

IACUC	IACUC Semiannual Inspections and Program Evaluation	
SOP #114.00	IACUC Approval: 10/7/2022	IO Approval: 12/20/2022

Purpose:

The purpose of this SOP is to describe the Institutional Animal Care and Use Committee's (IACUC) policy and procedures for conducting semi-annual facility inspections and program evaluation. **Scope**:

This SOP applies to the animal care and use program at Texas A&M University-San Antonio and satellite facilities.

Background

The IACUC is mandated by federal law (Public Health Service (PHS) Policy and USDA Animal Welfare Act (AWA) to review the Institution's animal research program components, facilities, and animal use areas. In performing this review on a regular basis, the IACUC ensures animal well-being of the animals and compliance with Federal Regulations and Guidelines. The AWA and PHS policy require that these reviews occur at least once every six months.

Policy

Semiannual Animal Facility Inspections:

The IACUC will conduct inspections of animal housing facilities and study areas every six months using the A&M-SA IACUC Facility Inspection checklist. The inspections include:

- All animal housing locations where A&M-SA vertebrate animals are held for greater than 12 hours. Support areas such as feed & bedding storage, cage wash, & loading facilities are also included.
- All surgical locations.
- A&M-SA owned animal transport vehicles and trailers.
- Other animal support areas may be added based upon need and circumstances.

Semiannual Program Review

The IACUC will conduct a complete review of the A&M-SA Animal Care and Use Program every six months using the A&M-SA program review checklist, which is based on the checklist created by OLAW.

Procedures Semiannual Facility/ Laboratory Inspection

The IACUC must have access to all animal housing and use areas for the purpose of verifying that the housing conditions are consistent with the <u>AWA Regulations</u> and <u>ILAR Guide</u> and that activities involving animals are conducted in accordance with the proposal approved by that committee. The IACUC Office will contact the area supervisor/manager (facility manager, investigator, research personnel) or the PI a few weeks before the inspection to schedule the site visit. The area supervisor/manager coordinating the inspection must have access to the facility and be familiar with procedures.

The IACUC will look for specific regulatory requirements, including but not limited to:

- Training records for personnel
- Animal use consistent with approved protocol
- Animal containment, safety & space requirements
- Animal husbandry including daily monitoring, feeding, watering & frequency of sanitation
- Appropriate drug storage, control, and expiration date monitoring

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- Expired drugs & supplies are separated, marked, and/or disposed of properly
- Drug/controlled substances log
- Current (up to date) calibration of anesthetic vaporizers & appropriate scavenging of anesthetic waste gases
- Separate surgery areas for preparation, procedure, and recovery for USDA regulated species
- Aseptic technique used in all survival surgeries
- Anesthesia and surgical records
- Animal use, monitoring, treatment & medical records
- Staff knowledgeable of protocol
- General cleanliness of lab areas
- Physical plant conditions associated with safety, sanitation, security and HVAC
- SOPs are appropriately displayed or accessible as approved by IACUC as part of the protocol
- Occupational safety measures
 - o Hazard identification & standard operating procedures posted
 - o Current biosafety cabinet or fume hood testing
 - o Required personal protective equipment present & in use
 - o No human food and/or drink in any animal housing room
 - o Door signage and other notices

If any IACUC checklists of the previous site visit cycle are available, they will be presented to the IACUC inspection team and facility manager or investigators.

Inspection Team

The IACUC Inspection teams are coordinated by the IACUC Office and are comprised such that they are in compliance with all applicable regulations. The inspection team typically will include at least one IACUC member, but more members are often utilized. At least, two IACUC members are required to complete the inspection in areas where AWA regulated animals are housed. In facilities which house non-USDA-covered species, a single member may perform the inspection. In accordance with PHS Policy, the IACUC may also use qualified ad hoc consultants to perform facility inspections in facilities not housing USDA-covered species.

The IACUC remains responsible for the evaluation and reports. Each committee member is expected to participate in at least one facility inspection every six months. All members are given the opportunity to participate in the review of any facility. In some facilities, special entry requirements for non-essential personnel due to their controlled environments (e.g. specific pathogen free facilities), or special occupational health issues (e.g. Current TB Test) may need to be considered before allowing access to members.

Videos or use of live video streaming can be utilized to allow members to review facilities in unique circumstances. Summaries of the visits will be prepared by the IACUC staff however the IACUC is responsible for review and approval for the final report.

Conduct of Inspections

Inspection team members are provided with inspection checklists. During the inspection, the team assesses the different aspects of the animal care and use program, as recommended for evaluation by the Office of Laboratory Animal Welfare (OLAW) and the AWA and listed in the final inspection report. The inspection is conducted in accordance with what is allowed by regulations and approved by the IACUC. The magnitude of any deficiencies and any other comments related to the inspected areas are documented. The timeline for the correction of each deficiency is indicated on the inspection report. An exit meeting with the facility manager should occur at the conclusion of each inspection so they are

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aware of any of the site visitors concerns and have an opportunity to clarify any potential misunderstandings.

Deficiencies & Suggestions for Improvement

The IACUC may cite any deficiency they observe. Deficiencies fall into two categories, "minor" and "significant."

- Significant Deficiency: A deficiency that is, or may be, a threat to the health or safety of animals.
- Minor Deficiency: Deviation(s) in policy, procedure, or facility condition from the standards enunciated in The Guides, PHS Policy, the AWA Regulations, A&M-SA IACUC SOP's and procedures, which are/were not justified exceptions to those standards. In comparison to the significant deficiencies noted above, minor deficiencies are variances which require correction, but which are not serious breaches of policy or conditions endangering the health and safety of the animals and/or people.

Follow-up

The semi-annual inspection evaluation findings are provided to the IACUC for their review and approval during the semi-annual program review meeting. The IACUC may require further actions or explanation of any finding or the corrective action timeline. The IACUC staff documents all meeting decisions, communicates any additional requirements, or requests to the responsible parties and coordinates the resolution. All IACUC members present at the convened meeting will electronically sign the program evaluation inspection finding report.

Corrective Actions

<u>Deficiencies</u>: 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 office. It is the responsibility of the facility manager/investigator to correct the deficiencies identified in the report by the date required by the IACUC and to inform the IACUC staff of the corrective actions taken. 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 to the appropriate regulatory agencies within 15 business days following the specified date. Any 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.

Reporting of Results to the Institutional Official (IO)

The semiannual report to the IO includes the findings from both the facility inspections and the program evaluation along with a list of all of the exceptions to the Guide or Animal Welfare Act that have been approved by the IACUC during the previous six months. Any delays, minority views or other issues related to the inspections are documented in the report.

References

- 1. USDA Animal Welfare Act and USDA Animal Welfare Act Inspection Guide
- 2. Guide for the Care and Use of Laboratory Animals, 8th ed. 2011. National Research Council.
- 3. Guide for the Care and Use of Agricultural Animals in Research and Teaching, 3rd ed. 2010. Federation of Animal Science Societies. https://www.aaalac.org/about/Ag Guide 3rd ed.pdf
- 4. Public Health Service Policy on Humane Care and Use of Laboratory Animals https://olaw.nih.gov/policies-laws/phs-policy.htm

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