POLICY

The IACUC is under federal mandate to provide continual monitoring and oversight of all research activities related to animal use. The IACUC will review and investigate any reported incidents. Absent a conflict of interest, no member of the IACUC will be involuntarily excluded from participating in any review or investigation.

To assist the IACUC in fulfilling this requirement, all known incidents adversely affecting the welfare of animals used in research or teaching should be reported to the IACUC. The purpose of reporting incidents to the IACUC is to ensure that animal welfare concerns have been fully addressed by the research team, the veterinary staff, and the IACUC as they occur. Timely reporting allows the institution to provide the highest quality animal care by engaging all available resources, and to determine whether proactive measures could circumvent or alleviate recurrence.

Incidents that should be reported to the IACUC include:
1) Noncompliance – reports of negligence or willful disregard of institutional policies/procedures, and/or federal regulations.
2) Unexpected outcomes - incidents related to experimental procedures that may have resulted in an increased level of pain or distress in an animal that required intervention or euthanasia or resulted in death that was not anticipated and described in the approved protocol.
3) Adverse Events - incidents that may or may not be related to the experiment, such as an act of nature, or an incident caused by mechanical failure of equipment that may have resulted in an increased level of pain or distress in an animal that required intervention or euthanasia, or resulted in death.

Incidents related to federally funded projects that meet the conditions for reportable noncompliance described in the Office of Laboratory Animal Welfare’s (OLAW) “Guidance on Prompt Reporting”, will be reported to OLAW by the IACUC in conjunction with the Institutional Official (IO). However, the IACUC and the IO reserve the right to report any noncompliance to OLAW, regardless of funding source.

REGULATIONS

Animal Welfare Act in accordance with, (9 CFR Ch. 1), Part 2 – Subpart C, 2.31(c)(4), Review, and if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees.

The Public Health Service (PHS) Policy in accordance with IV.B.4. Review concerns involving the care and use of animals at the institution;

Office of Laboratory Animal Welfare NOT-OD-05-034 “OLAWS Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals”

The Guide Eighth Edition, pg 28, “Because of the potential for unexpected outcomes that may affect animal well-being when highly novel variables are introduced, more frequent monitoring of animals may be required.”

PROCEDURE
1.0 All incidents adversely affecting animal welfare must be reported to the IACUC for immediate review. These incidents may require immediate investigation and/or appropriate intervention.

2.0 Individuals who may report incidents:
   2.1 Incidents are identified by: a) voluntary reports by the PI, b) anyone witnessing an incident, c) Comparative Medicine (CM) staff observations, d) IACUC semiannual inspections, e) assessments by the Protocol Assessment Liaison (PAL), or f) institutional employee reports.

3.0 How to report:
   3.1 Notices are located in the animal facilities, and on the IACUC and CM websites advising individuals how and where to report identified animal welfare concerns.
      A. Individuals may report via email, phone, or in person.
      B. An online Incident Report form is available on the IACUC site on the Research Support System (RSS). The form may be completed and submitted online via the RSS.
   3.2 The IACUC shall attempt to maintain the confidentiality of an individual who reports concerns or misconduct. However, confidentiality cannot be guaranteed, and disclosure of the individual's identity may be necessary in order to fully investigate the concern. There is no retribution or discipline for anyone who reports a concern in good faith.

4.0 The IACUC Executive Chair, the IO and the Attending Veterinarian (AV) will be immediately notified of the reported incident.

5.0 Conducting an investigation:
   5.1 PAL in conjunction with CM personnel and IACUC members as necessary or requested, will conduct an investigation. The investigation will include, but is not limited to:
      A. Interviewing of personnel involved;
      B. Observing animals and determining if their welfare has or is being jeopardized;
      C. Reviewing pertinent records;
      D. Initiating any necessary immediate preventative/corrective action, e.g., required veterinary intervention; education on the PHS Policy, USDA Regulations, UNMC/UNO IACUC or CM Policies; or halting of the animal activity.

6.0 PAL will develop a report documenting the incident and investigation and all corrective action taken to date.
   6.1 The report will be supplied to the PI to ensure accuracy of the report provide the PI and/or personnel involved to supply additional supportive information.
   6.2 This report will then be presented to the IACUC Subcommittee (IS). The IS consists of at least, the IACUC Executive Chair/designee, the AV/designee, members of the IACUC, and PAL.

7.0 The IS will meet as soon as possible to review the report.
   7.1 All members of the IACUC will be notified of the date of the meeting and invited to attend.

8.0 The IS will make a recommendation on the following:
   8.1 Whether or not the investigation is complete or if additional investigation is required.
   8.2 Whether or not any immediate preventative/corrective action was appropriate or if additional action is required.
   8.3 What category the incident is defined as; noncompliance, adverse event, or unexpected outcome.
   8.4 Whether the incident/concern constitutes serious and/or continuing noncompliance or a serious deviation from the Guide reportable to OLAW per NOT-OD-05-034 Guidance on Prompt Reporting to OLAW and the UNO/UNMC OLAW Assurance.
9.0 The IS will determine the type of review required by the IACUC; Designated Member Review (DMR) or Full Committee Review (FCR).

10.0 On behalf of the IS, PAL will update the report summarizing the investigation, preventative/corrective action taken and IS recommendations.
10.1 The PI will be sent a copy of the updated report and will be given the opportunity to provide any additional information, and be given the opportunity to appeal in accordance with a set deadline.
10.2 Following IACUC review, formal notification documenting the decision of the IACUC will be sent to the PI and IO.

11.0 Incidents reportable to OLAW:
11.1 The IACUC and the IO will ultimately make the final determination that the incident was a reportable incident and the IO will report to OLAW, AAALAC, and USDA as applicable.
11.2 In some reported cases OLAW may request that the university contact the funding component with details of an incident and whether or not federal funds were used to pay for the specific procedures, Sponsored Programs Administration will be provided with the details of the incident and following consultation with the department provide OLAW with the requested information.
11.3 Upon response from OLAW or AAALAC, as applicable, indicating no further action is required, the reported incident and the documentation will be filed in the IACUC office.
11.4 Reports to OLAW involving Department of Defense (DOD) or National Strategic Research Institute (NSRI) funded protocols; the PI is responsible for immediately notifying the Animal Care and Use Review Office (ACURO).