

IACUC SOP:	TAMU-S-016	Title:	Initial Inspection of New Animal Facilities, Satellite Facilities and Surgical
			Study Areas

Location	Effective Date	Review By
College Station/Dallas/Galveston/Kingsville	10/01/2023	09/30/2026
Houston	11/01/2023	09/30/2026

1. PURPOSE

- 1.1. To describe the process for conducting initial inspection of new PI managed satellite locations or animal study areas not currently under IACUC oversight; or inspection of PI managed animal study areas utilized for non-surgical procedures currently under IACUC oversight where performance of surgery is proposed.
- 1.2. To describe the process for conducting initial inspections for newly built or renovated animal facilities.

2. SCOPE

- 2.1. This SOP applies to:
 - 2.1.1. Locations for which oversight of the IACUC is applicable
 - 2.1.2. New animal facilities, satellite locations, and animal study areas where surgery is performed
 - 2.1.3. Current non-surgical animal study areas where performance of surgery is proposed
- 2.2. This SOP does not address the semiannual inspection process for previously approved locations; refer to TAMU-S-010 for this information.

3. RESPONSIBILITY

- 3.1. The **IACUC** is responsible for determining the best means of evaluating the institution's animal study areas and facilities, including the use of ad hoc consultants in the performance of evaluations.
- 3.2. The **AWO Staff** is responsible for the coordination and scheduling of initial inspection visits and preparing and maintaining inspection documents; including sample checklists used to facilitate the inspection process, documentation of the performance and outcome of the inspection process. Additionally, AWO staff will convey inspection results to location contacts and follow-up as applicable on corrective actions taken.
- 3.3. **Ad-hoc consultants** are responsible for conducting inspections as directed by the IACUC. Ad-hoc consultants may perform initial inspections along with IACUC members or autonomously.
- 3.4. **PIs/Lab staff/Animal facility care personnel** are responsible for assisting inspectors during an inspection, responding to inspection findings and noted deficiencies by the timeline for correction indicated by the IACUC.

4. DEFINITIONS AND/OR ACRONYMS

- 4.1. Ad-hoc Consultant: Individual who is not an IACUC member, but who has sufficient training and experience to conduct an inspection or participate in a review or evaluation on behalf-of the IACUC. Most often an experienced faculty member, veterinarian or AWO staff member, depending on the activity to be performed. When ad hoc consultants are utilized, the IACUC remains responsible for the evaluation, determination of corrective action, and reporting of all findings.
- 4.2. **Amendment**: Significant change to on-going animal activity or research project as described in an approved animal use protocol.
- 4.3. **Animal Activities**: Activities with live vertebrate animal species, including research, teaching, and testing; as well as husbandry and/or maintenance of animals in support of these activities.
- 4.4. **Animal Facility**: Centralized vertebrate animal housing location managed by a Core Support unit. Includes vehicles owned by the facility used for live animal transport.
- 4.5. **Animal Study Area**: Location outside of a central animal facility where activities with live animals occur, inclusive of classroom spaces.
- 4.6. **AUP:** Animal Use Protocol. Document submitted by the PI indicating the housing and procedures involving animals.

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- 4.7. **AV:** Attending Veterinarian. Individual designated by Texas A&M University to fulfil the regulatory role of AV. May also describe veterinary staff who report directly to, and have delegated authority from, the AV.
- 4.8. AWO: Animal Welfare Office. Supports the IACUC administratively.
- 4.9. **IACUC:** Institutional Animal Care and Use Committee. Institutional body responsible for ensuring adherence to federal regulation and institutional policy relating to the care and use of animals in teaching, testing and research. Appointed by the Institutional Official.
- 4.10. **(Semiannual) IACUC Inspection:** The inspection, at least semiannually, of the institution's animal facilities, satellite housing and animal study areas where surgery occurs.
- 4.11. **IO**: Institutional Official. Individual within the University with the administrative and operational authority to commit institutional resources to ensure that the animal care and use program will comply with the requirements of federal regulation.
- 4.12. **Initial Inspection**: Inspection of a location not currently under IACUC oversight, such as a new or renovated animal facility, new satellite location, or new animal study area. Includes inspection of a non-surgical procedure location currently under IACUC oversight that is proposed to be utilized for surgery.
- 4.13. **Location Contact**: Refers to individuals affiliated with animal facilities and animal study areas who may be contacted in reference to a semiannual inspection or oversight visit.
- 4.14. **PI**: Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.
- 4.15. **SAI:** Semiannual Inspection. See (Semiannual) IACUC Inspection.
- 4.16. **Satellite Location:** PI managed building, room, area, enclosure, or other containment where animals are housed or held outside of the primary housing location for over 12 hours (USDA regulated species) or 24 hours (non-USDA regulated species).
- 4.17. SFI: Suggestion for improvement
- 4.18. **Significant Deficiency:** Inspection or programmatic review finding which is inconsistent with federal regulation and in the judgement of the IACUC and IO is or may be a threat to the health or safety of the animals.
- 4.19. **SOP:** Standard Operating Procedure. SOP documents are developed by the IACUC to provide procedural standards for the activities performed by the committee.
- 4.20. **Surgery**: Cutting into the body through the use of a tool such as a scalpel blade, surgical scissors, laser, or other suitable device. May also refer to an invasive measurement under anesthesia.
- 4.21. **USDA:** United States Department of Agriculture. USDA Animal Care, a unit under the Animal and Plant Health Inspection Service, administers the Animal Welfare Act (AWA) and associated Animal Welfare Act Regulations (AWAR).
- **4.22. USDA Covered Species**: A term that refers to animals whose care is governed by the <u>Animal Welfare Act</u>. USDA-Covered Species include all live or dead warm-blooded animals used in research except birds bred in captivity, rats of the genus *Rattus*, and mice of the genus *Mus* bred for research. This also excludes "cold-blooded" animals such as fish, reptiles, and amphibians.

5. PROCEDURE

5.1. Location Identification

5.1.1. Locations requiring initial inspection may be identified on AUP and amendment submissions, through the semiannual inspection process, notification to the IACUC, AWO, or AV (or designee), or other mechanism

5.2. Inspectors

- 5.2.1. New or existing animal study areas:
 - 5.2.1.1. Inspections are conducted by at least one (1) IACUC member or ad hoc consultant
- 5.2.2. New satellite locations and new or renovated animal facilities:
 - 5.2.2.1. Inspections are conducted by at least the AV (or designee)

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- 5.2.2.1.1. If the AV (or designee) is unavailable, the IACUC Chair or AWO Director (or designees) may perform the inspection in place of the AV (or designee)
- 5.2.2.1.2. Additional IACUC members or ad hoc consultants may participate in the inspection
- 5.2.3. IACUC members may not inspect their own animal study area(s)

5.3. Inspection Timing:

5.3.1. Areas that must be inspected prior to animal housing or use:

- 5.3.1.1. New PI managed location utilized for USDA covered species
- 5.3.1.2. New satellite locations
- 5.3.1.3. New or renovated animal facilities
- 5.3.1.4. Animal study area used by first time PI
- 5.3.1.5. New animal study area where surgery is performed
- 5.3.1.6. New animal study area that is also used for human subjects
- 5.3.1.7. Existing approved non-surgical animal study areas where performance of surgery is proposed 5.3.1.7.1. Only performance of surgery is restricted prior to inspection

5.3.2. Areas that are not required to be inspected prior to use:

- 5.3.2.1. Note: The IACUC may determine at any time that a location normally excluded must be inspected prior to use
- 5.3.2.2. New non-surgical animal study area
- 5.3.2.3. Existing animal study areas where new non-surgical procedures are proposed

5.4. Initial inspection process

- 5.4.1. Initial inspections are conducted similarly to the Inspection process outlined in Section 5.9 of TAMU-S-010 with the following exception:
 - 5.4.1.1. Recent inspection findings will be omitted from inspection materials

5.5. Inspection Findings

- 5.5.1. AWO staff maintains documentation of the initial inspection process
- 5.5.2. Relevant SFIs, notes, comments, findings and corrective actions are conveyed to the location contact(s) by the inspector(s) or AWO staff
- 5.5.3. AWO staff collect responses when submitted to the AWO

5.6. Location Approval

- 5.6.1. Animal study areas
 - 5.6.1.1. May be approved for use by the inspector(s) at the time of inspection or when corrective actions, if any, have been completed
- 5.6.2. Animal facilities and satellite locations
 - 5.6.2.1. May be approved by the AV/IACUC Chair/AWO Director or designees (dependent upon who performed the inspection) for use at the time of inspection or when corrective actions, if any, have been completed
 - 5.6.2.2. Approval may be granted with limitations or restrictions, and may cover a portion of the facility or location
- 5.6.3. Regardless of location type:
 - 5.6.3.1. Follow-up inspection may be performed as needed by IACUC members, ad hoc consultants or AWO staff to confirm completion of corrective actions
 - 5.6.3.2. Location contacts will be notified when the location may be used for the intended purpose 5.6.3.2.1. AWO staff will be notified when confirmation is provided directly to the location contact by inspectors

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- 5.6.3.3. New locations will be incorporated into the appropriate IACUC SAI or oversight cycle (as applicable), after the initial inspection
 - 5.6.3.3.1. SAI/oversight to be performed as described in TAMU-S-010
 - 5.6.3.3.2. SAI to occur no more than six (6) months from the initial inspection month; with an acceptable 30-day extension as described in TAMU-S-010

5.7. IACUC Notification

5.7.1. The IACUC is notified when a new or (completely) renovated animal facility is approved for use 5.7.1.1. Note: Notification to the IACUC is not required for satellite locations and/or animal study areas

6. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

- 6.1. Regulatory resources:
 - 6.1.1. USDA Animal Welfare Regulations 9 CFR Ch.1 Subpart C § 2.31
 - 6.1.2. PHS Policy on Humane Care and Use of Laboratory Animals
- 6.2. References:
 - 6.2.1. <u>CITI Program</u> (requires registration & log-in) Semiannual Evaluations in Depth (online training program)
 - 6.2.2. OLAW Webinar Facility Inspections
 - 6.2.3. OLAW FAQ Should the IAUC inspect laboratories or other sites where investigators use animals?
- 6.3. <u>IACUC/AWO Referenced Documents</u>: (requires TAMU NetID authentication)
 - 6.3.1. TAMU-C-006 Inspection Checklist Initial Inspection
 - 6.3.2. TAMU-S-006 Composition, Appointment, Responsibilities, and Training of the IACUC
 - 6.3.3. TAMU-S-010 Semiannual Facility Inspections

7. HISTORY

Effective Date	Version #	Description
12/01/2020	000	College Station/Galveston: New document
03/01/2021	001	Houston/Kingsville: New document
03/16/2021	002	Dallas: New document
03/24/2022	003	College Station/Dallas/Galveston: Merging of Dallas animal care and use
		program with College Station/Galveston
10/20/2022	004	College Station/Dallas/Galveston/Kingsville: Merging of Kingsville animal care
		and use program with College Station/Dallas/Galveston.
10/01/2023	005	College Station/Dallas/Galveston/Kingsville: Renewal; minor changes to
		definitions, inclusion of required initial inspection for PI managed locations
		utilized for USDA species. Reviewed and approved via TEAMs.
11/01/2023	006	Houston: Renewal; minor changes to definitions, inclusion of required initial
		inspection for PI managed locations utilized for USDA species. Reviewed and
		approved via TEAMs.