



IACUC SOP:	<b>TAMU-S-013</b>	Title:	<b>Continuing Review of Animal Use Protocols - Triennial</b>	
		Location	Effective Date	Review By
		<b>College Station/Dallas/Galveston/Kingsville</b>	08/01/2024	7/31/2027
		<b>Houston</b>	12/27/2021	10/31/2024

**1. PURPOSE**

- 1.1. To describe the process for triennial continuing review of approved **AUPs animal use protocols** as required under federal regulation.

**2. SCOPE**

- 2.1. Triennial continuing review applies to all **AUPs animal use protocols** regardless of species, activities performed, or funding.

**3. RESPONSIBILITY**

- 3.1. As described in TAMU-S-002 for IACUC submission review; with the following addition(s) below
- 3.2. The **IACUC** is responsible for performing continuing review triennially for currently approved and on-going AUPs regardless of species, activities performed, or funding.
- 3.3. The **PI** is responsible for submitting a renewal AUP in iRIS (or other web system currently in use), or a new AUP to replace the expiring AUP, when activities with live animals will be performed beyond the expiration date of the AUP to **assist** the IACUC in satisfying federal requirements for triennial continuing review
- 3.4. The **AWO Staff** is responsible for sending reminders to PIs and other applicable individuals when submission deadlines are approaching, notifying the IACUC Chair when PI responses have not been received in a timely manner, notifying the IACUC when deadlines for continuing review have not been met, and drafting appropriate correspondence related to corrective action taken by the IACUC upon request.

**4. DEFINITIONS AND/OR ACRONYMS**

- 4.1. **AAALAC:** AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.
- 4.2. **AUP:** Animal Use Protocol. Document submitted by the PI indicating the housing and procedures involving animals.
- 4.3. **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.
- 4.4. **IACUC Leadership:** Committee comprised of the IACUC Chair, IACUC Vice-Chair(s), Attending Veterinarian and Animal Welfare Office Director.
- 4.5. **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.
- 4.6. **iRIS:** Web-based compliance submission system
- 4.7. **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.
- 4.8. **PAM:** Post-Approval Monitoring. Mechanism used for continuing IACUC oversight of animal activities within the animal care and use program.
- 4.9. **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.
- 4.10. **PI:** Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.
- 4.11. **TAMU:** Texas A&M University

- 4.12. **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).
- 4.13. **USDA Regulated:** Species or activities which fall under the AWA/AWAR.

## 5. PROCEDURE

### 5.1. Triennial Continuing Review

- 5.1.1. The IACUC is required to conduct a continuing review of previously approved, ongoing projects no less than once every three years as described in PHS Policy and in the USDA Animal Welfare Regulations. This requirement is extended to all AUPs regardless of species, **activities performed**, or funding.
- 5.1.2. Triennial continuing review may occur through the following mechanisms (both options ~~met~~ **meet** the USDA requirement for a “new submission”):
  - 5.1.2.1. IACUC review of a renewal AUP submitted by the PI
  - 5.1.2.2. IACUC review of a new AUP submitted by the PI as a replacement for the expiring AUP
- 5.1.3. IACUC review and approval is to be performed in a timely manner to facilitate approval of the renewal/new AUP prior to expiration, however, the IACUC acknowledges that timeliness of review is also dependent upon actions of the PI
- 5.1.4. When a renewal/new AUP has not been submitted, or has been submitted but will not be approved prior to expiration, and animals remain in a TAMU facility or there is the potential for animal activities to continue outside of a TAMU facility (e.g.; wildlife studies in the field, client owned animals), the IACUC expects the following:
  - 5.1.4.1. PI:
    - 5.1.4.1.1. Halt all activities with live animals; and
    - 5.1.4.1.2. Transfer all animals to another AUP; or
      - 5.1.4.1.2.1. Note: Use of holding protocols and/or SOPs must be congruent with IACUC Guidance TAMU-G-033
    - 5.1.4.1.3. Perform disposition of animals as described in the expiring AUP; or
    - 5.1.4.1.4. Provide confirmation that animal activities have been halted for animals that are not housed in a TAMU facility; e.g.: studies with wildlife in the field; client owned animals
  - 5.1.4.2. AWO:
    - 5.1.4.2.1. Notify the IACUC Chair of any potential noncompliance related to protocol expiration
- 5.1.5. The IACUC will determine applicable corrective actions in cases where the IACUC was unable to perform triennial continuing review on or before the expiration date and research with live animals continued in absence of IACUC approval. This may include:
  - 5.1.5.1. Additional training requirements for the PI, AWO staff or IACUC membership, as applicable
  - 5.1.5.2. Classification and reporting of the incident as PI non-compliance as described in TAMU-S-012
  - 5.1.5.3. Notification to IO and reporting of programmatic failure to OLAW, USDA, and AAALAC, as applicable (note: reporting process to be performed as described in TAMU-S-012)
  - 5.1.5.4. Other corrective actions determined by the IACUC

## 6. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

- 6.1. [PHS Policy on Humane Care and Use of Laboratory Animals section IV.C](#)
- 6.2. [USDA Animal Welfare Regulations Part 2 Subpart C § 2.31.d.2](#)
- 6.3. [IACUC/AWO Referenced Documents](#): (requires TAMU NetID authentication)
  - 6.3.1. TAMU-G-033 Guidelines for the use of Holding Protocols and SOPs
  - 6.3.2. **TAMU-S-002 Mechanisms of IACUC Review, Veterinary Consultation and Confirmation**
  - 6.3.3. TAMU-S-012 Review and Investigation of Animal Welfare Concerns and Potential Noncompliance

## 7. HISTORY



Effective Date	Version #	Description
11/02/2020	000	College Station/Galveston: New document
01/04/2021	001	Houston/Kingsville: New document
01/19/2021	002	Dallas: New document
11/01/2021	003	College Station/Galveston: Renewal; updated definitions; Reviewed and approved via e-mail.
12/01/2021	004	Houston/Kingsville: Renewal; updated definitions
12/27/2021	005	Houston/Kingsville: Removal of annual continuing review process with no modification to expiration date. Added DoD reference. Approved on 12/13/2021 with delayed start date to match final rule effective date.
12/27/2021	006	Dallas: Renewal; updated definitions and references, removal of annual continuing review process. Approved on 12/14/2021 with delayed start date to match final rule effective date.
12/27/2021	007	College Station/Galveston: Removal of annual continuing review process with no modification to expiration date. Added DoD reference. Approved on 12/16/2021 with delayed start date to match final rule effective date.
03/24/2022	008	College Station/Dallas/Galveston: Merging of Dallas animal care and use program with College Station/Galveston
10/20/2022	009	College Station/Dallas/Galveston/Kingsville: Merging of Kingsville animal care and use program with College Station/Dallas/Galveston.
08/01/2024	010	College Station/Dallas/Galveston/Kingsville: Renewal; updated purpose, scope, and references sections; modified procedure section to match purpose

(NOTE: items above in red have only been approved by the College Station/Dallas/ Galveston/Kingsville IACUC.)