UC SANTA BARBARA

Institutional Animal Care and Use Committee

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IACUC GUIDELINE:	EVALUATION OF CONCERNS OF MISTREATMENT OF ANIMALS OR IACUC PROTOCOL NON-COMPLIANCE
DATE IMPLEMENTED:	April 23, 2010
REVISION APPROVED:	November 8, 2024

Background:

General Action Guidelines for Persons Receiving Concerns of Animal Care and Treatment

A. The following paragraphs are publicized:

1. UCSB strives to maintain the highest standards for animal welfare. The campus is committed to meeting all applicable government guidelines and regulations for animal care and use. A federally mandated campus regulatory committee, the IACUC, and the Attending Veterinarian are responsible for ensuring that animals used on campus, at other UCSB facilities, or elsewhere by UCSB affiliated personnel are well cared for, used appropriately and in minimum numbers.

2. At UCSB we are concerned about actual and perceived deficiencies in animal care and treatment of animals used in teaching, and research.

3. Anyone may report a concern about animal use. Anyone reporting an animal use concern is protected from reprisal under the UCOP Whistleblower and Whistleblower Protection Policy. Animal use concerns can be reported to the Attending Veterinarian at 805-893-7344 or 805-451-5931, the IACUC Chair at 805-893-2659, the IACUC Office at 805-893-5855, the Research Integrity Office within the Office of Research at 805-893-4286, or to any member of the ARC staff. All concerns will be reviewed and further investigated as necessary.

Definitions:

Significant Deficiency: A deficiency that, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of animals.

Noncompliance: Any activity not in accordance with federal, state regulations and/or Institutional policies regarding animal care and use.

Procedure:

A. The following general guidelines will be applied when an animal use concern is received:

1. All concerns will be evaluated promptly, and any required investigation will occur in a timely manner.

2. Initially this investigation will entail information gathered from the person(s) lodging or self-reporting the concern. Information gathered should include:

   - What has occurred?
   - Where did it happen? (some University projects occur off campus); How did the person raising the concern come to know of the occurrence? (witnessed or "heard about"?)
   - When did it happen?
   - What species of animal was involved?
   - Who were the University personnel responsible for the alleged deficiency?
   - What is the name and contact information of the person lodging the concern? (This information is not required; but without it, a thorough investigation may not be possible.)
   - Whether the person raising the concern requests anonymity. (An anonymous concern will be evaluated, but it may prove difficult to develop independent evidence of a one-time event).

   These are only examples of information that should be gathered. The answers to only a few of the questions above may be sufficient to determine the accuracy of the report, or other information may need to be gathered for further investigation.

   The manner and extent of further investigation of the concern will be dependent on the specificity and credibility of the information gathered.

   Note: A report that describes an ongoing or recurring event that jeopardizes the health or well-being of animals requires an immediate response by the Attending Veterinarian. The Attending Veterinarian has direct or delegated authority to provide appropriate and competent clinical veterinary care, which includes stopping an activity that jeopardizes animal health or well-being, if neccessary.[1, 2]

3. The IACUC Chair will determine if the concern requires further investigation. If the IACUC Chair is unavailable or has a conflict of interest, then another member of the committee who is not associated with the report will review the concern. If a concern is deemed not to warrant further action, the IACUC and the IO will nonetheless be informed of the incident and its resolution. When an incident requires further investigation, the IACUC Chair or member may appoint a subcommittee of two or more IACUC members who are not associated with the concern to perform a formal investigation. The IACUC Chair or member may also consult with the Director of Research Integrity for regulatory guidance and expertise in the review of potential non-compliant activities. After a subcommittee has been appointed, the IACUC Chair or member will then notify the Principal Investigator(s) (PI) that an animal use concern has been received and that an investigation will occur. The substance of the concern should be described, insofar as is possible, in a manner that avoids identifying the person raising the concern (e.g., an undergraduate student in a course) who has requested to remain anonymous.

If the person raising the concern does want to remain anonymous, it is important to remind the PI and all others involved to not attempt to identify that person. The Chair, or Committee after review of a preliminary report by the subcommittee, will also notify the PI whether the study involved in the noncompliance can continue or must be postponed until the completion of the investigation. The health and well-being of the animals will be taken into consideration when determining the status of the study.

4. The IACUC, and the subcommittee investigating the animal use concern, will adhere to general University Policy pertaining to due process in dealing with alleged academic, professional or staff misconduct[3]. The subcommittee (or the IACUC Chair, if the subcommittee so requests) may interview the person raising the concern, if further information is required, and must interview the subject(s) of the investigation at an early stage to establish matters of fact (which may include requesting copies of surgical, research and husbandry records), and identify any points of disagreement concerning the allegations made. The goal is to develop an accurate narrative of the events that formed the basis for the concern.

5. The investigating subcommittee will draft an investigation report. The IACUC Coordinator will ensure that interview notes, copies of records requested, and other relevant materials are maintained in accordance with the UC records retention schedule. The report will include the alleged concern and the findings of the investigations, which should consider questions such as:

    - Were there any adverse events on the animals being used?
    - Might any adverse events have been prevented if the procedures had been reviewed by the IACUC and the veterinary staff?
    - Was medical intervention by the veterinary staff required?
    - Were the individuals involved aware that IACUC approval was required before performing the procedures?
    - Has the PI or their personnel repeatedly violated IACUC guidelines, procedures, or policies? Were the previous violations the same or different than the current action?

6. The draft of the investigation report will then be sent to the PI and relevant lab personnel. The PI will be asked to review the text for factual accuracy and whether they have any comments regarding the report draft. The draft may be revised by the IACUC based on the PI's and/or lab's comments.

7. If the draft investigation report detailing the animal use concern is not ready to be presented to the IACUC at the next regularly scheduled meeting, the IACUC Chair or member may provide a preliminary summary to the Committee. When the report is reviewed during an IACUC meeting, the Committee should assess the incident for the following:

    - Have the actions jeopardized the health or well-being of the animals being used or resulted in animals being harmed or dying? Is there evidence that the investigator and/or his or her staff were non-compliant with the IACUC corresponding approved protocol or applicable guidelines, procedures, or policies?
    - Have personnel been placed at risk? The IACUC will often identify corrective actions (i.e., remediation plan), for the PI and/or lab members that are intended to prevent recurrence

(e.g., requiring retraining or additional training, supervision of husbandry, or veterinary supervision of procedures). Corrective actions should be commensurate with the scope of the noncompliance event(s) documented. The IACUC may also apply sanctions, the nature of which will be conveyed to the investigator(s) and possibly to the IO (in more serious instances), and may include suspension of activities or personnel within a protocol, or the protocol itself (suspension of a protocol requires notification of the IO), until such time as reasonable conditions for reinstatement imposed by the IACUC have been met.

8. Following presentation and discussion of the draft investigation report at a convened meeting, the IACUC may request additional information from the PI and/or the subject(s) of the investigation. Any questions and comments from the IACUC will be sent to the PI and the subjects(s) of the investigation, along with a copy of the draft investigation report. Any disputed items will be reviewed by the convened IACUC before remedial actions or sanctions are finalized and before oversight agencies are notified (if applicable). If there are no additional questions or comments following the Committee's review of the report, they will vote to approve the report and whether the incident is reportable to oversight agencies (OLAW and/or AAALAC).

9. Following the IACUC's vote on the investigation report, the PI will be contacted by the IACUC Office and provided with a final copy of the investigation report, which includes a summary of IACUC findings, remedial actions, and whether the IACUC determined the incident to be reportable. The PI may send a written response to the IACUC and/or the IO if they wish to do so. If the individual(s) filing the concern requested notification of the outcome of the investigation, this will be provided at this time.

    a) For incidents that are determined to be reportable to federal oversight agencies, the following campus individuals will be notified:

        - Principal Investigator and Co-PI (when applicable)
        - Lead investigator on the grant if different than the protocol PI
        - Department Chair (if funding for the incident was administered by a department or an event occurred in space controlled by a department or the PI on the project is a member of a department)
        - ORU Director (if funding for the incident was administered by an ORU or an event occurred in space controlled by an ORU or the PI on the project is a member of an ORU)
        - Sponsored Projects
        - Research Integrity Director
        - Institutional Official

    b) For incidents that are determined to not be reportable to federal oversight agencies, the following campus individuals will be notified:

        - Principal Investigator and Co-PI (when applicable)
        - Research Integrity Director

- Institutional Official

B. As of October 1, 2015, PHS Policy also applies to NSF-supported activities with live vertebrate animals. Any time there is an instance of serious or continuing noncompliance on an IACUC protocol that is supported by NIH or NSF funding, this noncompliance must be reported to OLAW. Further, OLAW recommends that: "Institutions should use rational judgment in determining what situations meet the provisions of IV.F.3 and fall within the scope of the examples below, and consult with OLAW if in doubt."[5]

Animal work described in a protocol will be considered to be supported by Federal funds if those funds were used to pay for any live animal related activities or items, such as: animal purchases or shipping/transfer costs; vivarium per-diem, supplies (e.g., special diets) or services (e.g., breeding management) associated with the maintenance and care of animals; purchase of drugs, chemicals, or reagents listed in protocol Tables 11, 12, or 13; and personnel costs (e.g., labor and training) associated with the performance of the live animal activities described in this protocol.

OLAW has provided the following guidance and examples on the prompt reporting requirements under the PHS Policy on Humane Care and Use of Laboratory Animals (*Policy*)[4] with respect to the following three areas:

1. Any serious or continuing noncompliance with the PHS *Policy*

    - conducting 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
    - conduct of animal-related activities beyond the expiration date established by the IACUC
    - failure to correct deficiencies identified during the semiannual evaluation in a timely manner. Such a deficiency would also need to be reported to the USDA

2. Any serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals*.

    - 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
    - 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 CO_2)

- failure of animal care and use personnel to carry out veterinary orders (e.g., treatments)

3. Any suspension of an activity by the IACUC

    - an IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity involving animals due to noncompliance with the *Policy*, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance

    - Any suspension of animal activity must be reported to the USDA, if it involves covered-species.[6]

C. The reporting requirements for USDA regulated activities in the Animal Welfare Act are: any change in operation, or a protocol suspension or an uncorrected significant deficiency from a Semi-Annual facility inspection that involves a USDA regulated species.

D. All issues that are reportable to OLAW or USDA require immediate reporting to AAALAC. If a serious noncompliance issue is not reportable OLAW or USDA, but still includes one of the following situations, it should be promptly reported to AAALAC:

- Unexpected animal death
- Conditions that resulted in unexpected animal harm or deaths
    - Accidents or errors
    - Equipment failure
    - Natural disaster
- Significant animal rights activities
- Significant human health issue directly related to the animal care and use program
- Inappropriate euthanasia techniques and/or failure to confirm euthanasia
- Allegations/concerns/reports regarding animal welfare concerns
- Inadequate veterinary care
- OLAW/USDA investigations
- Changes in unit contact (please include degree, title, address, phone and fax numbers, and email)
- Changes in facility size, location, name <u>if</u> site visit is pending before Annual Report is to be submitted

Reference:

1. Animal Welfare Act Regulations §2.33,a,2

2. *Guide for the Care and Use of Laboratory Animals*, 8th Edition. Pg 14.

3. Campus Procedures for Enforcement of the Faculty Code of Conduct; Formal Complaint Procedures. http://senate.ucsb.edu/bylaws.and.regulations/division/Part_III/Appendix_4/B.cfm

4. *Policy on Humane Care and Use of Laboratory Animals*. IV.F.3

5. *Guidance on Prompt Reporting to OLAW under PHS Policy on Humane Care and Use of Laboratory Animals.* NOT-OD-05-034.

6. Animal Welfare Act Regulations §2.31,d,7

7. AAALAC International website; Maintaining Accreditation; Reporting Requirements. http://aaalac.org/accreditation/faq_landing.cfm#H