POLICY

The IACUC will review at least once every six months the institution’s program for humane care and use of animals, and the Institution’s animal facilities, including satellite facilities and study areas using the “Guide,” Public Health Service (PHS) Policy, and United States Department of Agriculture (USDA) regulations as a basis for review and evaluation.

The program review encompasses institutional policies and responsibilities (lines of authority and reporting channels), IACUC membership and functions, and IACUC record keeping and reporting procedures. It will also include a review of the adequacy and appropriateness of the veterinary medical care program, the training program for personnel, and the occupational health and safety program.

The facility review is a physical inspection of all buildings, rooms, areas, enclosures and vehicles (including satellite facilities) that are used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation.

Laboratories where routine procedures are conducted, such as immunization, dosing, and weighing, will be evaluated by other means such as random inspections. However, the institution, through its IACUC, is responsible for all animal-related activities regardless of where animals are maintained or the duration of the housing. The IACUC must have reasonable access to these areas for the purpose of verifying that activities that involve animals are being conducted in accordance with the proposal approved by the IACUC.

REGULATION

Animal Welfare Act in accordance with, (9 CFR Ch. 1), Part 2 – Subpart C, 2.32(4c) With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (1) Review, at least once every six months, the research facility’s program for humane care and use of animals, using title 9, chapter I, subchapter A--Animal Welfare, as a basis for evaluation; (2) Inspect, at least once every six months, all of the research facility’s animal facilities, including animal study areas, using title 9, chapter I, subchapter A-Animal Welfare, as a basis for evaluation; (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.

The Public Health Service (PHS) Policy in accordance with IV.B. 1.-3. All of the institution’s programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months, and reports prepared, maintained by the institution and made available to OLAW upon request.

PROCEDURE

1.0 Prior to the semiannual inspection, all IACUC members are given:

1.1 Schedule of the inspections
1.2 Copy of the current Office of Laboratory Animal Welfare (OLAW) Sample Semiannual Program Review and Facility Review Checklists to be utilized in conjunction with the Guide.
1.3 A list of current IACUC approved exceptions from the Guide, and reasons for the departure.
1.4 The current UNMC Animal Welfare Assurance
2.0 A semiannual inspection team is comprised of the following, at a minimum:
   2.1 A subcommittee(s), which must consist of at least two IACUC members.
   2.2 The IACUC Administrator/designee or the Protocol Assessment Liaison (PAL).
   2.3 No IACUC member will be excluded should she or he wish to participate in an inspection. Ad hoc consultants may be used although the IACUC remains responsible for the evaluations and reports.
   2.4 A record of attendance of the inspection team present will be filed with the report.

3.0 The inspection team, utilizing the OLAW Sample Semiannual Facility Inspection Checklist, conducts an on-site evaluation of:
   3.1 Animal Housing and Support Areas
   3.2 Cage wash
   3.3 Aseptic Surgery Areas
   3.4 Procedure Areas
   3.5 Non-survival Surgery Areas
   3.6 Laboratories
   3.7 Rodent Surgery Areas

4.0 The inspection team, utilizing the PHS Policy, USDA Regulations, the Guide and the OLAW Sample Semiannual Program Review checklist, convenes to discuss and evaluate the following:
   4.1 IACUC Policies and Responsibilities:
      A. Animal Care and Use Program
      B. Disaster Planning and Emergency Preparedness
      C. IACUC
      D. IACUC Protocol Review - Special Considerations
      E. IACUC Membership and Functions
      F. IACUC Training
      G. IACUC Policies, SOPs, Records and Reporting Requirements
      H. Veterinary Care
      I. Personnel Qualifications and Training
      J. Occupational Health and Safety of Personnel
      K. Personnel Security
      L. Investigating & Reporting Animal Welfare Concerns
   4.2 Veterinary Medical Care
      A. Clinical Care and Management
      B. Preventive Medicine/Animal Procurement and Transportation
      C. Surgery
      D. Pain/Distress/Analgesia/Anesthesia
      E. Euthanasia
      F. Drug Storage and Control
   4.3 Institution's UNMC Animal Welfare Assurance
   4.4 Lines of authority and reporting channels

5.0 During review of the program and inspection of the facilities and laboratories, specific deficiencies are identified by the inspection team and recorded by the IACUC, PAL/designee.

6.0 The inspection team will review the deficiencies at the time of the inspection and determine if the deficiencies are significant or minor, and implement a plan of correction for each deficiency:
   6.1 A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.
      A. The concern or problem will be immediately addressed by appropriate intervention or investigation.
      B. Significant deficiencies will be reviewed by the IACUC to evaluate to determine a specific plan and schedule for correction.
C. Significant deficiencies may be referred to PAL as an incident requiring further investigation by the IACUC and PAL.

D. The IACUC Chair will verbally notify the Institutional Official (IO) immediately of significant (S) deficiencies identified.

E. Significant deficiencies in a USDA regulated activity that fail to adhere to the scheduled plan shall be reported, in writing, within 15 business days by the IACUC through the IO to the Animal Plant Health and Inspection Service (APHIS). OLAW will be notified in accordance with PHS Policy at IV.F.3.

6.2 A minor deficiency may include but is not limited to: expired drugs that have not been used on animals, not wearing appropriate PPE, unprotected sharps, surgery/training/controlled drug records incomplete or unavailable, expired food, porous storage containers and/or equipment, missing ceiling tiles, dripping faucet, cracks in the wall.

6.3 PAL/designee will record the findings of the inspection on the RSS online inspection form or hard copy inspection form at the time of the inspection and verbally inform the PI/representative of the inspection team findings.

6.4 The electronic inspection report is maintained on the RSS. If a hard copy form was utilized during the inspection the notes will be transcribed into the electronic form and saved and submitted.

A. The PI/Director and the lab/facility representative present at the time of the inspection will receive the details of the inspection report via an automated letter as soon as the form is completed/submitted.

B. The automated letter will serve as the official IACUC notification informing the PI/Director that there were either no deficiencies, or describe the minor deficiency and outline the required action.

6.5 A response confirming that the required action has been completed must be received from the PI/Director or designee via email 30 days from the date of the notice. A request for an extension of time to complete the correction may be requested, but must be reviewed and approved by the IACUC via Full Committee Review or Designated Member Review.

6.6 Notifications and responses to minor deficiencies will be confirmed and recorded by the IACUC Administrator/designee and will be filed with the report.

6.7 Other observations or questions by the inspection team not determined to be a deficiency at the time of the inspection will be referred to PAL/designee for additional inquiry. If PAL determines that there is a minor deficiency the inspection team and the PI/Director will be notified and the inspection report will be modified.

6.8 PAL will provide follow-up education as necessary throughout the inspections.

7.0 PAL, the IACUC Administrator or designee prepares reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3.

7.1 The report reflects the nature and extent of the institution’s adherence to the Guide and PHS Policy.

7.2 The Report identifies specific departures from the provisions of the Guide and PHS Policy, and the reason for each departure.

7.3 The Report distinguishes minor deficiencies from significant deficiencies as defined above and by the PHS Policy (IV.B.3).

7.4 The Report will contain a reasonable and specific plan and schedule for correcting any program or facility deficiency.

7.5 The Report will identify all facilities accredited by AAALAC International.

8.0 The semiannual inspection report will be submitted to the IACUC for review and discussion at the next convened meeting following the inspections.

8.1 Any minor deficiencies requiring an extension of the correction deadline must be reviewed and approved by the IACUC.

8.2 A vote to accept the report is taken and any minority views are recorded and included in the report.

8.3 The report is signed by a quorum of the IACUC members.
9.0 Situations requiring additional review by the IACUC Full Committee:
   9.1 Any deficiencies that have not been responded to by the responsible person within the scheduled
time frame will be reviewed by the IACUC Chair to determine if additional action is necessary. It will
then be reviewed by the IACUC.

10.0 Within 10 days after the IACUC has reviewed and accepted the semiannual inspection report (no
more than 60 days following the inspection):
   10.1 A copy is sent to the IO.
   10.2 A copy is sent to other appropriate officials as necessary.
   10.3 Upon completion of all corrections the IO will be notified.

11.0 All reports of the semiannual inspection of animal facilities will be maintained by the institution
and made available to OLAW upon request.

LINKS TO RELATED FORMS, RECORD LOGS, AND SOPS

OLAW SEMIANNUAL PROGRAM REVIEW AND FACILITY INSPECTION CHECKLIST