Policy #2: Semiannual Program Review and Facility/Laboratory Inspection

Policy:

The IACUC will review the institution’s program for humane care and use of animals, and the Institution’s animal facilities at least once every six months, including satellite facilities and study areas using the Guide for Care and Use of Laboratory Animals and Public Health Service (PHS) Policy 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 inspected. 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 verifying that activities that involve animals are being conducted in accordance with the proposal approved by the IACUC.

Applicable Regulations:

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. Prior to the semiannual inspection, all IACUC members are given:
   A. Schedule of the inspections
   B. 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.
   C. A list of current IACUC approved exceptions from the Guide, and reasons for the departure.
   D. The current PHS Animal Welfare Assurance

2. A semiannual inspection team is comprised of the following, at a minimum:
   A. A subcommittee is designated by the Chair
   B. The IACUC Administrator/designee
   C. No IACUC member will be excluded should she/he wishes to participate in an inspection. Ad hoc consultants may be used although the IACUC remains responsible for the evaluations and reports.
   D. The members of the inspection team present will be indicated in the site visit checklist. This is the record of their attendance.

3. The inspection team, utilizing the OLAW Sample Semiannual Facility Inspection Checklist, conducts an on-site evaluation of:
   A. Animal Housing and Support Areas
   B. Cage wash
C. Aseptic Surgery Areas
D. Procedure Areas
E. Non-survival Surgery Areas
F. Laboratories where animals are housed
G. Rodent Surgery Areas

4. 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:
   A. IACUC Policies and Responsibilities:
      I. Animal Care and Use Program
      II. Disaster Planning and Emergency Preparedness
      III. IACUC
         (1) IACUC Protocol Review- Special Considerations
         (2) IACUC Membership and Functions
         (3) IACUC Training
         (4) IACUC Policies, SOPs, Records and Reporting Requirements
   IV. Veterinary Care
   V. Personnel Qualifications and Training
   VI. Occupational Health and Safety of Personnel
      VII. Personnel Security
      VIII. Investigating and Reporting Animal Welfare Concerns
   B. Veterinary Medical Care
      I. Clinical Care and Management
      II. Preventive Medicine/Animal Procurement and Transportation
      III. Surgery
      IV. Pain/Distress/Analgesia/Anesthesia
      V. Euthanasia
      VI. Drug Storage and Control
Reporting Findings:

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.

The findings will be presented to the IACUC to review the deficiencies and determine if the deficiencies are significant or minor, and implement a plan of correction for each deficiency:

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 require an emergency fully convened committee meeting to evaluate and determine a specific plan and schedule for correction.
   C. Significant deficiencies will also be referred to administrator requiring further investigation by the IACUC and IACUC Office.
   D. The IACUC Chair will verbally notify the Institutional Official (IO) immediately of significant (S) deficiencies identified.
   E. Significant deficiencies that fail to be corrected as per 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.

2. A minor deficiency does not cause significant impact on the welfare of the animals.
   A. It 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 unavailable, expired food, unsealed wood, missing ceiling tiles, dripping faucet, cracks in the wall.
   B. Minor (M) deficiencies have 30 days to be corrected from the date that the notification of the deficiency is sent to the person responsible for correcting the deficiency.
C. The Inspection Team will record the findings of the inspection on an IACUC Semi-Annual Inspection Checklist Form and present it to the IACUC.

D. All records of Semi-Annual Inspection will be maintained at ORP, IACUC Office.

E. After the IACUC decides the nature of deficiencies, IACUC Chair or ORP Director or designee will notify the persons responsible for correcting the minor deficiencies.

F. The deficiencies should be corrected within 30 days or as noted by IACUC.

Dissemination of Site Visit Findings:

1. Site visit findings, along with the checklist, will be sent to the PIs after the IACUC has provided feedback regarding the nature of deficiency and the date to correct by.

2. These findings will be sent by IACUC Chair or ORP Director or Designee.

3. The responsible person will acknowledge the receipt of the document and submit a completion report within the stipulated time.

4. Requests for 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.

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

6. Suggestions for improvement may be provided by the committee and may not raise the level of minor or major deficiency at the time of inspection. These will be followed up with education and opportunities for preparing SOP, guidelines or training.

Reporting to IACUC:

1. The IACUC Administrator or designee prepares reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3. The report reflects the nature and extent of the institution’s adherence to the Guide and PHS Policy.

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

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

The semiannual inspection report will be submitted to the IACUC for review and discussion at the next convened meeting following the inspections. Any minor deficiencies requiring an extension of the correction deadline must be reviewed and approved by the committee at the next fully convened meeting.

A vote to accept the report is taken and any minority views are recorded and included in the report. The report is signed by a quorum of the IACUC members.

Situations requiring additional review by the IACUC Full Committee:
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 at a full committee meeting.

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

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

Links Related to Forms:


VU IACUC Policy May 15, 2018