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 AUP modifications, including IACUC reviewed amendments, pilot study updates with AUP modifications, VVC and administrative processing by AWO 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 is responsible for verifying that requests for protocol modifications meet the IACUC approved requirements for AR.
   3.4. The CMP Veterinary Staff under the authority of the Attending Veterinarian, or Attending Veterinarian for Dallas and Houston programs, is responsible for performing a review of any amendment which includes procedures which may cause more than momentary or slight pain or distress. Additionally, VVC is performed by CMP/ARU Veterinary staff.
   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 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 research 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. 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.
   4.9. 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.
4.10. **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.

4.11. **IACUC Chair**: Chair of the IACUC appointed by the Institutional Official.

4.12. **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.

4.13. **PI**: Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.

4.14. **Pilot Study**: A small-scale test of the methods and procedures to be used on a larger scale.

4.15. **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).

4.16. **SOP**: Standard Operating Procedure

4.17. **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. Addition of new strain
5.2.2.6. 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 sex of previously approved animal species
5.3.2.5. Changes related to surgery, except where excluded
5.3.2.6. Change in source of animals
5.3.2.7. Increase in previously approved animal numbers (large USDA species <5%; all other species <30%)
5.3.2.8. Final disposition of the animal
5.3.2.9. Changes in euthanasia
5.3.2.10. 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 otherwise 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 (≥ 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 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. Replacing PI with Co-PI
      5.5.2.3. Change in funding
      5.5.2.4. Change in housing or study location, where location is not excluded by Section 5.4 above
      5.5.2.5. Removal of strains or breeds
      5.5.2.6. Change in strain nomenclature of an approved strain
      5.5.2.7. Removal of hazards
      5.5.2.8. Removal of experimental compounds or substances
      5.5.2.9. 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. TAMU-S-004 Veterinary Verification and Consultation
6.5. TAMU-S-005 Change to Approved Protocols by Administrative Review

7. HISTORY

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Version #</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/21/2019</td>
<td>000</td>
<td>College Station/Galveston: New Document; replaced AWAP 309 &amp; “Definition of Significant vs. Minor Changes...” document</td>
</tr>
<tr>
<td>01/16/2020</td>
<td>001</td>
<td>College Station/Galveston: Added pilot study procedures</td>
</tr>
<tr>
<td>01/21/2020</td>
<td>002</td>
<td>Dallas: New Document; replaced CD-108</td>
</tr>
<tr>
<td>01/27/2020</td>
<td>003</td>
<td>Houston/Kingsville: New Document; replaced IBT-108</td>
</tr>
<tr>
<td>11/01/2021</td>
<td>004</td>
<td>College Station/Galveston: Renewal; updated definitions, clarification of eligible changes by type. Reviewed and approved via e-mail.</td>
</tr>
<tr>
<td>12/01/2021</td>
<td>005</td>
<td>Houston/Kingsville: Renewal; updated definitions, clarification of eligible changes by type. Reviewed and approved via e-mail.</td>
</tr>
<tr>
<td>12/14/2021</td>
<td>006</td>
<td>Dallas: Renewal; updated definitions, clarification of eligible changes by type (Note: version reviewed by this board did not include annual continuing review)</td>
</tr>
<tr>
<td>12/27/2021</td>
<td>007</td>
<td>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.</td>
</tr>
<tr>
<td>12/27/2021</td>
<td>008</td>
<td>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.</td>
</tr>
<tr>
<td>03/24/2022</td>
<td>009</td>
<td>College Station/Dallas/Galveston: Merging of Dallas animal care and use program with College Station/Galveston</td>
</tr>
<tr>
<td>10/20/2022</td>
<td>010</td>
<td>College Station/Dallas/Galveston/Kingsville: Merging of Kingsville animal care and use program with College Station/Dallas/Galveston.</td>
</tr>
</tbody>
</table>