GUARDIENS FOR EVALUATING INVESTIGATOR NONCOMPLIANCE

Approved: ______________________

Mandate

The PHS Policy on Humane Care and Use of Laboratory Animals (Policy) identifies three areas that require prompt reporting to OLAW (Section IV.F., paragraph 3):

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

OLAW Guidance

According to OLAW, the IACUC should apply professional judgment in determining whether a problem falls within the letter or spirit of either (a) or (b) and if it should be reported to them. OLAW has provided examples of occurrences that they have determined meet the reporting criteria: {May need to be revised based on 2/24/05 OLAW guidance.}

(a) serious or continuing noncompliance with the PHS Policy
   1. failure to correct situations identified in previous semiannual evaluations as significant deficiencies
   2. conducting animal-related activities without appropriate IACUC review and approval
   3. failure of animal care and use personnel to adhere to IACUC - reviewed and approved institutional policies and procedures

(b) serious deviation from the provisions of the Guide
   1. conditions that jeopardize the health or well-being of animals, including accidents, natural disasters and mechanical failures resulting in actual harm or death to animals
   2. shortcomings in programs of veterinary care, occupational health or training, identified during semiannual program review and not corrected within the institutionally determined time frame.

(c) suspension of an activity by the IACUC
   1. an IACUC intervention that results in the temporary or permanent interruption of an activity involving animals

Information Gathering and Committee Assessment

When incidents are identified in which investigators have conducted animal-related activities without appropriate IACUC review and approval or failed to adhere to IACUC - reviewed and approved institutional policies and procedures, the IACUC Office or veterinary staff should provide the committee members with factual information on the incident. This should include the type of incident (e.g., unapproved procedure, housing violations, lack of skill/training, neglect, wasted animals) and details of the specific events (e.g., species, procedures performed, adverse effects, individuals involved).

Committee members should then consider the following questions in determining whether to report the incident to OLAW. {May need to be revised based on 2/24/05 OLAW guidance.}

1. In what humane use category would the procedures have been?
2. What were the adverse effects on the animals being used?
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3. Might the adverse effects have been prevented if the procedures had been reviewed by the IACUC and the veterinary staff?

4. Was medical intervention by the veterinary staff required?

5. Were the individuals involved aware that IACUC approval was required before performing the procedures?

6. Has the investigator repeatedly violated IACUC policies? Were the previous violations the same or different than the current action?

7. Was it necessary for the IACUC to intervene to temporarily or permanently interrupt the activities? (Note: If the answer to this question is yes, the incident must be reported.)

After considering the above questions, the committee members should assess the incident for the following:

1. Have the actions jeopardized the health or well-being of the animals being used or resulted in animals being harmed or dying?

2. Is there evidence that the investigator and/or his or her staff disregarded the institutional animal care and use policy in order to perform procedures without obtaining approval from IACUC?

Committee Actions

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With regard to reporting requirements, the IACUC may take any of the following actions. (Note: These actions need not be taken sequentially.)

1. verbal warning to the investigator

2. written warning to the investigator without copying the investigator’s departmental chair

3. written warning to the investigator with a copy to the investigator’s departmental chair.

Although judgment must be rendered on a case by case basis, prior experience with reporting incidents to OLA W suggests that the following guidelines are consistent with the philosophy of institutional self regulation.

1. If there was intent to circumvent IACUC authority and animals were harmed in some manner, the committee should report the incident to OLAW.

2. If there was no intent to circumvent IACUC authority and animals were not harmed in some manner, the committee should consider issuing a warning to the investigator but is not required to report the incident to OLAW. {May need to be revised based on the 2/25/05 OLAW guidance.}

3. If there was intent to circumvent IACUC authority but animals were not harmed in some manner, the committee should consider issuing a warning to the investigator prior to or in addition to reporting the incident to OLAW. {May need to be revised based on 2/24/05 OLAW guidance.}

4. If there was no intent to circumvent IACUC authority but animals were harmed in some manner, the committee should consider issuing a warning to the investigator prior to or in addition to reporting the incident to OLAW. {May need to be revised based on 2/24/05 OLAW guidance.}