

Guidelines for Investigating and Reporting Animal Care and Use Concerns

As stipulated by the Federal Animal Welfare Regulations, the Animal Care and Use Committee (ACUC) has the responsibility for investigating animal care and use concerns. To ensure consistency in the investigation and handling of concerns, the ACUC has developed the following guidance. It is important to note that the following is suggested guidance, intended for general use, and may not be applicable in all situations.

Initial Evaluation and Action

Upon receipt of a concern (written or oral) regarding the care and use of animals, the ACUC Chair may convene a meeting of an ACUC investigative subcommittee to include (1) the NCI at Frederick Attending Veterinarian; (2) the applicable facility manager/technical staff; (3) the Director of the LASP; and (4) a representative of the NCI at Frederick Office of Scientific Operations. At that time, the subcommittee will determine (1) if further investigation is required; (2) if immediate action is required; or (3) if no action is needed. [If immediate action is warranted because animal or human welfare may be compromised, then the Attending Veterinarian, Institutional Official, Occupational Health & Safety Staff or other relevant personnel should be notified immediately to initiate corrective action.] The subcommittee will also recommend to the ACUC Chair whether a memorandum to the applicable Principal Investigator and/or Program Area is necessary. If so, the memo should include the following information:

- A description of the concern
- The current status [i.e., the issue is currently under investigation, the issue will be reviewed by the ACUC at the next scheduled meeting, etc.]
- The recommended action [i.e., discontinue use of agent until further review by the ACUC]
- Request that the Principal Investigator and/or Program Area provide a written response addressing the concern for ACUC review

Copies of this memorandum will be provided (1) to the ACUC; (2) to the Institutional Official; (3) to the Lab/Branch Chief [if applicable]; and (4) to the applicable facility manager.

Further Investigation (if necessary)

If it is determined that further investigation is required, the Chair will appoint individuals responsible for the investigation with a completion date for the report to be prepared and presented to the ACUC. It is important to avoid actual or perceived conflicts of interest in this process. The report will be sent to the Principal Investigator with a copy to the ACUC members and should include the following information: (1) description of the concern; (2) condition of the animals; (3) the results of interviews/findings; (4) supportive documentation; (5) citing of Federal regulations and/or institutional policies that were violated; and (6) recommended action [if

applicable]. The Principal Investigator and/or Program Area must provide a written response addressing these concerns to the ACUC.

Outcomes and Final Actions

Upon receipt and evaluation of the report and the response(s), the ACUC may request further information or find that:

- There was no evidence to support the concern;
- The investigation suggests that some related aspects of the animal care and use program require additional review; or
- The concern was valid.

If applicable, the ACUC is required upon determination that a concern is valid to issue a letter of reprimand to the Principal Investigator and/or Program Area detailing the investigation report and the recommended action(s) [please see below]. The letter of reprimand will indicate that additional unauthorized procedures or inappropriate care and treatment may result in the suspension of animal activities. This memorandum will be sent from the ACUC Chair, through the Institutional Official with copies to (1) the Lab/Branch Chief [if applicable]; (2) the applicable facility manager; and (3) ACUC members.

ACUC actions may include (but are not limited to):

- Recommend the implementation of additional measures to prevent recurrence
- Suggest counseling
- Mandate specific training aimed at preventing future incidents
- Mandate monitoring of technical procedures or training by ACUC appointed individuals
- Recommend temporary suspension of the Principal Investigator's relevant Animal Study Proposal(s) [requires compliance with specific ACUC conditions before the Animal Study Proposal is reinstated]
- Recommend permanent suspension of the Principal Investigator's relevant Animal Study Proposal(s)
- Recommend to the Institutional Official that institutional sanctions be imposed (i.e., restrict facility access, reassignment, etc.)

Recommendations for these actions require a majority vote of a quorum obtained at a convened meeting of the ACUC.

The ACUC is required to report to OLAW the circumstances and actions taken in the following instances:

- Any serious or continuing noncompliance with the *PHS Policy*
- Any serious deviation from the provisions of the *Guide*
- Any suspension of activity by the Institutional Official [IO]

When it is determined that OLAW reporting is required (please also refer to the *Guidelines for Categorizing Significant Deficiencies and OLAW Reporting*) the ACUC Chair through the Institutional Official will promptly send a formal report describing the circumstances and any actions taken. A copy of this report should also be forwarded to AAALAC International.

Adapted from the OLAW/ARENA Institutional Animal Care and Use Committee Guidebook - 2nd Edition (2002).