

Institutional Animal Care and Use Committee

Santa Barbara CA 93106-5062

Tel: (805) 893-5855

Fax: (805) 893-2005

Email: [iacuc@lifesci.ucsb.edu](mailto:iacuc@lifesci.ucsb.edu)

<https://www.research.ucsb.edu/compliance/animal-subjects/>

IACUC GUIDELINE:	EVALUATION OF CONCERNS OF MISTREATMENT OF ANIMALS OR IACUC PROTOCOL NON-COMPLIANCE
DATE IMPLEMENTED:	April 23, 2010
DATE(S) REVISED:	April 20, 2012; September 17, 2015; April 20, 2018 (Review only); July 30, 2019

---

## General Action Guidelines for Persons Receiving Concerns of Suspected Deficiencies in 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.

B. 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 lodging 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 necessary.<sup>1, 2</sup>

3. The IACUC Chair will determine if the concern requires further investigation. 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 will appoint a subcommittee of two or more IACUC members who are not associated with the concern to perform a formal investigation. The IACUC Chair 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 will then notify the investigator(s) 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 confidentiality. The Chair 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<sup>3</sup>. 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.

The investigating subcommittee will provide an investigation report using the UCSB IACUC Investigation Checklist. 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.

5. Either a preliminary summary or the investigation report will be presented to the IACUC regarding the animal use concern at an upcoming regularly scheduled meeting. The report will include the alleged concern and the findings of the investigations, which should consider questions such as:

- Were there any adverse effects on the animals being used?
- Might any adverse effects 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 investigator repeatedly violated IACUC guidelines, procedures, or policies? Were the previous violations the same or different than the current action?

6. After considering the above questions, the subcommittee members 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 disregarded the IACUC guidelines, procedures, or policies in order to perform procedures?
- Have personnel been placed at risk?

7. Following presentation and discussion of the subcommittee report at a convened meeting, the IACUC may request additional information or vote on a course of action. Actions should be commensurate with the scope of the noncompliance events documented, and be intended to prevent recurrence (as, for example, by requiring retraining or additional training, supervision of husbandry, or veterinary supervision of procedures). 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 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 IACUC review of the subcommittee report/UCSB IACUC Investigation Checklist, the investigator(s) charged with noncompliance will be contacted by the IACUC Office or Chair and provided with a copy of the subcommittee report, which includes a summary of IACUC findings, remedial actions, and whether the IACUC determined the incident to be reportable to federal agencies (OLAW, USDA, and AAALAC). The investigator(s) will be afforded an opportunity to respond and/or clarify inaccuracies identified in the subcommittee report. Any disputed items will be re-reviewed by the convened IACUC before remedial actions or

sanctions are finalized and before oversight agencies are notified (if applicable). 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

C. 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*)<sup>4</sup> with respect to the following three areas. 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."<sup>5</sup>

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<sub>2</sub>)
      - 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.<sup>6</sup>
- D. It is not a requirement to report all adverse events involving animals to USDA-APHIS. Only the following are required to be reported by the Animal Welfare Act: 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.
- E. 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
  - Natural disasters
  - Significant animal rights activities
  - Inappropriate euthanasia techniques and/or failure to confirm euthanasia
  - Allegations/concerns/reports regarding animal welfare concerns

- Lack of 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 if 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*, 8<sup>th</sup> 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](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](http://aaalac.org/accreditation/faq_landing.cfm#H)