Title: IACUC Non-compliance

1. PURPOSE
This policy applies to all elements of research, testing, and teaching procedures that involve the care and/or use of animals under the purview of the National Wildlife Research Center (NWRC) Institutional Animal Care and Use Committee (IACUC) in accordance with SOP AD003.

2. INTRODUCTION
As part of its mandate to ensure that all vertebrate animals are humanely cared for and used in accordance with the highest ethical standards, the NWRC IACUC reviews, approves, and monitors activities involving animals for conformance with all applicable laws, regulations, policies, and procedures. The IACUC is also responsible for reviewing and, if warranted, fully investigating allegations of animal mistreatment or protocol non-compliance. This policy provides a mechanism to respond to such allegations.

3. DEFINITIONS
Animal Mistreatment – Neglectful, abusive or wrongful physical or psychological treatment of an animal associated with animal-related activities.

Protocol Non-compliance – Failure of an individual involved in animal-related activities to follow applicable laws, regulations, policies, procedures, approved protocols, and/or directives. Typically, non-compliance refers to intentional, blatant disregard for policy, protocol or directive.

4. EXAMPLES
Examples of non-compliance include but are not limited to the following:

Conducting animal-related activities (including field studies) without an Attending Veterinarian consultation, without IACUC review and approval, or outside the study start and completion dates of the protocol approved by the Director’s Office.
APHIS Animal Care Policy:

a. (Policy #3) Failing to maintain appropriate animal-related records (e.g., identification, care, monitoring, medical treatment, procedures, and husbandry).

b. (Policy #3) Using outdated materials (drugs; experimental agents, suture, sterile supplies, etc.) or failing to follow proper technique which results in invalid data and requires activities with animals to be unnecessarily repeated.

Animal Welfare Regulations (9 CFR)

a. 2.31 (c)(6) - Conducting animal-related activities that have not been reviewed and approved by the IACUC. This includes trapping, transporting, research and other animal-related activities.

b. 2.31 (d)(1) – Implementing any significant change to animal-related activities that has not been reviewed and approved by the IACUC (e.g., change in study objectives, study director, animal species or sex, or number of animals used; or addition of non-invasive sampling, treatment, or procedures).

c. 2.33(b)(3) – Failing to convey information about problems with animal health, behavior, and well-being to the Attending or Consulting Veterinarian in a timely fashion.

d. 2.33(b)(4) – Failing to follow guidance from the Attending or Consulting Veterinarian regarding proper handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia of animals.

e. 3.125 - Maintaining animals in facilities with inadequate structural strength, water or electric power (if required), storage, waste disposal, or washroom and sinks.

5. PROCEDURE

Reporting
Any person may report allegations of animal mistreatment or protocol non-compliance to one or more of the following:

NWRC IACUC Chair (Steve Greiner, (970) 266-6169).
NWRC Attending Veterinarian (Gordon Gathright, (970) 266-6204).
NWRC Institutional Official (Larry Clark, (970) 266-6036).

Any NWRC official receiving a complaint regarding an alleged animal mistreatment or protocol non-compliance shall promptly notify the IACUC Chair and/or the Attending Veterinarian.

Immediate Action
Upon receipt of an allegation, the Attending Veterinarian or his/her designate will determine the seriousness and the potential for harm to the animals, and consult with the parties involved. This will enable provision of required and adequate veterinary care and/or husbandry.
Preliminary Review

Preliminary review is the first step in addressing an allegation of animal mistreatment or protocol non-compliance. The preliminary review shall be conducted by the IACUC Chair, or the Chair and the Attending Veterinarian and/or other IACUC members, as deemed appropriate by the Chair and excluding personnel with related conflicts of interest. The purpose of the preliminary review is to ensure that frivolous or uninformed allegations are dismissed.

As deemed appropriate by the IACUC Chair, the preliminary review may consist of confidential consultations with the informant, the respondent, potential witnesses, other IACUC members, and/or the Animal Care staff to determine the merits of the allegation. If no animal mistreatment or protocol non-compliance is determined by the IACUC Chair, no further review is required.

IACUC Review

If potential for animal mistreatment or protocol non-compliance is determined by the IACUC Chair, further review shall be conducted by the IACUC, as deemed appropriate by the Chair and excluding personnel with related conflicts of interest. The purpose of the IACUC review is to determine the presence or absence of animal mistreatment or protocol non-compliance.

A meeting of the IACUC shall be convened to review relevant materials, documents, and information gathered during fact finding interviews. Interviews may be conducted with the informant, the respondent, potential witnesses, Animal Care staff, or other individuals who might have information regarding key aspects of the allegation.

In order for a formal decision to be made at a convened IACUC meeting, a quorum of the IACUC members must first be present (e.g., >50% of the IACUC members must be present either in person or via conference call to establish a quorum). Decisions will be made based on the results of a majority (>50%) of the analogous votes cast from the quorum. If a quorum is not established then a vote cannot be taken and formal decisions cannot be made until a quorum of members can be assembled. Only official IACUC members can vote, and there will not be any substitutes or proxy votes allowed.

If a majority of the IACUC quorum determines that there is no animal mistreatment or protocol non-compliance, then no further consideration or action is required.

If animal mistreatment or protocol non-compliance is determined by a majority of the IACUC quorum, the following considerations will be required.

6. CONSIDERATIONS

When determining appropriate actions, the IACUC shall consider the following:

a. Extent to which harm or mistreatment of animals or personnel resulted from the incident(s).

b. Extent to which the incident(s) represents a repeated mistreatment of animals or protocol non-compliance.

c. Extent to which individuals demonstrated negligence or willful disregard.

d. Extent to which the incident(s) was self-reported by the Study Director or associated personnel.
e. Proactive corrective actions taken in response to the incident(s).
f. Whether the incident(s) violated federal regulations or institutional policies.

7. POTENTIAL ACTIONS
Upon a majority vote of the quorum, the IACUC may impose one or more of the following corrective actions (in a timely manner) to resolve the existing incident(s) and to prevent subsequent mistreatment of animals and protocol non-compliance.

For minor events:
- A meeting between the respondent and the IACUC Chair or the IACUC.
- Additional training for the respondent, or the respondent and associated personnel.
- Temporary assumption of the work by other personnel.
- Written warning from the IACUC Chair to the respondent with copies provided to the supervisor(s) and the Institutional Official.

For moderate events:
Recommendation to the Institutional Official that subsequent animal-related activities be restricted, as deemed necessary by the IACUC.

For significant or serious events:
- Suspension of ongoing animal-related activities.
- Recommendation to the Institutional Official that subsequent animal-related activities be suspended, as deemed necessary by the IACUC.
- Notification of violations to the appropriate authorities per the Animal Welfare Regulations.

Minutes of all IACUC meetings involving deliberations of alleged animal mistreatment or protocol non-compliance (and associated actions taken) will be included in the report of the corresponding semi-annual IACUC review.

8. UNAPPROVED MODIFICATIONS TO PROTOCOLS
In most instances when a study director deems an adjustment to an approved protocol is necessary, he/she can follow the current procedure of contacting the Chair and procuring an approved amendment. It is not the intent of the IACUC to sanction any unapproved adjustments to approved protocols or amendments (SOP AD 003). However, the Committee recognizes that in extremely rare instances, studies may take place in areas where communications are not readily available and Study Directors must make an on-the-spot adjustment (unapproved modification) to an existing protocol when animals are adversely affected or proposed methods prove unrewarding. In other instances, study directors might discover that, for whatever reason, the methods prescribed in an approved protocol or amendment were not followed and thus an unapproved modification has occurred.

In either instance (above) the study director must contact the Chair at the earliest possible and feasible opportunity and provide notification that an unapproved modification has occurred.

These cases will be dealt with on an individual, case-by-case basis depending on the Chair's determination of the events surrounding the situation that led to the unapproved modification and the degree to which animals were affected. If the Chair determines that the modification resulted from negligence or that the study director potentially acted
inappropriately, the case may be considered as non-compliance and dealt with according to the procedures outlined in this document.

APPROVAL SIGNATURE

The NWRC Official IACUC Non-compliance Policy was reviewed and approved by:

Larry Clark, Director

3/10/10

effective date