6.0  Review of Noncompliance

The IACUC investigates concerns involving the care and use of animals raised by complaints or reports of noncompliance received from the public or from research personnel or employees [9 CFR 2.31(c) (4)]. The University is required to report results of some investigations to OLAW, the USDA and/or AAALAC.

6.1 Identification of Compliance Issues

Anyone who has a concern or question about animal care and use at Creighton University, including protocol noncompliance or animal treatment, is expected to contact the IACUC Chair or the ARF Director, or to call the Confidential Research Hotline at 855-256-0478. The Attending Veterinarian, ARF personnel and individual IACUC members must also report any suspected incidence of noncompliance. Reports made through the Confidential Research Hotline are delivered to the IACUC Chair for investigation (see Policy R&C-IACUC-6.0 section 6.2). Strict confidentiality will be maintained to the extent possible and allowable by law. Creighton University prohibits retaliation against any employee who makes a good faith report of known or suspected noncompliance in the care and use of animals at Creighton University.

Concerns include situations or activities in which animals are in immediate jeopardy and those in which violations of the Federal Animal Welfare Regulations or the Assurance are alleged but animals are not in apparent danger. They may also be past violations of the IACUC or ARF Policies and Procedures or protocol noncompliance.

6.2 Investigation of Animal Care and Use Concerns

6.2.1 Initial Evaluation and Actions

The Attending Veterinarian has authority to immediately halt activity on a protocol if he or she has reason to believe that animal welfare is being compromised. The Attending Veterinarian immediately notifies the affected Principal Investigator and the IACUC Chair in writing.

Upon receipt of a concern from any party, the IACUC Chair or his/her designee may convene an emergency meeting of the IACUC to determine whether the concern requires further investigation and immediate action, further investigation but no immediate action, or no action.

Veterinary medical intervention, halting of a research activity, and/or notification of appropriate safety, occupational health, or other officials, are examples of actions that may be taken immediately. Situations that involve potential criminal activity or human safety are reported promptly to Creighton University’s Public Safety or occupational health and safety officials. If immediate action is warranted to protect animal or human welfare, the IACUC notifies the Institutional Official or the Institutional Official’s designee(s). Any formal suspension of activity
is reported to regulatory agencies (see Policy R&C-IACUC-6.0 Section 6.6).

6.2.2 Investigation

If further investigation is required, the Chair or a subcommittee appointed by the Chair conducts the investigation and reports its findings to the IACUC by an assigned completion date. To avoid actual or perceived conflicts of interest in the investigation process, no person with an unresolved personal, professional or financial conflict of interest with the affected investigator or personnel is involved in the investigation.

The investigation may involve:

- Interviewing complainants, any persons against whom allegations were directed, and pertinent program officials
- Observing the animals and their environment
- Reviewing pertinent records, (e.g., animal health records, protocol)

The report to the IACUC summarizes:

- The concern(s)
- The results of interviews
- The condition of animals and their environment
- The results of document reviews

The report must also contain:

- Any supporting documentation such as correspondence, reports, and animal records
- Conclusions regarding the substance of the concerns
- Recommended actions

6.2.3 Outcomes and Final Actions

Upon receipt and evaluation of the report, the IACUC may request further information or make one of the following findings:
- There was no evidence to support the concern or complaint
- The concern or complaint was not sustained, but aspects of the animal care and use program or other institutional programs may require review
- The concern or complaint is valid

Actions of the IACUC may include:

- Notifying the complainant, any persons against whom allegations were directed, and pertinent program officials (appropriate supervisory and management staff, human resources, institutional attorneys, etc.)
- Implementing measures to prevent recurrence
- Notifying the Institutional Official
- Notifying funding or regulatory agencies

### 6.3 Noncompliance with IACUC Policies

Failure to comply with IACUC policies or to adhere to the procedures of an approved protocol constitutes noncompliance. Examples of noncompliance are performing unauthorized surgery, unauthorized persons participating in a research project, or administering drugs that the IACUC has not approved.

The IACUC’s first goal when noncompliance is found is to restore compliance. In determining its response to a finding of noncompliance, the IACUC may consider:

- Self-reporting by the Principal Investigator or staff
- Proactive corrective action(s) taken in response
- The extent to which the incident(s) represent a continuing, or repeated violation and the length of time between incidents of noncompliance
- The extent to which harm to an animal resulted from the incident(s)

The response of the IACUC may include:

- Counseling
6.4 Consequences of Noncompliance

If, in the opinion of the IACUC, sanctions are not appropriate, they need not be applied. If the IACUC finds that sanctions are appropriate, they may include;

- Requiring the Principal Investigator to present plans for corrective action to the IACUC
- Issuing letters of reprimand
- Notification to the Principal Investigator’s Departmental Chair or immediate supervisor
- A letter to the Principal Investigator from the Institutional Official outlining the problem and requesting a detailed plan of corrective action
- Restriction of access to the ARF
- Suspension of protocol and/or loss of animal use privileges
- Permanent revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals
- Recommending to the Institutional Official that institutional sanctions be imposed. (e.g., reassignment, termination of employment)

6.4.1 Suspension of a Protocol

The IACUC may suspend activities on a protocol if it finds violations of the Institutional Policy, PHS Policy, the Assurance, or Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with the affirmative vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reason for suspension. The Institutional Official or the Institutional Official’s designee(s) is required to take appropriate corrective action and report the action to regulatory agencies with full explanation. (see Policy R&C-IACUC- 6.0 section 6.6).

6.5 Programmatic Deficiencies and Corrective Actions
The IACUC semiannual evaluations are tools for institutional self-identification and correction of facility and program deficiencies. Program deficiencies include:

- Failure to correct situations identified as significant deficiencies in a timely manner
- Shortcomings in the programs of veterinary care, occupational health, training, or with the IACUC
- Conditions that jeopardize the health or well-being of animals, including accidents, natural disasters and mechanical failures resulting in actual harm or death to animals

Programmatic deficiencies must be categorized as acceptable, minor, or significant. The corrective action for a significant deficiency must include a reasonable plan to correct the issues as well as a date by which the issue will be corrected. Significant programmatic deficiencies must be reported to the applicable regulatory agencies if the deficiency jeopardizes the health and welfare of the animals, or if Creighton University is unable to make the correction by the specified date.

### 6.6 Reporting Requirements

The IACUC, through the Institutional Official or the Institutional Official’s designee, shall promptly report to OLAW, the USDA, and AAALAC, as appropriate, circumstances and actions taken with respect to:

- Any serious or continuing noncompliance with PHS Policy
- Any serious deviation from the provisions of *The Guide*
- Any suspension of an activity by the IACUC

In addition, the IACUC, through the Institutional Official or the Institutional Official’s designee, must report within 15 days any failure to correct a significant deficiency to the USDA and any federal agency funding the activity in which the significant deficiency was found.

Examples of reportable incidents include:

- Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals
- Conduct of 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

• Conduct of official IACUC business requiring a quorum in the absence of a quorum

• Conduct of official IACUC business during a period of time that the IACUC is improperly constituted

• Failure to correct deficiencies identified during the semiannual evaluation in a timely manner

• 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

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

• IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the PHS Policy, Animal Welfare Act, *The Guide*, or the University’s Animal Welfare Assurance

### 6.6.1 Agency-Specific Reporting Requirements

**Office of Laboratory Animal Welfare (OLAW)**

The Institutional Animal Care and Use Committee (IACUC), through the Institutional Official or the Institutional Official’s designee(s), must contact the office of the Director of Compliance at
OLAW immediately after:

- Suspension of any activity by the IACUC
- A finding of serious or continuing noncompliance with the PHS Policy
- A finding of significant deviation from the provisions of *The Guide*

After review of any allegation of non-compliance by the IACUC and the Institutional Official or the Institutional Official’s designee(s), a formal written report will be filed with OLAW within three months of the event stating a full explanation of circumstances, a description of corrective actions taken, any minority views filed by the IACUC, and the status of the research program.

**United States Department of Agriculture (USDA)**

The IACUC, through the Institutional Official or the Institutional Official’s designee(s), must contact the Western Regional Director of Animal Care immediately in the following instances:

- Suspension of any activity by the IACUC
- Failure to adhere to a plan to correct a significant deficiency

**Federal Funding Agencies**

The IACUC, through the Institutional Official or the Institutional Official’s designee(s), must contact any Federal agency funding an activity involving the use of animals immediately in the following instances:

- The activity is suspended by the IACUC
- The institution fails to adhere to a plan to correct a significant deficiency that affects the activity

**Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC)**

Copies of all correspondence with OLAW and USDA regarding issues of noncompliance are forwarded to AAALAC in a timely manner.

6.6.2 Non-reportable Incidents
Examples of incidents that are not normally required to be reported are:

- The death of animals that have reached the end of their natural life spans
- The death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate
- Animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed
- Animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol
- Infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, must be reported promptly along with corrective plans and schedules)