IACUC Policy # 400: IACUC Policy for Semi-Annual Inspections

The intent of this policy is to define the requirements and process for the conduct, reporting and follow up of the IACUC inspections of animal facilities. This policy is intended for use by the members of the IACUC, the IACUC administrative office, and the facility managers or Principal investigators responsible for the management and operation of the facilities.

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1) Policy
A. All animal facilities housing live, vertebrate animals for research, testing or teaching purposes must be inspected semi-annually by the IACUC. An animal facility includes buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, procedures, or experiments. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 12 hours.
B. Every IACUC member is expected to participate in semi-annual inspections. IACUC members may not be excluded from an inspection if they wish to participate.
C. The IACUC must have access to all approved Cornell University animal facilities 24 hours/day, 7 days a week. Access is defined as the ability to enter an approved animal facility immediately for a pre-scheduled inspection and within 2 hours of an unannounced inspection. Any exceptions must be mutually agreed upon by the individual responsible for the facility and the inspection team.
D. Any deficiency identified in the report must be categorized as “minor” or “significant” and an appropriate time frame and a specific date for correction must be included.
E. The inspectors may request the implementation of immediate corrective actions during the inspection or immediately following the inspection, particularly for deficiencies that may have a substantial impact on animal health or human safety.
F. Each inspection report must be submitted to the IACUC for review/approval and a summary of all findings must be included in the Semiannual report to the Institutional Official (IO).
G. Facility managers must ensure that all deficiencies identified during the inspection are corrected within the time frame required by the IACUC.
H. Inspection of facilities used only for a short duration will be done, when possible, at a time when the animals are housed there.

2) Procedures
A. Scheduling of Inspections: Semi-annual inspections are scheduled in advance. Although not required, the facility manager or investigator (for procedure rooms) is usually notified of the date and time of the inspections, as well as the rooms to be inspected. The manager/investigator or a designated alternate serves as a point-of-contact during the inspection of that facility. Random, unannounced inspections may also occur and will be organized by the Center for Animal Resources and Education (CARE) or the IACUC inspection coordinator.
B. **Inspection team:** Inspection teams are comprised such that at a minimum, they are in compliance with all applicable regulations. Even if not required by regulations, the inspection team will ordinarily include a minimum of two IACUC members, one of whom will be a CARE veterinarian. Public Health Service (PHS) policy allows the option of including *ad hoc* consultants to assist during inspections, in consultation with the IACUC or the IACUC Chair. IACUC members may not be excluded from an inspection if they wish to participate. In some facilities, special entry requirements for non-essential personnel are required because of controlled environments (e.g. specific pathogen free facilities) or special occupational health issues (e.g. Biosafety Level 3 facility).

C. **Scope of inspections:** The IACUC evaluates all aspects of the animal facility during the inspection, including:
   1. housing
   2. environmental conditions
   3. feed
   4. bedding
   5. water
   6. cleaning/sanitation
   7. specialized space
   8. animal care including review of medical and procedural records
   9. personnel
   10. occupational health and safety
   11. infrastructure/construction
   12. Cornell owned vehicles used to transport animals
   13. expiration dates, storage, and proper labelling of substances administered to animals.

D. **Conduct of inspections:** Subcommittee members are provided with inspection forms. During the inspection, the subcommittee assesses the different aspects of the animal care and use program, as recommended by the Office of Laboratory Animal Welfare (OLAW), the USDA and items listed in the form. The mode of the inspection is conducted in accordance with what is authorized by regulations and approved by the IACUC. Minor or significant deficiencies and any comments related to the inspected areas are documented. The timeline for the correction of each minor or significant deficiency is indicated on the inspection form. A free text area is available on the form for the subcommittee’s remarks. At the end of the inspection, each member of the subcommittee reviews the report. Minority opinions and suggestions for improvement are documented on the form and discussed at a convened IACUC meeting.

E. **Corrective actions:** The IACUC staff sends a copy of the initial inspection report to the facility manager or the PI responsible for the space, as well as to CARE, and works with them to resolve any deficiencies by the timeline noted in the report. Unless specified otherwise, the timeline for corrective actions begins when the facility manager or the PI responsible for the space receives formal notification from the IACUC staff. It is the responsibility of the facility manager/investigator to correct the deficiencies by the dates required by the IACUC, and to inform the IACUC staff when the corrective actions are completed. The PI or facility manager may write to the IACUC Chair to request an extension if the timeline for corrective actions is unattainable. The IACUC Chair will make a final decision relative to granting the proposed extension. The IACUC staff documents these corrections.
Any significant deficiency that is not corrected by the specified date is reported to the Institutional Officer (IO) immediately and the appropriate regulatory agencies are notified within 15 business days following the specified date. A minor deficiency that is not corrected by the specified date is reviewed by the IACUC and necessary action is determined on a case-by-case basis.

F. Reporting to the IACUC: The semi-annual inspection reports are provided to the IACUC for review and subsequent approval at the next committee meeting. The IACUC may require further actions or an explanation of any finding or corrective-action timeline. The IACUC staff documents all meeting decisions, communicates additional requirements or requests to the responsible individuals and coordinates the resolution. If any changes are made to the inspection report, the final report is provided to the facility manager and to CARE within two weeks of acceptance by the IACUC.

G. Reporting of inspections to the IO: The Semiannual program report to the IO includes a complete list of all facilities where inspections were conducted during the reporting period, dates of inspections, members of the inspection team, any deficiencies identified, corrective actions and timelines for completion of the corrective actions. Any delays, minority reports or other issues related to the inspections are documented in the report.

3) Regulatory requirements and guidelines

PHS policy, the Animal Welfare Act Regulations (AWAR) and Cornell University Policy 1.4 designate the IACUC as the committee responsible to conduct inspections of the institution’s animal facilities.

A. Animal Welfare Regulations:

- Sec 1.1 Definitions
  “Housing facility means any land, premises, shed, barn, building, trailer, or other structure or area housing or intended to house animals.”

  “Study area means any building room, area, enclosure, or other containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 12 hours.”

- Sec 2.31 Institutional Animal Care and Use Committee (IACUC)
  The IACUC shall:
  “... (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; Provided, however, That animal areas containing free-living wild animals in their natural habitat need not be included in such inspection;
  (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 of the research facility; Provided, however, That the IACUC may determine the best means of conducting evaluations of the research facility's programs and facilities; and Provided, further, That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports shall be updated at least once every six months upon completion...
of the required semiannual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity;”

B. PHS Policy

“Functions of the Institutional Animal Care and Use Committee

As an agent of the institution, the IACUC shall with respect to PHS - conducted or supported activities:

...2. inspect at least once every six months all of the institution's animal facilities (including satellite facilities) using the Guide as a basis for evaluation;…..

B. Animal Facility - Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.

Footnote 8:
The Institutional Animal Care and Use Committee (IACUC) may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.”

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