

**STANDARD OPERATING PROCEDURE
UTAH STATE UNIVERSITY
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**

IACUC SOP#: 1

Inception Date: February 17, 2006

Modification Date:

Title: IACUC Response to Animal Care and Use Concerns

- I. Regulations, Policies, and Guidelines Regarding Evaluation of Animal Care and Use Concerns
 - a. The research institution is required to have a mechanism for reporting deficiencies in animal care and treatment (Animal Welfare Act (AWA) 7 U.S.C. 2142; Section 13; Animal Welfare Regulations (AWRs) 9 CFR Part 2, Subpart C, 2.32(c)(4))
 - b. The IACUC is required to “review and, if warranted, investigate concerns involving the care and use of animals at the facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees” (9 CFR Part 2, Subpart C, 2.31(c)(4))
 - c. The AWRs (9 CFR, Part 2, Subpart C, Section 2.32(c)(4)) requires protection of complainants from reprisal for reporting a violation of the standards or regulations under the AWA
 - d. USU Policy #407.8.5 indicates the intended treatment of the complainant (Accuser) and the Respondent during the investigation of concerns of scientific misconduct. The IACUC will apply this policy to the potential misuse of animals in research.
 - i. 407.8.5 University employees who receive or learn of an allegation of scientific misconduct will treat the Accuser with fairness and respect and, when the allegation has been made in good faith, will take reasonable steps to protect the position, confidentiality, and reputation of the Accuser and other individuals who cooperate with the University against retaliation. Likewise, University employees who receive or learn of an allegation of scientific misconduct will treat the Respondent with fairness and respect. In both instances, University employees will protect, to the maximum extent possible, the confidentiality of information regarding the Accuser, the respondent, and other affected individuals.
 - e. Every reasonable effort will be made to maintain the confidentiality or anonymity of the complainant when requested.
 - i. A complainant may remain anonymous if they so wish.
 - ii. Anyone submitting a complaint should be aware that reports prepared and made part of IACUC meeting minutes, or those submitted by the IACUC to government agencies (USDA, PHS,

etc) may be made public under “sunshine” laws or the Freedom of Information Act. Therefore, if the complainant wishes to be identified his or her name will become part of the public record.

II. Receipt of Concerns

- a. Concerns can be submitted to any member of the IACUC
 - i. Concerns may be submitted directly to IACUC members
 - ii. Concerns may be submitted indirectly via:
 - 1. University officials
 - 2. Animal care staff
- b. The IACUC will respond to and review all concerns received regarding the care and use of live vertebrate animals associated with Utah State University (USU)
 - i. Common sources of concerns or complaints:
 - 1. Animal care and research personnel
 - 2. Other USU personnel
 - 3. General public
 - 4. Media
 - 5. Anonymous
- c. When the complainant is known the IACUC will acknowledge receipt of the complaint in writing within 7 working days if the complainant so requests and a copy of the letter will be included in the IACUC report.
- d. If the complainant wishes to remain anonymous the IACUC will act as the complainant

III. Response to Concerns

- a. Any concern submitted to a member of the IACUC will be promptly reported to the IACUC chairperson or the USU Attending Veterinarian (USU AV) if the chair is unavailable
- b. Upon receipt of a concern the IACUC Chairperson (or designee) shall conduct an initial review to determine the course of action.
 - i. A preliminary investigation of the concern may be warranted
 - ii. If, following initial review and investigation, the IACUC Chairperson determines there is an immediate threat to animal health or welfare the animal work may be immediately halted by order of the IACUC chairperson.
 - 1. Decisions regarding stoppage must be made in consultation with the USU AV and the protocol AV.
 - 2. The USU AV will assume responsibility for animal care and will provide all necessary care to alleviate pain and/or distress until a convened IACUC meeting can determine a course of action.
 - 3. Following any stoppage of animal work by the IACUC Chairperson an IACUC meeting must be quickly convened to vote upon the suspension and determine a final course of action.
- c. All concerns will be reviewed by a convened meeting of the IACUC

- i. Depending upon the severity of the concern the Chairperson may call an emergency meeting of the IACUC, or may defer to the next scheduled IACUC meeting.
 - 1. In cases of potential harm to animal health or welfare convenience is an insufficient reason for delaying action upon a concern until the next regularly scheduled IACUC meeting.
- d. After review of the concern the IACUC shall determine by majority vote of a convened quorum that the concern requires:
 - i. Further investigation and immediate action
 - ii. Further investigation but no immediate action
 - iii. No action
- e. Actions that may be taken by the IACUC include, but are not limited to:
 - i. Veterinary medical intervention
 - ii. Suspension of research activity (9 CFR 2.31 (c)(8),(d)(6)
 - 1. Suspension of research activity requires prompt notification, via the Institutional Official (IO), of:
 - a. APHIS (9 CFR, Part 2, Subpart C, Section 2.31(d)(7)) for animals covered under the animal welfare act and notification of funding source
 - b. Any federal funding agency
 - c. OLAW for any PHS supported work (PHS Policy, IV.F.3)
 - d. Any private funding source
 - iii. Notification of appropriate safety, occupational health, or other officials
 - iv. Refer to IACUC SOP #2 *Sanctions of Animal Users for Issues of Non-Compliance* for procedures.
- f. Following the determination of the course of action the IACUC will determine which individuals or other institutional or non-institutional offices may require notification at this time
 - i. Institutional Official
 - ii. USDA/APHIS
 - iii. OLAW
 - iv. Granting agencies (NIH, etc)
- g. If Animal Activities are suspended the IACUC AV or another Veterinarian as designated by the IACUC AV will direct the care of Animals involved, including decisions regarding
 - i. Euthanasia
 - ii. Medical care
- h. If the IACUC chairperson has a conflict of interest regarding the concern (i.e. target of the complaint) the IO will appoint another individual as Acting Chairperson to conduct IACUC business in regard to reviewing the concern.
 - i. The Acting Chairperson may be selected from within or without the current members of the IACUC.

- IV. Complaint Investigation, Reports, and Final Actions
- a. If additional investigation is determined necessary the Chairperson, or another individual/subcommittee designated by the Chairperson shall conduct the investigation and report back to the IACUC
 - i. Conflicts of interest should be avoided in determining individuals conducting the investigation
 - b. The IACUC shall determine a completion date for the investigation, and should identify the requirements for information gathering
 - i. The nature of the information required varies depending upon circumstance, but often involves:
 1. Interviewing complainants (if known), any persons against whom complaints were directed, animal care staff, and pertinent program officials
 2. Observing animals and their environment
 3. Reviewing any pertinent records (e.g. animal health records, Animal Use Protocol, and other documents)
 4. Other pertinent information
 - c. The target of an investigation will be notified in writing prior to beginning the investigation
 - i. Copies of the letter will be sent to the individuals supervisor or department head, College Dean, and to the IO
 - ii. The individual will be reminded in that letter that any retaliation against a "whistleblower" is prohibited by federal law and University policy.
 - d. The designated investigator(s) shall provide a report to the IACUC verbally and in writing
 - i. Investigators should respect the confidential and potentially proprietary nature of research records and respect the privacy and rights of individuals involved in research.
 1. Investigators should employ all reasonable steps to maintain confidentiality of research records.
 2. Investigators should employ all reasonable steps to ensure the privacy and rights of research individuals are protected.
 - ii. The report should summarize
 1. The concerns/complaints submitted to the IACUC
 2. Results of interviews with involved personnel
 3. Conditions of animals and their environment
 4. Reviews of records and other documents
 5. Other information as deemed appropriate
 - iii. The report should also include as appropriate
 1. Any supporting documentation
 2. Conclusions regarding the substance of the concerns in light of:
 - a. AWRs
 - b. PHS Policy
 - c. *The Guide*

d. USU policies and procedures

3. Recommended actions

- iv. The IACUC will submit a written copy of the report to the IO
- v. The decision to report to the complainant, and the nature of the report (i.e. details, final outcome, etc) will be left to the discretion of the IACUC
- e. Subsequent actions of the IACUC may include:
 - i. Implementation of measures designed to prevent recurrence
 - ii. Notification of the IO and the AV for the Protocol in question of the IACUC's actions
 - iii. As required, notification of funding or regulator agencies via the IO
 - iv. Notification of the complainant, any persons against whom allegations were directed, and pertinent program officials (appropriate supervisors, public affairs office, etc.)
- f. The IACUC has no authority to instigate any form of punishment against any individual.
 - i. Any punitive or administrative actions will be conducted by the appropriate USU personnel and/or legal authorities and in compliance with all federal, state, and local laws, and with University policies.