

University of Colorado at Boulder; Office of Research Integrity; Institutional Animal Care and Use Committee

SOP # 2 Title: For-Cause Assessments of Non-Compliance

Date: 2/29/2008 Revision: initial Effective Date: 2/29/2008 Pages: 5

1. PURPOSE

Allegations of noncompliance with university or regulatory agency requirements for the humane care and use of research animals must be thoroughly and promptly investigated. Allegations of noncompliance may arise from complaints (described in SOP 1) or as a result of normal IACUC procedures and reviews.

The first priority in responding to potential non-compliance is to ensure the safety and welfare of research animals and staff. If immediate action is required, the procedures described in section 5 of SOP 1 should be followed. The purpose of this SOP is to describe procedures involved in follow-up for-cause assessments of potential noncompliance.

2. DEFINITIONS

Reportable incidents are described in “Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals”

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>) and include:

- conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals; conduct of animal-related activities without appropriate IACUC review and approval;
- failure to adhere to IACUC-approved protocols;
- implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;
- conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
- conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;
- conduct of official IACUC business during a period of time that the Committee is improperly constituted;
- failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
- chronic failure to provide space for animals in accordance with recommendations of the Guide unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification;
- participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;

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- failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);
- failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
- failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO²);
- failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or
- IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide , or the institution's Animal Welfare Assurance.

3. STEPS IN THE ASSESSMENT PROCESS

3.1. The IACUC Chair or designee will form a committee to conduct a For-Cause Assessment procedure. The sub-committee will consist of the Institutional Veterinarian, the IACUC administrator, and at least one non-veterinarian IACUC member.

3.1.1. Should the allegations relate to biological, chemical or radiological safety, the IACUC Chair will work with the Director of the Office of Research Integrity to convene a subcommittee with sufficient expertise to investigate. Deficiencies compromising the immediate health and well-being of personnel will be corrected immediately by the appropriate institutional official.

3.1.2. If the incident appears to represent reportable noncompliance, the IACUC will promptly provide a preliminary report to OLAW via fax, email or a telephone call. The preliminary response will then be followed by a detailed report of the assessment.

3.2. The assessment committee will submit a written report to the full IACUC within an appropriate time period set by the IACUC Chair or designee.

3.3. At a convened meeting with a quorum present, the IACUC will develop recommendations for action and/or sanctions deemed necessary to bring the protocol and related activities into compliance with federal laws/regulations and institutional policies. The review of the allegation and recommended actions and/or sanctions by the full committee will be as follows:

- Review the incident and discuss the allegations
- Substantiate the validity of the allegation by a majority opinion of the IACUC
- Record a listing of non-compliance issues
- Record all minority opinions of the non-compliance issues
- Record a listing of recommended corrective actions/sanctions for the investigator
- Record all minority opinions of the recommended corrective actions/sanctions

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- Decide on the response to the originator of the allegation. Depending on the nature of the complaint and the role of the complainant in the allegation, the complainant may or may not be informed of the outcome of the assessment.

The minutes of the IACUC meeting will record these findings.

3.4. The IACUC Chair will notify the investigator in writing describing the non-compliance issues and the required corrective actions/sanctions with related deadlines prescribed by the IACUC. The letter will include a description of the appeal process. If no actions and/or sanctions are necessary, the IACUC Chair or designee notifies the investigator in writing or email that the investigation is closed. The IACUC chair may also inform the initiator of the concern about the resolution, following the recommendations provided by the IACUC (see step 6 above).

3.5. The IACUC Chair will notify the Institutional Official in writing or by email delineating the non-compliance issues and the recommended corrective actions/sanctions. The Institutional Official, in consultation with the IACUC, may impose further corrective actions/sanctions. The Institutional Officer will inform any other institutional or regulatory offices or officials, as appropriate.

3.5.1. The Institutional Official will inform OLAW of the circumstances and actions taken with respect to (a) any serious or continuing noncompliance with the *PHS Policy on Humane Care and Use of Laboratory Animals*; (b) any serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals*; or (c) any suspension of an activity by the IACUC.

4. DETERMINATION OF CORRECTIVE ACTION

4.1. Serious or Continuing Non-compliance Issues

Acts of non-compliance are deemed serious if they can or do affect the health, safety or well-being of animals or personnel. If the IACUC determines that the reported problem represents serious or continuing non-compliance with federal regulations and/or IACUC requirements or determinations, it may apply one or more of the following sanctions:

- Terminate the IACUC approval of the research study

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- Suspend IACUC approval of the research study pending completion and acceptance by the IACUC of a written plan for the correction and prevention of the problem
- Suspend further animal orders and/or breeding for the research study pending completion and acceptance by the IACUC of the written plan for the correction and prevention of the problem
- Take other action as the IACUC deems appropriate

4.1.1. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the [Animal Welfare Act](#), the [Guide](#), the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy.

4.1.1.1. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.

4.1.1.2. If the IACUC decides to suspend or terminate approval of a study this decision and the reason(s) for this decision will be reported in writing immediately to the investigator and the Vice Chancellor of Research (Institutional Official), and Department Chair.

4.1.1.3. The Institutional Official will report the incident of non-compliance to OLAW, and if applicable, the USDA Animal and Plant Health Inspection Service and any other federal agency funding the study.

4.2. Minor Non-Compliance Issues

Acts of non-compliance are deemed minor if they do not affect the health, safety or well-being of animals or personnel. If the IACUC determines that the reported problem represents a minor non-compliance with federal regulations and/or IACUC requirements or determinations, it may take one or more of the following actions.

- Elect to make corrective action only
- Provide a verbal and/or written list of the issue of non-compliance to the investigator and require a corrective action plan at a regular meeting of the IACUC and record the incident in the IACUC minutes.
- Provide a written listing of the issue of non-compliance to the investigator requiring a corrective action plan within a specified time period. The letter may or may not be

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copied to the investigator's department chair depending on the IACUC's decision on the sanction.

5. RE-EVALUATION/APPEAL OF IACUC DECISIONS

Subsequent to the decision being made by the IACUC, if the investigator has new information which was not part of the investigation or there is an issue regarding due process, the investigator may appeal the decision of the IACUC as follows:

- 5.1. Submit in writing to the IACUC office the issue of concern and position with supporting documents within thirty days of receipt of the letter from the IACUC.
- 5.2. The IACUC office will acknowledge receipt of the letter in writing and forward the letter and supporting documents to the full IACUC committee.
- 5.3. The IACUC will discuss the investigator's appeal at a convened meeting with a quorum present. The investigator may request an appearance before the IACUC to present arguments for the reversal of a decision or to propose a change of the protocol based on the advice of the committee. A written record of the discussion and the meeting will be made.
- 5.4. Following the discussion at the IACUC meeting, the investigator will be informed of the outcome.
- 5.5. A summary of the written record along with the IACUC's re-evaluation/appeal decision will be sent to the investigator and to the Institutional Official. The Institutional Officer will inform any other institutional or regulatory offices or officials, as appropriate.