



IACUC SOP:	<b>TAMU-S-005</b>	Title:	<b>Change to Approved Protocols by Administrative Review</b>
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	Location	Effective Date	Review By
	<b>College Station/Dallas/Galveston/Kingsville</b>	08/01/2024	07/31/2027
	<b>Houston</b>	09/01/2024	07/31/2027

**1. PURPOSE**

- 1.1. To describe the modification to Animal Use Protocols applicable for Administrative Review.

**2. SCOPE**

- 2.1. This SOP applies to modifications reviewed by Administrative Review. Modifications must meet the description for Administrative Review eligibility as described in TAMU-S-003.

**3. RESPONSIBILITY**

- 3.1. **IACUC Members** are responsible for establishing the contents of this SOP.
- 3.2. The **AWO Staff** is responsible for verifying that requests for AUP modification meet the IACUC approved requirements listed below.
- 3.3. The **PI** is responsible for notifying the AWO when a modification is required.

**4. DEFINITIONS AND/OR ACRONYMS**

- 4.1. **AR:** Administrative Review. Performed by AWO staff.
- 4.2. **AUP:** Animal Use Protocol. Document submitted by the PI indicating the housing and procedures involving animals.
- 4.3. **AWO:** Animal Welfare Office. Supports the IACUC administratively.
- 4.4. Centrally administered support service for animal research and teaching programs at Texas A&M University:
  - 4.4.1. **ARU:** Animal Resource Unit supports the College of Dentistry vivarium
  - 4.4.2. **CMP:** Comparative Medicine Program supports the Texas A&M College Station campus
  - 4.4.3. **PAR:** Program for Animal Resources supports the Institute of Biosciences and Technology vivarium
  - 4.4.4. **PRF:** Pharmaceutical Research Facility supports the Kingsville Pharmaceutical Science Facility vivarium
  - 4.4.5. **Sea Life:** The Sea Life Facility supports the Galveston campus
- 4.5. **IACUC:** Institutional Animal Care and Use Committee. Institutional body responsible for ensuring adherence to federal regulations relating to the care and use of animals in teaching, testing and research. Appointed by the Institutional Official.
- 4.6. **PI:** Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.

**5. PROCEDURE**

**5.1. Change in Personnel other than PI**

- 5.1.1. The AWO staff may perform the following modifications upon PI request or on discovery:
  - 5.1.1.1. Removal of personnel
    - 5.1.1.1.1. If the individual is the sole participant listed on the protocol who performs surgery, an alternate surgeon must be identified
  - 5.1.1.2. Addition of personnel
    - 5.1.1.2.1. Personnel must meet all IACUC training and certification requirements prior to being added to the protocol as described in TAMU-G-029.

**5.2. Change in Funding**

- 5.2.1. The AWO staff may perform the following modifications upon PI request:
  - 5.2.1.1. Removal of extramural funding
  - 5.2.1.2. Addition of non-PHS funding
  - 5.2.1.3. Addition of PHS funding for NIH centers and institutes

- 5.2.1.3.1. Grant congruency must be performed
- 5.2.1.3.2. The grant congruency review must match the scope of work

**5.3. Change in Transportation, Housing or Study Location**

- 5.3.1. The AWO staff may perform the following modifications upon PI request or incidental discovery:
  - 5.3.1.1. Removal of transportation of live animals
  - 5.3.1.2. Replacement of PI performed transportation of live animals with transportation performed by core support personnel.
  - 5.3.1.3. Removal of a study or housing location:
    - 5.3.1.3.1. If the location is the sole location listed on the protocol, an alternative location must be provided before the location can be removed
    - 5.3.1.3.2. If the location is the sole location for an approved activity (surgery, imaging, behavioral testing, euthanasia), an alternative location must be provided before the location can be removed
  - 5.3.1.4. Addition or modification of a housing or study location:
    - 5.3.1.4.1. The new location(s) must have been previously approved for animal activities as described in TAMU-S-016, or for wild species studied in their natural environment, the new location is congruent with applicable permits
    - 5.3.1.4.2. The activity to be performed in the location must be approved on the protocol
  - 5.3.1.5. Modification to the duration that animals are in the location:
    - 5.3.1.5.1. Reduction in duration from > 24 hours to <24 hours for non-USDA regulated species
    - 5.3.1.5.2. Reduction in duration from > 12 hours to < 12 hours for USDA regulated species
  - 5.3.1.6. Locations to be added must meet requirements for AR as per TAMU-S-003

**5.4. Modification of species, strain or breed**

- 5.4.1. The AWO staff may administratively remove an approved species, strain or breed upon PI request where the protocol includes other species, strains or breeds.
- 5.4.2. The AWO staff may administratively review PI requests for updates to strain or breed nomenclature

**5.5. Removal of Hazards**

- 5.5.1. The AWO staff may administratively remove an approved hazard upon PI request; e.g., removal of isoflurane as the sole hazard where the protocol already includes an approved alternate anesthetic drug with no further modification.

**5.6. Removal of experimental compounds or substances**

- 5.6.1. The AWO staff may administratively remove an experimental compound or substance upon PI request.

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

- 6.1. List of NIH Institutes, Centers and Offices: <https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices>
- 6.2. Contacts for centrally administered support service units:
  - 6.2.1. ARU: (214) 828-8149
  - 6.2.2. CMP: (979) 845-7433
  - 6.2.3. PAR: (713) 677-7471
  - 6.2.4. PRF: (361) 221-0770
- 6.3. [IACUC/AWO Referenced Documents](#): (requires TAMU NetID authentication)
  - 6.3.1. TAMU-G-029 Guidelines for Animal Protocol Participation and Handling
  - 6.3.2. TAMU-S-003 Significant and Minor Changes to Approved Animal Activities
  - 6.3.3. TAMU-S-016 Initial Inspection of New Animal Facilities, Satellite Facilities and Surgical Study Areas



**7. HISTORY**

Effective Date	Version #	Description
05/16/2019	000	College Station/Galveston: New document
01/16/2020	001	College Station/Galveston: Inclusion of CMP equivalent units within Dallas and Houston/Kingsville animal programs; addition of replacing PI with Co-PI
01/21/2020	002	Dallas: New document; partially replaces CD-108
01/27/2020	003	Houston/Kingsville: New document; partially replaces CD-108
11/01/2021	004	College Station/Galveston: Renewal; updated definitions, congruency with TAMU-S-016; Reviewed and approved via e-mail.
12/01/2021	005	Houston/Kingsville: Renewal; updated definitions, congruency with TAMU-S-016; Reviewed and approved via e-mail.
12/14/2021	006	Dallas: Renewal; updated definitions, congruency with TAMU-S-016.
03/24/2022	007	College Station/Dallas/Galveston: Merging of Dallas animal care and use program with College Station/Galveston
10/20/2022	008	College Station/Dallas/Galveston/Kingsville: Merging of Kingsville animal care and use program with College Station/Dallas/Galveston.
08/01/2024	009	College Station/Dallas/Galveston/Kingsville: Renewal; updated definitions; change in procedures to remove replacement of PI with co-PI, update to eligible changes related to transportation and/or location, and species
09/01/2024	010	Houston: Renewal; updated definitions; change in procedures to remove replacement of PI with co-PI, update to eligible changes related to transportation and/or location, and species