

**UNIVERSITY OF CALIFORNIA SAN DIEGO
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**

Policy and Guidelines for Non-Compliance

Background: The Institutional Animal Care and Use Committee (IACUC) is often asked to deal with a wide variety of compliance issues. Most of these issues are resolved utilizing procedures described in this document. The PI may be charged for all work required by the IACUC and ACP in remedying a compliance issue. Examples of such charges include professional veterinary time, diagnostic charges, per diem, etc.

Examples of non-compliance include but are not limited to:

1. Neglect or cruelty to animals.
2. Conducting animal research that has not been approved by the IACUC.
3. Performance of procedures by personnel who are not listed in the approved protocol.
4. Performance of procedures that are not listed in the approved protocol.
5. Anesthetics, analgesics, tranquilizers, antibiotics, or other medications used in the lab are not noted in the protocol, are different from those listed in the protocol, or are not used in accordance with the protocol or policy.
6. Survival surgery is not performed using aseptic technique.
7. Euthanasia procedures that differ from those listed in the protocol and/or a method for ensuring death (e.g. after CO₂ exposure) are not employed.
8. Lab personnel lack the necessary training to appropriately perform procedures listed in the protocol.
9. Supporting documentation for animal care, post-op care, or other study procedures is incomplete or unavailable.
10. Conditions are not safe for humans and/or animals.
11. Outdated materials (drugs, experimental agents, suture, sterile supplies, etc.) are used on animals.
12. Animal overcrowding or failure to follow breeding policies.
13. Work is conducted outside of approved facilities.
14. Animals are not acquired or not transferred as approved in the protocol.
15. Housing and husbandry standards are not met.

Procedures for dealing with non-compliance

When an example of non-compliance is found, the compliance officer/animal welfare specialist or AWP will notify the PI of the deficiency and document the issue for inclusion in a report presented monthly to the IACUC Executive Subcommittee. In most cases, the compliance issue may be resolved with immediate corrective actions. At the time that a compliance issue is detected, the CO/AWS (or other party) should make an initial determination as to whether immediate notification of campus Veterinary Services and the members of the IACUC Executive Subcommittee is additionally required. Non-compliance that represents a threat to the health or safety of animals would require such notification as would any substantive deviations from approved protocols. The Chair, in consultation with the IACUC Executive Committee may decide that the non-compliance should be reported.

The IACUC Executive Subcommittee, on behalf of the IACUC, may take the following actions:

1. Require additional training for the PI or staff.

2. Require that the PI appear at an Executive Subcommittee or full IACUC meeting.
3. Require that ACP temporarily take over animal care with PI responsible for costs.
4. Temporarily suspend animal use privileges.
5. Notify the PI's Department Chair, the Dean, and the Institutional Officer.

All serious or unresolved minor issues will be discussed at the full IACUC meeting where the following will be determined:

1. Are additional actions required to resolve the compliance issues?
2. Should animal use privileges and protocol approvals be suspended or revoked?
3. Is additional reporting or follow-up reporting to OLAW, USDA, AAALAC, and the appropriate funding agencies required?

Investigators should be aware of the university's requirements to report non-compliance as described by PHS (OLAW), USDA, and AAALAC.

1. Public Health Service (Office of Lab Animal Welfare)

Public Health Service Policy on Humane Care and Use of Laboratory Animals

IV. B.

As an agent of the institution, the IACUC shall with respect to PHS - conducted or supported activities:

3. prepare reports of the IACUC evaluations conducted as required by IV.B.1. and 2. of this Policy, and submit the reports to the Institutional Official; (NOTE: The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the institution and made available to OLAW upon request. The reports must contain a description of the nature and extent of the institution's adherence to the Guide and this Policy and must identify specifically any departures from the provisions of the Guide and this Policy, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency. If some or all of the institution's facilities are accredited by AAALAC International or another accrediting body recognized by PHS, the report should identify those facilities as such.)

IV.F.3. The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- a. any serious or continuing noncompliance with this Policy;
- b. any serious deviation from the provisions of the Guide or
- c. any suspension of an activity by the IACUC.

2. USDA

9 CFR 2.31(c)3

Prepare reports of its evaluations conducted as required by paragraphs (c) (1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; ...The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and

copying upon request. The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter 1, subchapter A--Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity;

3. AAALAC

AAALAC Rules of Accreditation, Section 2, Standards, Paragraph 7

In addition, the accredited unit shall promptly notify AAALAC International (e.g., through copies of correspondence) of adverse events relating to the animal care and use program. Examples include investigations by the USDA or OLAW, as well as other serious incidents or concerns that negatively impact animal well-being.