Policy 9 – Guidelines and Procedures for Conducting Inquiries and Investigations into Non-compliances, Deviations, and cases of Animal Misuse or Abuse (7/2002)

9.1.0 Purpose

The University is required to conduct inquiries and to investigate incidents in which personnel may have conducted animal-related research and/or teaching/training activities without IACUC review and approval or have failed to comply with IACUC approved protocols, disregarded institutional policies and procedures, violated governmental laws and regulations governing animal use, and participated in activities that may have misused or abused animals.

9.2.0 Statement

Serious non-compliances or deviations are required to be reported to federal regulatory agencies (OLAW and USDA-APHIS), and in many cases, even the granting agencies (NIH and NSF) or private sponsors. In conducting inquiries and investigations, the committee should be diligent in evaluating only factual information on these incidences. For example, the committee should take into account the type of incident (unapproved procedures, housing violations, improper training or incompetent skill level, negligence or wasted animals) and the specific details of the noncompliance or deviation (e.g., species involved, procedures used, adverse effects on the animals, personnel involved).

9.3.0 Checklist For Gathering Information And Assessment

1. The Committee may take into consideration the following questions in determining whether to report the incident to respective oversight agencies and awarding sponsors:
   • In what pain and/or distress category would the procedures have been placed?
- What were the adverse effects on the animals being used?
- Might the adverse effects have been prevented if the procedures had been reviewed by the IACUC and University Veterinarian?
- Was medical intervention by the veterinary staff required?
- Were the individuals involved aware that IACUC approval was required before performing the procedures?
- Have the individuals repeatedly violated or disregarded IACUC policies? Were the previous violations the same or different than the current incident?
- Was it necessary for the IACUC to intervene to temporarily or permanently interrupt the incident?

2. After considering the questions listed above, the committee should assess the incident for the following:
- Have the actions jeopardized the health or well-being of the animals used or resulted in the animals being harmed or dying?
- Is there evidence that the personnel involved willfully disregarded the institution’s policy in order to perform procedures without obtaining approval from the IACUC?

9.4.0 Committee Action — Internal Procedures

The committee will consult with the Designated Institutional Official on any final action. The severity of the noncompliance will determine the level of action the committee will administer.
- Verbal warning to the noncompliant personnel.
- Written warning to the noncompliant personnel without copying the departmental chair or unit head (Dean or Director).
- Written warning to the noncompliant personnel with a copy to the departmental chair or unit head (Dean or Director). Copy to Office of the Vice President for Research and Innovation.

9.5.0 Committee Action — Reporting To Agencies And Sponsors

Professional judgment shall be exercised by the committee on a case-by-case basis to determine whether reporting the incidents to the oversight agencies and funding sponsors are consistent with the philosophy of institutional self-regulation.
• If there was intent to circumvent IACUC authority and animals were used or harmed. The IACUC will report.
• If there was no intent to circumvent IACUC authority and animals were not used or harmed. The committee should consider issuing a warning to the noncompliant party. The IACUC may elect to report.
• If there was intent to circumvent IACUC authority but animals were not used or harmed. The committee should consider issuing a warning to the noncompliant party prior to or in addition to reporting the incident to the agencies.
• If there was no intent to circumvent IACUC authority but animals were used or harmed. The committee should consider issuing a warning to the noncompliant party prior to or in addition to reporting the incident to the agencies.

9.6.0 Additional Sanctions

In addition to the items listed in subsection Committee Action — Internal Procedures, the severity of the noncompliance may result in additional administrative sanctions that result from failure to comply with IACUC protocol review, institutional policies and procedures, government laws and regulations governing animal use, or misusing or abusing animals in University research and teaching/training activities.

• Suspension of all of an investigator’ protocols until problem(s) is corrected.
• Suspension of a specific protocol during retraining or education.
• Denied access to animal facility.
• Permanent suspension of animal use privileges.
• Other research staff must take over work.
• Require to attend IACUC meetings.
• Charge noncompliant personnel for extra work by veterinary staff or animal care staff.
• Significant salary reduction for 6 months.
• Significant monetary fine.
• Dismissal of noncompliant personnel.
• Loss of research funds.
• Require the addition of research staff.
Other* – Not limited to the current listing.
9.7.0. Effective Date

July 2002 IACUC Approved

References:

1. OPRR Reports — Requirements for Prompt Reporting of Problems to OPRR, July 1994
2. University of Michigan IACUC — Guidelines for Evaluating Investigator Noncompliance