



IACUC SOP:	<b>TAMU-S-011</b>	Title:	<b>Semiannual Programmatic Review</b>
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Location	Effective Date	Review By
<b>College Station/Dallas/Galveston/Kingsville</b>	09/01/2024	8/31/2027
<b>Houston</b>	10/01/2024	08/31/2027

**1. PURPOSE**

- 1.1. To describe the overall process for conducting semiannual evaluation of the Institution’s program for humane care and use of animals in accordance with AWAR and PHS policy.

**2. RESPONSIBILITY**

- 2.1. **IACUC Members** are responsible for conduct of semiannual programmatic review of the animal care and use program as described in TAMU-S-006 and this document.
- 2.2. The **IACUC** is responsible for reviewing, at least once every six months, the Institution’s program for humane care and use of animals; evaluating compliance with applicable regulations and guidelines; establishing a reasonable and specific plan and schedule for correcting program deficiencies; and reporting the outcome of the evaluation to the IO.
- 2.3. The **IO** is responsible for reviewing the report of the outcome of the programmatic evaluation performed by the IACUC and taking appropriate action, as needed.
- 2.4. The **AWO Staff** is responsible for the coordination and organization of the program review; preparing and maintaining review documents including sample checklist(s) or documents used to facilitate the review process and documentation and outcome of the review process (including the report to the IO).
- 2.5. **Ad-hoc consultants** are responsible for participating in program review as directed by the IACUC. However, when ad hoc consultants are utilized, the IACUC remains responsible for the evaluation of the review findings, establishing a corrective action and timeline for correction and reporting to the IO. Ad-hoc consultants may assist IACUC Members in the performance of semiannual performance review but may not replace Members.

**3. DEFINITIONS AND/OR ACRONYMS**

- 3.1. **ACUP:** Animal Care and Use Program. Comprises all activities related to research, teaching and testing conducted by and at an institution that have a direct impact on the well-being of animals, including animal and veterinary care, policies and procedures, personnel and program management and oversight, occupational health and safety, IACUC functions, and animal facility design and management.
- 3.2. **ACURO:** Animal Care and Use Review Office of the United States Army Medical Research and Development Command.
- 3.3. **Ad-hoc Consultant:** Individual who is not an IACUC member, but who has sufficient training and experience to conduct an inspection or participate in programmatic 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.
- 3.4. **Ag Guide:** Guide for the Care and Use of Agricultural Animals in Research and Teaching. Primary reference document for meeting the needs and requirements of agricultural animals utilized in research and teaching.
- 3.5. **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.
- 3.6. **AWAR/AWR:** Animal Welfare Act Regulations. Also known as Animal Welfare Regulations. Regulations administered by the United States Department of Agriculture (USDA). 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.
- 3.7. **AWO:** Animal Welfare Office. Supports the IACUC administratively.
- 3.8. **Conflict of Interest:** A situation in which a person has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties; or exploits the relationship for personal benefit.

- 3.9. Core Support:** Individuals performing professional activities such as husbandry or technical services as a function of a dedicated service organization.
- 3.10. Departure:** IACUC approved deviation from standards described in the *Guide*. Departures are reported in the semiannual report to the IO.
- 3.11. DMR:** Designated member review. Review performed by qualified IACUC member(s) appointed by the IACUC Chair to serve as the designated reviewer(s) as described in TAMU-S-002.
- 3.12. Exception:** IACUC approved deviation from standards established in the AWR. Exceptions are reported in the semiannual report to the IO and USDA Annual Report.
- 3.13. FCR:** Full committee review. Review and formal vote performed by a convened quorum of the members of the IACUC as described in TAMU-S-002.
- 3.14. (The) Guide:** The *Guide for the Care and Use of Laboratory Animals*. Primary reference document for meeting the needs and requirements of animals used in biomedical research. The PHS Policy requires institutions to use the *Guide* as a basis for developing and implementing an institutional program for activities involving animals.
- 3.15. 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.
- 3.16. IACUC Chair:** Chair of the IACUC appointed by the Institutional Official.
- 3.17. 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.
- 3.18. Minor Deficiency:** Inspection or programmatic review finding which may be inconsistent with federal regulations but in the judgement of the IACUC does not represent a threat to the health or safety of the animals.
- 3.19. OLAW:** Office of Laboratory Animal Welfare. Provides guidance and interpretation of the Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals (Policy) for PHS-funded research and monitors compliance with the Policy by Assured Institutions.
- 3.20. PHS:** Public Health Service. Federal agency under the United States Department of Health and Human Services responsible for oversight of the PHS Policy.
- 3.21. PHS Assurance:** PHS Welfare Assurance. Document executed by OLAW which describes the institution's compliance with PHS Policy; and is required to receive direct or indirect PHS funds through a grant or contract award.
- 3.22. PHS Policy:** PHS Policy on Humane Care and Use of Laboratory Animals. Federal policy established by the Health Research Extension Act of 1985 and administered by OLAW.
- 3.23. Program Review:** Semiannual programmatic review.
- 3.24. SAPR:** Semi-annual program review. IACUC review of the institution's program for humane care and use of animals at least once every 6 months as required by Animal Welfare Act Regulations and the Public Health Service Policy on Humane Care and Use of Laboratory Animals; which requires the use of the *Guide for the Care and Use of Laboratory Animals* as the basis for evaluation.
- 3.25. Significant deficiency:** Inspection or programmatic review finding which is inconsistent with federal regulations and in the judgement of the IACUC and Institutional Official is or may be a threat to the health or safety of the animals.
- 3.26. SOP:** Standard Operating Procedure.
- 3.27. 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).
- 3.28. USDA Regulated:** Species or activities which fall under the AWA/AWAR.

#### 4. PROCEDURE

##### 4.1. Participation:

- 4.1.1. IACUC members will be notified when program review is to be conducted with sufficient time to request participation.
- 4.1.2. No IACUC member that wishes to participate in any portion of the review, including subcommittee participation, will be involuntarily excluded.
- 4.1.3. The IACUC will determine when it is appropriate to invite qualified ad hoc consultants to assist the IACUC with the reviews. When ad hoc consultants are utilized, the IACUC remains responsible for the evaluation, determination of corrective action(s), and reporting of all findings.

##### 4.2. Emphasis:

- 4.2.1. All areas of the animal care and use program are to be reviewed in accordance with AWAR title 9, chapter I, subchapter A – Animal Welfare and the PHS Policy, and must use the *Guide* as a basis for evaluation.
- 4.2.2. Key aspects of the animal care and use program that should be emphasized in the review or evaluation are:
  - 4.2.2.1. Regulations, policies, and principles; including
    - 4.2.2.1.1. Adherence to:
      - 4.2.2.1.1.1. AWR
      - 4.2.2.1.1.2. PHS Policy
      - 4.2.2.1.1.3. The *Guide*
      - 4.2.2.1.1.4. TAMU Rule 15.99.07.M1
    - 4.2.2.1.2. Existence of written procedures for application of standards in:
      - 4.2.2.1.2.1. IACUC Guidance and SOPs
  - 4.2.2.2. Program Management; including
    - 4.2.2.2.1. IO, AV, IACUC
    - 4.2.2.2.2. Personnel management, training and education
    - 4.2.2.2.3. Occupational health and safety
    - 4.2.2.2.4. Animal experimentation involving hazards (e.g.: IBC, EHS review)
    - 4.2.2.2.5. Investigating and reporting animal welfare concerns
  - 4.2.2.3. Program Oversight; including
    - 4.2.2.3.1. Role of the IACUC (protocol review, post approval monitoring)
    - 4.2.2.3.2. List of IACUC Approved Exceptions and Departures
  - 4.2.2.4. Disaster Planning and Emergency Preparedness
  - 4.2.2.5. Environment, Housing, and Management; including
    - 4.2.2.5.1. Micro- and macro-environment
    - 4.2.2.5.2. Temperature, humidity, ventilation and illumination
    - 4.2.2.5.3. Space, environmental enrichment, behavioral and social management
    - 4.2.2.5.4. Husbandry, sanitation, pest control
    - 4.2.2.5.5. Note: Review of facility inspection process and inspection findings resulting from the current semi-annual review cycle may assist in this
  - 4.2.2.6. Veterinary Care; including
    - 4.2.2.6.1. Animal procurement and transportation
    - 4.2.2.6.2. Preventative medicine (quarantine/stabilization; disease surveillance, diagnosis, treatment and control)
    - 4.2.2.6.3. Clinical care and management
    - 4.2.2.6.4. Surgery (training, planning, facilities, aseptic technique, intraoperative monitoring, post-operative care)
    - 4.2.2.6.5. Pain and distress
    - 4.2.2.6.6. Analgesia and anesthesia
    - 4.2.2.6.7. Euthanasia

4.2.2.6.8. Note: Review of facility inspection process and inspection findings resulting from the current semi-annual review cycle and the list of IACUC Approved Exceptions and Departures may assist in this

4.2.2.7. Physical Plant; including

4.2.2.7.1. Functional areas

4.2.2.7.2. Construction guidelines (design, HVAC, environmental monitoring)

4.2.2.7.3. Special facilities (surgical suites, barrier facilities, imaging locations, hazard containment areas, behavioral study locations, aquatic housing)

4.2.2.7.4. Security and access control

4.2.2.7.5. Note: Review of facility inspection process and inspection findings resulting from the current semi-annual review cycle and the list of IACUC Approved Exceptions and Departures may assist in this

**4.3. Materials and Documents**

4.3.1. Examples of reference materials that may be utilized to facilitate the review include, but are not limited to:

4.3.1.1. Current list of IACUC members with role and administrative unit affiliation

4.3.1.2. Organizational chart for ACUP

4.3.1.3. IACUC and vivarium or core support SOPs

4.3.1.4. IACUC program metrics

4.3.1.5. List of IACUC approved exceptions and departures

4.3.1.6. Inspection findings for current and past semi-annual review cycle

4.3.1.7. Past SAPR IO Report

4.3.1.8. Emergency plan for the ACUP

4.3.1.9. USDA Animal Welfare Inspection Guide

4.3.1.10. AWAR

4.3.1.11. PHS Policy

4.3.1.12. The *Guide*

4.3.1.13. The Ag Guide

4.3.1.14. *Occupational Health and Safety in the Care and Use of Animals*

4.3.1.15. CITI Semiannual Evaluations in Depth course

4.3.1.16. OLAW Semiannual Program Review webinar

4.3.2. Examples of documents that may be utilized to facilitate the review include, but are not limited to:

4.3.2.1. OLAW Sample Semiannual Program Review Checklist (TAMU-C-007)

4.3.2.2. USDA Animal Welfare Inspection Guide Checklist (TAMU-C-009)

4.3.2.3. AAALAC Program Description (for accredited programs)

4.3.2.4. PHS Assurance

4.3.2.5. Various journal articles regarding animal care and use programs that can be used to direct reviewers

**4.4. Scheduling:**

4.4.1. The IACUC will determine the most appropriate schedule to conduct the program review:

4.4.1.1. Semiannual

4.4.1.1.1. Conduct of program review once every six months

4.4.1.2. Rolling Schedule

4.4.1.2.1. A portion of the program is reviewed on a rolling schedule occurring up to monthly

4.4.2. Note: The timing of program review may extend up to 30 days beyond the six-month interval from the last review if there is no forward drift of the date from year to year.

**4.5. Format:**

4.5.1. The IACUC will determine the most effective way to conduct the review:

4.5.1.1. Review of portions of the program or the entire program at a convened meeting of a quorum of the IACUC without pre-review; and/or

4.5.1.2. Portions of the program or the entire program are pre-reviewed by a subcommittee of at least two IACUC members, with or without additional qualified ad hoc consultants to assist the members in the review, with findings presented to the IACUC for evaluation and final consideration at a convened meeting of a quorum of the IACUC.

**4.6. Pre-Review**

4.6.1. Reviewers:

- 4.6.1.1. IACUC members volunteer or are assigned a portion(s) of the program to review
- 4.6.1.2. Ad hoc consultants are assigned a portion(s) of the program to review
- 4.6.1.3. Review assignments may be made by the IACUC Chair (or designee) or AWO staff
- 4.6.1.4. To avoid real or perceived conflict of interest, IACUC members and ad hoc consultants may not be the only individuals assigned to review the aspects of the program for which those individuals are responsible; however, when unavoidable, one reviewer with a conflict of interest may be paired with one or more nonconflicted reviewer(s) to avoid potential bias in the evaluation that is performed.

4.6.2. Reviewers are provided with checklists and/or other materials by AWO staff as needed to conduct the review

4.6.3. Basic information about the assignment, including recent past review findings are provided to the reviewers by the AWO staff

4.6.4. Reviewers may request additional information or materials to conduct their review from:

- 4.6.4.1. AWO staff
- 4.6.4.2. Animal veterinary care staff
- 4.6.4.3. BOHP staff
- 4.6.4.4. Biosafety staff
- 4.6.4.5. EHS staff
- 4.6.4.6. Other personnel as necessary to complete their review

4.6.5. Reviewers may identify findings, suggest categorization of deficiencies as minor or significant, and propose a reasonable and specific plan and schedule for corrective action(s) for IACUC consideration

**4.7. IACUC Review**

4.7.1. The IACUC reviews the program, or findings presented by members and ad hoc consultants, at a convened meeting of a quorum of the membership and identifies and categorizes deficiencies as minor or significant, establishes a reasonable and specific plan and schedule for corrective actions.

4.7.1.1. Significant deficiencies include, but are not limited to:

- 4.7.1.1.1. Inoperable heating, cooling, electrical or watering systems or failure of such systems sufficient to affect critical housing and operational areas
- 4.7.1.1.2. Situations such as natural disasters that cause injury, death, or severe distress to animals
- 4.7.1.1.3. Inadequate husbandry staffing such that animals are not cared for appropriately resulting in injury, illness, death or severe distress to animals
- 4.7.1.1.4. Program deficiencies resulting from the institution or IACUC's failure to implement some aspect of the animal care and use program required by the AWR or PHS Policy; or failure to function according to commitments made in the PHS Assurance (program deficiencies may raise to the level of reportable noncompliance)

4.7.1.2. Minor deficiencies include, but are not limited to:

- 4.7.1.2.1. Problem for which an immediate solution is not necessary to protect life or prevent distress to animals; e.g.: emergency plan is not current

**4.8. Review Outcome**

4.8.1. A list of findings, corrective actions and schedule for correction is maintained by the AWO for the IACUC

4.8.2. Findings applicable to personnel or facilities is relayed in writing by the IACUC Chair (or designee) or AWO staff

- 4.8.3. Formal investigation and reporting of deficiencies determined to be serious or continuing noncompliance occurs as described in TAMU-S-012
- 4.8.4. The IACUC is notified by AWO staff when deficiencies are corrected to ensure all items are addressed as stipulated by the IACUC

**4.9. Overdue Review Findings**

- 4.9.1. Deficiencies remaining uncorrected beyond the timetable for correction will be reviewed by the IACUC to establish an appropriate course of action; up to suspension of the activity as described in TAMU-S-012 or reporting of the programmatic failure by the IACUC to OLAW through the IO.
- 4.9.2. Any significant deficiency regarding USDA covered species remaining uncorrected beyond its timetable for correction must be reported to USDA APHIS and any federal agency funding that activity as described below.

**4.10. Reporting of Findings:**

- 4.10.1. Regardless of scheduling option selected, the results of the IACUC's review of the program are reported to the IO every six months utilizing OLAWs sample memo (see TAMU-M-002) or another format which meets regulatory requirements for reporting.
  - 4.10.1.1. Notes:
    - 4.10.1.1.1. The IACUC or IACUC Chair (or designee), relays significant deficiencies to the IO as they are identified by the IACUC. The deficiency is included in the semi-annual report to the IO.
    - 4.10.1.1.2. The timing of the report to the IO may extend up to 30 days beyond the six-month interval from the last report if there is no forward drift from year to year
- 4.10.2. The semi-annual report to the IO is reviewed and signed by a majority of the IACUC members and includes minority opinions. The report is maintained as indicated in TAMU-S-001.
  - 4.10.2.1. The signature page may be signed in person, or via document routing software (e.g.: AdobeSign or other)
- 4.10.3. The IACUC reports deficiencies determined to be programmatic failure or serious or continuing noncompliance through the IO, with a full explanation of the circumstances and actions, as a written report as applicable to AAALAC, OLAW, ACURO and the USDA. This report will be prepared by AWO staff.
  - 4.10.3.1. Funding agency notification will occur as appropriate through Sponsored Research Services at the direction of the IO.
- 4.10.4. The IACUC, through the IO, reports in writing to USDA APHIS and any federal agency funding that activity, any uncorrected significant deficiency related to USDA regulated species within 15 business days of exceeding the deadline set by the IACUC.
  - 4.10.4.1. Funding agency notification will occur through Sponsored Research Services at the direction of the IO.

**5. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION**

**5.1. Regulatory resources:**

- 5.1.1. [USDA Animal Welfare Regulations 9 CFR Ch.1 Subpart C § 2.31](#)
- 5.1.2. [PHS Policy on Humane Care and Use of Laboratory Animals](#)
- 5.1.3. [USDA APHIS Animal Welfare Inspection Guide](#)
- 5.1.4. [Guide for the Care and Use of Laboratory Animals](#)
- 5.1.5. [Guide for the Care and Use of Agricultural Animals in Research and Teaching](#)
- 5.1.6. [Occupational Health and Safety in the Care and Use of Research Animals](#)
- 5.1.7. [OLAW NOT-OD-24-076](#) Guidance on Flexibilities for Conducting Semiannual Program Review
- 5.1.8. [OLAW NOT-OD-05-034](#) Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals
- 5.1.9. [OLAW NOT-OD-00-007](#) Guidance Regarding Reduction of Regulatory Burden



5.1.10. [TAMU Rule 15.99.07.M1](#) Use of Vertebrate Animals

**5.2. References:**

5.2.1. [ILAR News 1991; 33\(4\):68-70](#). The PHS Responds to Commonly Asked Questions.

5.2.2. [Contemporary Topics 1997; 36\(2\):47-50](#). FAQs about the PHS Policy on Humane Care and Use of Laboratory Animals.

5.2.3. [CITI Program](#) (requires registration & log-in)

5.2.3.1. Semiannual Evaluations in Depth course

5.2.4. OLAW 21<sup>st</sup> Century Cures Act – [Semiannual Program Review](#)

5.2.5. OLAW FAQ E2 – [How does the IACUC distinguish between significant and minor deficiencies?](#)

**5.3. [IACUC/AWO Referenced Documents](#):** (requires TAMU NetID authentication)

5.3.1. TAMU-C-007 SAPR - IACUC Semiannual Program Review Checklist [OLAW]

5.3.2. TAMU-C-009 SAPR - IACUC Semiannual Program Review Checklist [USDA]

5.3.3. TAMU-Me-002 SAPR - IO Report (available from AWO); utilized to report outcome of semiannual inspections and program review from IACUC to IO

5.3.4. TAMU-S-001 Document Management

5.3.5. TAMU-S-006 Composition, Appointment, Responsibilities, and Training of the IACUC

5.3.6. TAMU-S-012 Review and Investigation of Animal Welfare Concerns and Potential Noncompliance

**6. HISTORY**

Effective Date	Version #	Description
12/01/2020	000	College Station/Galveston: New format and content; replaced AWAP-402
02/01/2021	001	Houston/Kingsville: New document
02/23/2021	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.
09/01/2023	005	College Station/Dallas/Galveston/Kingsville: Renewal; minor changes to definitions, inclusion of 30-day extension in timing of program review and report to IO, clarification in use of subcommittee review consistent with 21 <sup>st</sup> Century Cures Act flexibility. Reviewed and approved via TEAMS.
10/01/2023	006	Houston: Renewal; minor changes to definitions, inclusion of 30-day extension in timing of program review and report to IO, clarification in use of subcommittee review consistent with 21 <sup>st</sup> Century Cures Act flexibility. Reviewed and approved via TEAMS.
09/01/2024	007	College Station/Dallas/Galveston/Kingsville: Renewal; updated definitions and references sections, updates to procedure to match OLAW Notice NOT-OD-24-076 related to review of USDA regulated species
10/01/2024	008	Houston: Renewal; updated definitions and references sections, updates to procedure to match OLAW Notice NOT-OD-24-076 related to review of USDA regulated species