



IACUC SOP:	TAMU-S-003	Title:	Significant and Minor Changes to Approved Animal Activities
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	Location	Effective Date	Review By
	College Station/Dallas/Galveston/Kingsville	08/01/2024	07/31/2027
	Houston	09/01/2024	07/31/2027

1. PURPOSE

1. To delineate between significant and minor changes to approved animal activities and to establish the mechanisms for IACUC review and approval, veterinary verification and consultation, or administrative staff processing.

2. SCOPE

- 2.1. This document applies to all animal use protocol modifications, including IACUC reviewed amendments, pilot study updates with animal use protocol modifications, veterinary verification and consultation and administrative processing by Animal Welfare Office staff.

3. RESPONSIBILITY

- 3.1. The **IACUC Chair** is responsible for appointing members to perform DMR.
- 3.2. **IACUC Members** are responsible for establishing the contents of this SOP and performing DMR or FCR, as applicable.
- 3.3. **AWO Staff** are responsible for verifying that requests for protocol modifications meet the IACUC approved requirements for AR.
- 3.4. The **AV (or designee)** is responsible for performing veterinary review of amendments and veterinary verification and confirmation (VVC) of eligible modifications as discussed below. Also see TAMU-S-002.
- 3.5. The **PI** is responsible for notifying the IACUC or AV/designee when a modification to the AUP is required.

4. DEFINITIONS AND/OR ACRONYMS

- 4.1. **Amendment:** Significant change to on-going animal activity or research project as described in an approved animal use protocol.
- 4.2. **AR:** Administrative Review. Performed by AWO staff.
- 4.3. **AUP:** Animal Use Protocol. Document submitted by the PI indicating the housing and procedures involving animals.
- 4.4. **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.
- 4.5. **AWO:** Animal Welfare Office. Supports the IACUC administratively.
- 4.6. Centrally administered support service for animal research and teaching programs at Texas A&M University:
 - 4.6.1. **ARU:** Animal Resource Unit supports the College of Dentistry vivarium
 - 4.6.2. **CMP:** Comparative Medicine Program supports the Texas A&M College Station campus
 - 4.6.3. **PAR:** Program for Animal Resources supports the Institute of Biosciences and Technology vivarium
 - 4.6.4. **PRF:** Pharmaceutical Research Facility supports the Kingsville Pharmaceutical Science Facility vivarium
 - 4.6.5. **Sea Life:** The Sea Life Facility supports the Galveston campus
- 4.7. **Change that impacts personnel safety:** Activity that would be reasonably expected to negatively impact personnel health or safety.
- 4.8. **Core Support:** Individuals performing professional activities such as husbandry or technical services as a function of a dedicated service organization.
- 4.9. **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.
- 4.10. **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.

- 4.11. **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.
- 4.12. **IACUC Chair:** Chair of the IACUC appointed by the Institutional Official.
- 4.13. **Minor Change:** Change to an approved animal use protocol of a minor nature which may be administratively processed by the Animal Welfare Office, such as changes in protocol personnel other than the PI and corrections to typographical errors, grammar and contact information for protocol participants.
- 4.14. **Negative Phenotype:** Unexpected or adverse characteristic observed in genetically modified animals which can impact animal well-being and may include conditions like early mortality, spontaneous tumor development, neurological issues, blindness, skin conditions, reduced fertility, or other unanticipated effects of a negative nature.
- 4.15. **PI:** Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.
- 4.16. **Pilot Study:** A small-scale test of the methods and procedures to be used on a larger scale.
- 4.17. **Significant Change:** Change to an approved animal use protocol 1) with real or potential negative impact on animal welfare (amendment), or 2) modification to an existing procedure with no increase in real or potential negative impact on animal welfare (VVC), or 3) to replace the PI (PCR), or 4) to increase animal numbers with no other modification (AR).
- 4.18. **SOP:** Standard Operating Procedure
- 4.19. **VVC:** Veterinary Verification and Consultation. Process by which the AV or designee confirms adherence to approved IACUC SOPs or Guidance documents. Does not apply to Houston animal program.

5. PROCEDURE

- 5.1. **Modification requests are categorized into significant and minor change classifications.**
 - 5.1.1. Categorization may be determined by:
 - 5.1.1.1. AWO staff during administrative pre-review, or
 - 5.1.1.2. The AV or designee during VVC.
- 5.2. **Significant Changes with Potential to Negatively Impact Animal Welfare**
 - 5.2.1. Must be reviewed by DMR or FCR
 - 5.2.2. Examples include:
 - 5.2.2.1. Change in species
 - 5.2.2.2. Change from non-survival to survival surgery
 - 5.2.2.3. Change resulting in greater pain, distress, or degree of invasiveness
 - 5.2.2.4. Addition of a new procedure regardless of classification (minor, significant)
 - 5.2.2.5. Removal of procedure that results in additional pain/distress and/or change in scope of approved project
 - 5.2.2.6. Addition of new strain with known, or potential, negative phenotype
 - 5.2.2.7. Change in age of animals with potential for increase in animal pain and distress
 - 5.2.2.8. Addition or modification to hazards
- 5.3. **Significant Changes without Potential to Negatively Impact Animal Welfare**
 - 5.3.1. May undergo VVC where IACUC approved SOPs exist, see SOP TAMU-S-004
 - 5.3.2. Examples include, but are not limited to:
 - 5.3.2.1. Changes in anesthesia, analgesia, antimicrobials and sedation
 - 5.3.2.2. Changes in experimental compounds or substances
 - 5.3.2.3. Change in duration, frequency, type or number of approved procedures
 - 5.3.2.4. Change in strain or addition of new strain with *no known, or potential, negative phenotype*
 - 5.3.2.5. Removal of procedure that does not result in additional pain/distress and/or change in scope of approved project.

- 5.3.2.6. Change in sex or age of previously approved animal species
- 5.3.2.7. Changes related to surgery, except where excluded
- 5.3.2.8. Change in source of animals
- 5.3.2.9. Increase in previously approved animal numbers (large USDA species <5%; all other species <30%)
- 5.3.2.10. Final disposition of the animal
- 5.3.2.11. Changes in euthanasia
- 5.3.2.12. Other changes as described in SOP TAMU-S-004

5.4. Significant Changes – Other

- 5.4.1. Significant changes without the potential to negatively impact animal welfare other-wise excluded from Section 5.3 must be reviewed by DMR or FCR
- 5.4.2. Examples include:
 - 5.4.2.1. Change in PI
 - 5.4.2.2. Change in study objectives
 - 5.4.2.3. Change that impacts personnel safety
 - 5.4.2.4. Increase in previously approved animal numbers (large USDA species >5%; all other species >30%)
 - 5.4.2.5. Addition of housing or use location that is not part of the animal program overseen by the IACUC
 - 5.4.2.6. Addition of new satellite housing (\geq 12 hour housing for USDA regulated species or 24 hour housing for non-USDA regulated species) for a particular PI
 - 5.4.2.7. Addition of a location with new corresponding activity (e.g., addition of surgery or PI performed transportation to the protocol)

5.5. Minor Changes

- 5.5.1. May undergo AR where IACUC approved SOPs exist, see SOP TAMU-S-005
- 5.5.2. Examples include, but are not limited to:
 - 5.5.2.1. Change in personnel other than PI
 - 5.5.2.2. Change in funding
 - 5.5.2.3. Change in housing or study location, where location is not excluded by Section 5.4 above, including change in study area for wild species studied in their natural habitat where the change is congruent with applicable permits
 - 5.5.2.4. Removal of transportation of live animals
 - 5.5.2.5. Replacement of PI performed transportation of live animals with transportation performed by core support personnel.
 - 5.5.2.6. Removal of species, strains or breeds
 - 5.5.2.7. Change in strain nomenclature of an approved strain
 - 5.5.2.8. Removal of hazards
 - 5.5.2.9. Removal of experimental compounds or substances
 - 5.5.2.10. Other changes as described in SOP TAMU-S-005

5.6. Other Changes

- 5.6.1. May undergo AR in absence of IACUC approved SOPs
- 5.6.2. Examples include:
 - 5.6.2.1. Correction of grammar or typographical errors
 - 5.6.2.2. Correction of animal number discrepancies between AUP sections discovered after IACUC review and approval
 - 5.6.2.3. Change in contact information; e.g.: official name, phone number, address or email address



- 5.6.2.4. Change in protocol title
- 5.6.2.5. Removal of personnel from a study
- 5.6.2.6. Early closure of AUPs due to:
 - 5.6.2.6.1. PI request; including requests made by email or through the final report process,
 - 5.6.2.6.2. IACUC approval of a replacement AUP,
 - 5.6.2.6.3. Department Head (or higher) request for a PI who is no longer affiliated with the institution
 - 5.6.2.6.4. Ineligibility of PI to be in the PI role where no replacement PI has been identified; includes PIs who have terminated their affiliation with the institution or have experienced a change in status such as retirement or change in title rendering the individual ineligible for the role

6. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

- 6.1. NOT-OD-14-126 [Guidance on Significant Changes to Animal Activities](#) describes the types of animal activities where the IACUC has the authority to establish and approve internal policies/procedures for the review and approval of protocol amendments.
- 6.2. USDA agreement with NOT-OD-14-126:
http://grants.nih.gov/grants/olaw/educational_resources.htm#a_08212014
- 6.3. PHS Policy on Humane Care and Use of Laboratory Animals, [section IV.C.1.a.-g.](#)
- 6.4. [IACUC/AWO Referenced Documents](#): (requires TAMU NetID authentication)
 - 6.4.1. TAMU-S-002 Mechanisms of IACUC Review, Veterinary Consultation and Confirmation
 - 6.4.2. TAMU-S-004 Veterinary Verification and Consultation
 - 6.4.3. TAMU-S-005 Change to Approved Protocols by Administrative Review

7. HISTORY

Effective Date	Version #	Description
02/21/2019	000	College Station/Galveston: New Document; replaced AWAP 309 & “Definition of Significant vs. Minor Changes...” document
01/16/2020	001	College Station/Galveston: Added pilot study procedures
01/21/2020	002	Dallas: New Document; replaced CD-108
01/27/2020	003	Houston/Kingsville: New Document; replaced IBT-108
11/01/2021	004	College Station/Galveston: Renewal; updated definitions, clarification of eligible changes by type. Reviewed and approved via e-mail.
12/01/2021	005	Houston/Kingsville: Renewal; updated definitions, clarification of eligible changes by type. Reviewed and approved via e-mail.
12/14/2021	006	Dallas: Renewal; updated definitions, clarification of eligible changes by type (Note: version reviewed by this board did not include annual continuing review)
12/27/2021	007	Houston/Kingsville: Removal of annual continuing review process with no modification to expiration date. Approved on 12/13/2021 with delayed start date to match final rule effective date.
12/27/2021	008	College Station/Galveston: Removal of annual continuing review process with no modification to expiration date. Approved on 12/16/2021 with delayed start date to match final rule effective date.
03/24/2022	009	College Station/Dallas/Galveston: Merging of Dallas animal care and use program with College Station/Galveston
10/20/2022	010	College Station/Dallas/Galveston/Kingsville: Merging of Kingsville animal care and use program with College Station/Dallas/Galveston.



08/01/2024	011	College Station/Dallas/Galveston/Kingsville: Renewal; updated definitions, change in procedures to expand examples of significant (amendment, VVC) and minor (administrative review) eligible changes
09/01/2024	012	Houston: Renewal; updated definitions, change in procedures to expand examples of significant (amendment, VVC) and minor (administrative review) eligible changes