsibility of the investigation to a non-conflicted IACUC member.
- C. The Institutional Official, legal counsel, complainant, and the person against whom the complaint is being made, may be invited to participate in the investigation.

2. Inquiry

- A. The IACUC Chair may serve as the primary contact in order to execute an inquiry. The Chair may also appoint a subcommittee to participate in the inquiry. While an inquiry may not result in a suspension of research activity, the IACUC may determine that corrective action is justified.

3. Suspension and Investigation

- A. An emergency meeting may be held in order to a) discuss an allegation of noncompliance or serious adverse event or b) determine whether an activity should be suspended. The UAA IACUC Chair may appoint a subcommittee in order to proceed with an investigation.
- B. If an investigation is warranted, the IACUC may need to collect information by any of the following means: a) interviews with people affiliated with the allegation, b) examine animals, and c) obtain surgical records, housing records, and any other relevant documentation.
- C. The [United States Department of Agriculture](#) (USDA) [Animal and Plant Health Inspection Service](#) (APHIS) Office requires that any suspended animal activity that involves USDA-regulated animals, such as dwarf hamsters or ground squirrels, be reported to APHIS immediately.

4. Outcomes of an Investigation

- A. It is the responsibility of the IACUC Chair, in consultation with the Compliance Office, to compile a final report for the Institutional Official. The Institutional Official is required by PHS Policy to submit the report to OLAW and, if applicable, funding agencies such as [National Institute of Health](#) (NIH) and USDA.
- B. In the report, the IACUC will determine one of the following actions:
 - a) There was no evidence to support the complaint.
 - b) The concern or complaint was not supported, but may require additional review of other components of the animal care and use program.
 - c) The complaint was valid and requires additional action from institutional administration and legal counsel.

- C. PHS Policy requires that the Institutional Official report any serious or continuing noncompliance to NIH.
- D. The Institutional Official will inform the whistleblower about the outcome of the investigation.
 - a) If the allegation is found to be malicious, or have ill intent, the outcome will be shared with appropriate institutional authorities.