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| <b>Title: Institutional Animal Care and Use Committee Policy on Non-Compliance, P-0001-01</b> |   |
| <b>Approval Date: 17-May 2006, 11-June 2015</b>   |   |
| <b>Authorized by: Institutional Animal Care and Use Committee</b>                             |   |
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**1. Purpose:**

The IACUC has developed this policy for evaluating issues of non-compliance with IACUC protocols, policies and regulatory guidelines. Although uniform standards can serve as a guide, each individual case is unique and will be judged on its own merits.

**2. Reporting:**

All personnel involved in the care and use of animals at Central Michigan University have an obligation to report concerns of noncompliance to the IACUC. Any person may report concerns anonymously to the IACUC, Attending Veterinarian or Office of Research Compliance.

**3. Applicability:**

All animal care and use activities at Central Michigan University are conducted in accordance with the terms of the Federal Assurance (A4076-01).

**4. Authority:**

The IACUC is charged with ensuring humane care and use of vertebrate animals used for research, instruction, and testing, and to adhere to the applicable federal and state regulations and institutional policies affecting such use at Central Michigan University Facilities as defined in the Federal Assurance Statement A4076-01. As a result, the IACUC monitors the animal care and use program and its various components for compliance with all the appropriate regulations and policies.

**5. Definitions:**

*Noncompliance* means not following:

- federal, state and local laws and regulations governing the use of animals in research or teaching;  
or
- institutional policies governing animal subjects; or

- directives or determinations of the Institutional Animal Care and Use Committee.

**Serious noncompliance** means noncompliance that adversely affects the health or welfare of animal subjects and/or staff and:

- results in a detrimental change to an animal subject's clinical status or psychological well-being; or
- harms or poses an increased risk of substantive harm to an animal subject or staff member; or
- compromises the integrity or validity of the research;

**Examples of serious noncompliance:**

- Performing surgery or other painful procedures without using appropriate anesthesia/analgesia as approved in the animal use protocol.
- Failing to report serious adverse events and/or unanticipated problems to the IACUC.

**Continuing noncompliance** means noncompliant activity that:

- recurs after a report of the activity has been evaluated by the IACUC and corrective action has been mandated.
- may be either minor or serious.

Continuing non-compliance that recurs after IACUC corrective action has been implemented is reportable to the IO and appropriate federal agencies as appropriate.

**Minor Noncompliance:**

Defined as any behavior, action or omission in the conduct or oversight of animal use activities that deviates from the IACUC approved research plan, federal regulations or institutional policies but, because of its nature, does not or did not:

- harm or pose an increased risk of substantive harm to animal subjects or animal care/research staff; or
- result in a detrimental change to a subjects clinical status or psychological well-being; or
- have a substantive effect on the value of the data collected.

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

- Changing study personnel without notifying the IACUC;
- Implementing minor wording or procedural changes in a study without first obtaining IACUC approval.

**6. Investigation and Remediation:**

- All allegations of noncompliance are directed to the Office of Research Compliance.
- Investigations are conducted in accordance with the Office of Research Compliance Standard Operating Procedure "Investigation of Allegations of Research Noncompliance".
- Investigation findings are forwarded to the IACUC for determination of noncompliance and remediation.

**7. Federal Reporting Requirements:**

Under the PHS Policy on Humane Care and Use of Laboratory Animals, the IACUC must promptly report (via the Institutional Official) to the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) the following:

- Any serious or continuing noncompliance with the PHS Policy;
- Any serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals (the Guide)*; and
- Any suspension of an activity by the IACUC.

The AWAR also requires that if the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, will review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to the United States Department of Agriculture (USDA) and any Federal agency funding that activity.

## **8. References:**

1. Animal Welfare Act Regulation. 9 CFR, Ch.1, 2.31, 2.33.
2. Committee for the Update of the Guide for the Care and Use of Laboratory Animals. *Guide for the Care and Use of Laboratory Animals*. 8th edn. (National Research Council, Washington, DC, 2011).
3. Health Research Extension Act of 1985, Public Law 99-158, November 20, 1985, "Animals in Research".
4. U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.
5. Public Health Service Policy on Humane Care and Use of Laboratory Animals