Guiding Principle

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

The program review encompasses animal care and use program, disaster planning and emergency preparedness, IACUC, IACUC protocol review-special considerations, IACUC membership and functions, IACUC training, IACUC records and reporting requirements, veterinary care (clinical care and management, animal procurement and transportation/preventive medicine, surgery, pain, distress, anesthesia, and analgesia, euthanasia, and drug storage and control), occupational health and safety of personnel, personnel security, and investigating and reporting animal welfare concerns.

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 in which routine procedures, such as immunization, dosing, and weighing, are conducted will be evaluated by other means such as random inspections. However, the Institution, through the IACUC, is responsible for all animal-related activities. The IACUC must have access to these areas for the purpose of verifying that activities involving animals are being conducted in accordance with the proposal approved by the IACUC.

Requirements

Animal Welfare Act in accordance with, (9 CFR Ch. 1), Part 2-Subpart C, 2.32 (4c) With response 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 1, 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 study areas, using title 9, chapter 1, 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 semi-annual 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 Semi-annual 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 NDSU PHS Animal Welfare Assurance

2.0 A semi-annual inspection team is comprised of the following, at a minimum:
   2.1 For USDA-regulated facilities, an inspection team of at least two voting IACUC members.
   2.2 For non-USDA-regulated facilities an inspection team of at least one voting IACUC member.
   2.3 The IACUC Administrator/designee.
   2.4 No IACUC member will be excluded should he or she wish to participate in an inspection. Ad hoc consultants may be used although the IACUC remains responsible for the evaluations and reports.
   2.5 A record of attendance will be signed by members of the inspection team present.

3.0 For semi-annual inspections at the NDSU Research Extension Centers the IACUC may utilize video conferencing capabilities with the following provisions:
   3.1 An inspection subcommittee will view the live video feed at a prearranged time.
   3.2 The video conferencing option cannot be used in consecutive inspections.
   3.3 The video will not be recorded.
   3.4 The video operator will film the complete facility and comply with the requests from the subcommittee members.

4.0 The semi-annual inspection team, utilizing the OLAW Sample Semiannual Facility Inspection Checklist, conducts an on-site evaluation of:
   4.1 Terrestrial animal housing and support areas
   4.2 Aquatic animal housing and support areas
4.3 Cagewash
4.4 Aseptic Surgery Areas
4.5 Special Facilities: Procedure areas, non-survival surgeries, laboratories, rodent surgeries, whole body irradiation, hazardous agent containment, behavioral studies

5.0 The IACUC, utilizing the PHS Policy, USDA Regulations, the Guide and the OLAW Sample Semiannual Program Review checklist, convenes to discuss and evaluate the following:

5.1 Institutional 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 Records and Reporting Requirements
   H. Veterinary Care
   I. Personnel Qualifications and Training
   J. Occupational Health and Safety of Personnel
   K. Personnel Security
   L. Investigating and Reporting Animal Welfare Concerns

5.2 Veterinary Care
   A. Clinical Care and Management
   B. Animal Procurement and Transportation/Preventative Medicine
   C. Surgery
   D. Pain, Distress, Anesthesia and Analgesia
   E. Euthanasia
   F. Drug Storage and Control

5.3 NDSU’s PHS Animal Welfare Assurance
5.4 Lines of authority and reporting channels

6.0 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 Administrator or designee.

7.0 The IACUC inspection team will review deficiencies at the time of inspection and determine if deficiencies are significant or minor, and implement a plan for correcting each deficiency:

   7.1 A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.

   7.2 The concern or problem will be immediately addressed by appropriate intervention or investigation.
7.3 Significant deficiencies may require an emergency fully convened meeting to evaluate and determine a specific plan and schedule for correction.

7.4 Significant deficiencies may also become a compliance case requiring further investigation by the IACUC.

7.5 The IACUC Chair/Attending Veterinarian (AV) will verbally notify the Institutional Official (IO) immediately of significant deficiencies identified.

7.6 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 Section IV. F.3.

7.7 A minor deficiency may include, but is not limited to expired food, unsealed wood, open feed bags, dripping faucet, cracks in wall.
   A. A correction schedule for minor deficiencies will be determined by the inspection team and responsible personnel (e.g. facility manager). The minor deficiencies must be corrected by the determined date and the timeline begins on the date the responsible personnel were notified.

7.8 The IACUC Administrator/designee will notify the persons responsible for correcting the minor deficiencies during the following information will be shared with facility personnel present during the inspection:
   A. A detailed description of the minor deficiency noted by the inspection team.
   B. The required response from the responsible person confirming completion by the correction schedule.

7.9 A request for an extension of time to complete the correction may be requested. The request will initially be reviewed by the AV and IACUC Administrator. In special circumstances, the request may be brought to the IACUC for review and approval.

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

7.11 Deficiencies not determined as significant may require additional investigation and/or education.

8.0 The IACUC Administrator or designee prepares reports of the IACUC evaluations as set forth in PHS Policy IV.B.3

8.1 The report reflects the nature and extent of the Institutions adherence to the Guide and PHS Policy, and the reasons for the departure.

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

8.3 The report distinguishes minor deficiencies from significant deficiencies as defined above and by the PHS Policy (IV.B.3).
8.4 The report will contain a reasonable and specific plan and schedule for correction any program or facility deficiency.

8.5 The report will identify all facilities accredited by AAALAC International.

9.0 The semi-annual report to the Institutional Official will be submitted to the full IACUC for review and discussion at the next convened meeting following inspections.

9.1 Any minor deficiencies requiring an extension of the correction deadline may be reviewed by the committee.

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

9.3 The report is signed by a quorum of the IACUC members.

10.0 Situations requiring additional review by the IACUC Full Committee:

10.1 Any deficiencies that have not been addressed by the responsible person within the scheduled time frame will be reviewed by the IACUC Chair to determine if additional action is necessary. The matter will then be brought to the IACUC at a full committee meeting.

11.0 Within 10 days after the IACUC has reviewed and accepted the semiannual report to the Institutional Official (no more than 60 days following the inspection):

11.1 A copy is sent to the IO

11.2 A copy is sent to other appropriate officials as necessary.

11.3 Upon completion of all corrections the IO will be notified.

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