



IACUC Policies and Guidelines

POLICY AND GUIDELINES FOR IACUC COMPLIANCE ISSUES

IACUC Approved: December 8, 2014

POLICY

Scientific research at San Diego State University includes projects that involve the care and use of animals. This work is carried out under the external oversight of the Public Health Service Office for Laboratory Animal Welfare (OLAW) and the US Department of Agriculture Animal Care program. Institutionally, the SDSU Institutional Animal Care and Use Committee (IACUC) oversees this animal work. Work with animals under circumstances that fall outside the expectations of federal and state laws and guidelines, and/or related SDSU policies and guidelines is termed noncompliance. All individuals working at SDSU are obligated to report perceived noncompliant animal use to the IACUC. The IACUC is required to investigate reported circumstances and take appropriate action.

BACKGROUND

The IACUC may review any of a wide variety of possible compliance issues. Often, these items are brought to the Committee's attention during discussion of specific protocols or as part of more formal post-approval monitoring. At times, reports by concerned individuals about apparent compliance problems are reported to the Committee through any of a variety of routes. This document provides examples and clarification of what constitutes non-compliance related to work with animals, and the process that occurs when such instances come to the IACUC's attention.

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

1. Neglect or cruelty to animals.
2. Failure to request the addition of new personnel to an approved active protocol. Un-approved personnel working on an IACUC approved project constitutes non-compliance.
3. Failure to resolve deficiencies identified in facility inspections.
4. Inadequate record keeping ***including the failure to submit animal protocol renewals and amendments, prior to expiration and in a timely manner.***

5. Failure to complete all the necessary training requirements prior to working with animals as needed (i.e., protocol-associated procedures, OLAC orientation, or the on-line Animal Health and Welfare Training, etc.)
6. Conducting animal research which has not been approved by the IACUC. If research is performed without an approved protocol, including work on a protocol that has expired, be aware that in addition to triggering an IACUC review, it will impede or prevent publication of experimental results in most journals.

Note: 'Pilot studies' are also considered research and need IACUC approval.

7. Unapproved changes and/or non-adherence to the written protocol. Examples include: adding procedures, changes in how animal procedures/ manipulations are performed, new drugs/anesthetic agents or changes in approved drug/anesthesia dose, adding/changing species and increases in the number of animals.
8. Failure to report unexpected adverse animal events to IACUC at the time of the occurrence.

Procedures for dealing with non-compliance outside of an IACUC meeting:

A report of non-compliance will be reviewed when there is a verbal or written complaint or if information becomes available that suggests a compliance infraction has occurred. If the compliance infraction is minor [see below for [OLAW Guidance](#)], such as an administrative infraction, or it is a single minor incident, the matter will be addressed with the principal investigator (PI) by the IACUC chair. The full IACUC will be made aware of all non-compliance reports/events. A letter of non-compliance will be sent to the PI and copies sent to the Institutional Official, and the PI's department chair.

If the infraction is serious or represents a repeated offense, the issue will be discussed first at a meeting between a subcommittee of the IACUC (typically, the Chair and at least one other IACUC member, and an institutional veterinarian), the PI, and PI's supervisory staff as deemed appropriate. Every effort will be made at this juncture to resolve the non-compliance issue with the PI. At minimum, once the infraction has been resolved, a letter of non-compliance outcomes and corrections will be sent to the PI and copies sent to the Institutional Official, and the PI's department chair.

If it is determined that a non-compliance incident must be referred to the full IACUC committee for discussion and vote, the IACUC subcommittee will write a report summarizing the situation and related issues up to the point of referral to the full Committee. For matters significantly affecting existing animal health and welfare, the veterinarian will make a decision regarding the status of any animals involved and whether it is appropriate for continued work in the particular procedures (at the risk of additional animal health problems) while the committee convenes regarding the issue. The PI must be notified in writing of the infractions and be provided an opportunity to address the IACUC during the meeting at which the non-compliance will be discussed.

Procedures for dealing with non-compliance during an IACUC meeting:

The Committee will review the report of the subcommittee, potentially interview any participants and the Principal Investigator, and if warranted investigate the non-compliance issue further. If the IACUC determines there has been a violation of applicable regulations or institutional policy, three sets of questions will be considered:

1. Has the violation resulted in harm to or mistreatment of animals and/or personnel? If so, the IACUC is obliged to take any and all appropriate actions to remediate the problem and prevent any recurrence in order to ensure that animal and/or personnel welfare is maintained. This could include suspension of the protocol.
2. How serious is the violation? Has the investigator been irresponsible, negligent or shown willful disregard for IACUC policies? This can determine what action the Committee will take and how it will describe and report its findings.
3. Is the incident a violation of federal, state, and/or local laws and regulations or San Diego State University policies? This will determine to whom the IACUC findings and corrective actions are reported, up to and including reporting to the department chair and Human Resources for potential disciplinary action.

Potential additional actions of the IACUC for significant non-compliance:

1. A period of suspension of some or all of a PI's ability to use animals in research may be implemented until there is assurance that all personnel and procedures are brought into compliance with federal laws and policies and SDSU policies.
2. The infraction will be considered during IACUC assessment of future protocol submissions by the PI, and may result in actions, including additional in-depth documentation of procedures and more frequent reporting to IACUC.
3. Mandatory notification to OLAW and the USDA (if USDA regulated animals are involved) if the protocols are suspended. Note: OLAW requires reporting for significant deficiencies as well as suspensions.
4. The PI's supervisor and/or department chair, and the Institutional Official will be informed of compliance infractions.

NIH OLAW guidance for examples of non-compliance:

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

http://grants.nih.gov/grants/olaw/reporting_noncompliance.htm