IACUC SOP:	**TAMU-S-004**	Title:	**Veterinary Verification and Consultation**

Location	Effective Date	Review By
College Station/Dallas/Galveston/Kingsville	11/01/2022	10/31/2024
Houston	N/A	N/A

1. PURPOSE

1.1. To describe the modification to AUPs applicable for Veterinary Verification and Consultation

2. SCOPE

2.1. This SOP applies to modifications reviewed by VVC. Modifications must meet the description for VVC eligibility as described in TAMU-S-003. Review to be performed as described in TAMU-S-002.

3. RESPONSIBILITY

3.1. **IACUC Members** are responsible for establishing the contents of this SOP

3.2. The **AWO Staff** is responsible for routing submissions for veterinary consultation if received directly from the PI, notifying the PI of the results of the consultation, maintaining records pertaining to the specific method of review for a given submission, and the outcome of that review.

3.3. The **AV (or designee)** is responsible for verifying that requests for modification to the AUP meet the IACUC approved requirements listed below for VVC.

3.4. The **PI** is responsible for notifying the IACUC or AV (or designee) 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. **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.

4.4. **EHS**: Environmental Health and Safety Department

4.5. **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.

4.6. **IBC:** Institutional Biosafety Committee. Institutional body responsible for the review and oversight of research, teaching, and testing activities utilizing biohazardous materials and Dual Use Research of Concern. Appointed by the Institutional Official.

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

4.8. **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. **In general, the modification requested must be in line with the approved scope of work and should enhance the quality/quantity of the scientific data obtained without increasing animal pain, distress, or degree of invasiveness from the approved protocol.**

5.2. **Anesthesia, Analgesia, Antimicrobials and Sedation**

5.2.1. The AV (or designee) may verify changes to:

5.2.1.1. Addition of a clinically relevant drug of the same class used (e.g.: adding or swapping one alpha 2 agonist for another alpha 2 agonist) to induce a similar outcome. May be used to replace an already approved anesthetic, analgesic, antimicrobial, or sedative drug; or provide an alternate drug that may be used due to shortages in supply.

5.2.1.2. Modify the dose, route, concentration, volume, and/or duration of an approved anesthetic, analgesic, antimicrobial, or sedative drug.
5.2.1.3. Additions or modifications must be in accordance with published veterinary formularies and may not result in a change in study objectives or greater pain, distress, or degree of invasiveness. Approved veterinary formularies are listed in the Reference section below.
5.2.1.4. **Note:** The addition of a non-pharmaceutical grade anesthetic, analgesic, antimicrobial, or sedative drug is not eligible for the VVC process.

5.3. Experimental Compounds or Substances

5.3.1. The AV (or designee) may verify changes to:
5.3.1.1. Add an additional experimental compound or substance of the same drug class (e.g.: adding or swapping one Nox inhibitor for another Nox inhibitor) used to induce a similar outcome to an existing experiment that is already approved for use of such compounds or substances.
5.3.1.2. Modify the timing, frequency, dose, route, concentration, volume, and/or duration of an approved experimental substance.
5.3.1.3. Additions or modifications may occur as long as the change does not result in a change in study objectives or greater pain, distress, or degree of invasiveness.
5.3.1.4. **Note:** The addition of an experimental compound or substance that requires review and approval by either IBC or EHS of a hazardous nature (e.g.: lack of published safety data, but compound is reasonably assumed to be hazardous based on other compounds of this class; published safety data sheet indicates compound is a carcinogen or has toxicity level of 1-4) is not eligible for the VVC process.

5.4. **Changes to duration, frequency, type, or number of approved procedures performed on an animal may be eligible for VVC, as long as the change is 1) a modification to an existing IACUC approved procedure and 2) does not result in greater pain, distress, degree of invasiveness, and/or a change in study objectives:**

5.4.1. The AV (or designee) may use his/her discretion to verify minor procedural changes provided that in the judgment of the veterinarian the change will not unduly impact animal welfare (e.g.: lessens or involves equivalent pain, acute or chronic stress, distress or effects upon animal welfare) and is consistent with current standards of veterinary practice or is specifically addressed in IACUC procedure or guidance. Common examples include:
5.4.1.1. Changes related to blood collection (e.g.: frequency, volume, vessel of access)
5.4.1.2. Change in sample collection method to a method with equal or lesser pain, distress or degree of invasiveness.
5.4.1.3. Revision of sample collection intervals or total samples collected.
5.4.1.4. Change in route of administration for an approved compound.
5.4.1.5. Additional peri-mortem tissue collection or tissue collection from a new organ system or anatomical site when the animal is under terminal anesthesia.
5.4.1.6. Substitution of one accepted biopsy method for another for tissue or DNA analysis (e.g.: tail snip vs ear notch)
5.4.1.7. Altering the duration or interval between procedures (e.g.: lengthening an imaging episode or the time between episodes).
5.4.1.8. Change in identification means (e.g.: ear tag vs microchip).
5.4.1.9. Adding or altering behavioral testing methods providing they do not involve greater pain and distress or degree of invasiveness.
5.4.1.10. Change in other protocol time-points not addressed above
5.4.1.11. **Note:** The addition of anesthesia where anesthesia is not currently used for an approved procedure is not eligible for the VVC procedure.

5.5. **Modification to strain, sex or age of previously approved animal species**

5.5.1. The AV (or designee) may verify the appropriateness of:

5.5.1.1. The addition of the opposite sex from what is approved in the protocol, e.g., addition of females when males are approved
5.5.1.2. Change in sex to the opposite sex
5.5.1.3. Change in age of animal
5.5.1.4. Change in strain or addition of new strain
5.5.2. If additional animals are requested, the increase in animals must be congruent with the guidelines in this SOP or TAMU-S-005.

5.6. Changes related to surgery

5.6.1. The AV (or designee) may verify modifications in the previously approved surgical procedure that do not increase invasiveness or expected adverse outcomes (e.g., change of suture material, closure method, surgical approach, number of samples collected).

5.7. Source of Animals

5.7.1. The AV (or designee) may verify a change in the source of animals as long as the new source is a previously approved vendor or source.

5.8. Increase in previously approved animal numbers

5.8.1. Limits on animal numbers are for the protocol approval period and are not cumulative
5.8.2. Modifications to protocol activities must meet the description for VVC as described on this SOP or AR as described on TAMU-S-005
5.8.3. The AV (or designee) may verify an increase in animal numbers for the following:
5.8.3.1. Non-rodent USDA-regulated species:
5.8.3.1.1. Replacement of animals lost as a result of reported adverse events
5.8.3.1.1.1. No more than the number of animals listed in a reported adverse event
5.8.3.1.2. Additional animals associated with another VVC classification
5.8.3.1.2.1. One animal or up to 5% of the number originally approved within that pain category
5.8.3.2. USDA-regulated rodents and non-USDA regulated species:
5.8.3.2.1. Replacement of animals lost as a result of reported adverse events
5.8.3.2.1.1. No more than the number of animals listed in a reported adverse event
5.8.3.2.2. Additional animals associated with another VVC classification
5.8.3.2.2.1. No more than 30% of the number originally approved within that pain category

5.9. Final Disposition of the Animal

5.9.1. The AV (or designee) may verify a change in the final disposition of the animal including change from euthanasia to adoption, or transfer to another protocol ("transfer to" AUP must be identified as a part of the request).
5.9.1.1. Note: Transfer of non-naïve animals to an invasive protocol such as one that includes major survival surgery, infectious disease studies, or unrelieved pain and/or distress requires the submission of an amendment for IACUC review.

5.10. Euthanasia

5.10.1. The AV (or designee) may verify a change in euthanasia to any method listed in the current AVMA Guidelines for the Euthanasia of Animals as acceptable or acceptable with conditions (when stipulated conditions are met), including the swapping of one method for another and/or the inclusion of new methodologies.

6. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

6.1. Anesthesia, analgesia, or sedation to referenced drugs and dosages for the species:
- 6.1.1. Anesthesia and Analgesia in Laboratory Animals
- 6.1.2. American College of Laboratory Animal Medicine Series
- 6.1.3. Exotic Animal Formulary
- 6.1.4. Fish and Danneman Anesthesia and Analgesia of Laboratory Animals
- 6.1.5. Fish et. al. Anesthesia and Analgesia in Laboratory Animals
- 6.1.6. Flecknell and Waterman-Pearson's Pain Management in Animals
- 6.1.7. Flecknell's Laboratory Animal Anesthesia
- 6.1.8. Fowler's Zoo and Wildlife Medicine
- 6.1.9. Goat Medicine - second edition by Mary C. Smith and David Sherman
- 6.1.10. Hagyard Pharmacy mobile formulary
- 6.1.11. Harkness and Wagner's Biology and Medicine of Rabbits and Rodents
- 6.1.12. Hawk and Leary's Formulary for Laboratory Animals
- 6.1.13. Laboratory Animal Medicine, ACLAM Series, Elsevier, 2002
- 6.1.14. Lumb and Jones Veterinary Anesthesia and Analgesia
- 6.1.15. Manual of Equine Emergencies - Orsini and Divers
- 6.1.16. Muir et. al. Handbook of Veterinary Anesthesia
- 6.1.17. Plumb's Veterinary Drug Handbook
- 6.1.18. Quesenberry and Carpenter's Ferrets, Rabbits and Rodents Clinical Medicine and Surgery
- 6.1.19. Swine in the Laboratory - M. Michael Swindle

6.2. AVMA Guidelines for the Euthanasia of Animals, 2013 Edition

6.3. Global Harmonization System (GHS) for determining chemical hazard category and risk level (https://www.osha.gov/law-regs.html).

6.4. AWO: (requires TAMU NetID authentication)
- 6.4.1. TAMU-S-002 Submission Review Mechanisms
- 6.4.2. TAMU-S-003 Significant and Minor Changes to Approved Animal Activities
- 6.4.3. TAMU-S-005 Change to Approved Protocols by Administrative Review

7. HISTORY

Effective Date	Version #	Description
04/18/2019	000	College Station/Galveston: New Document; replaced unnumbered document titled "IACUC Approved VVC Procedures"
01/16/2020	001	College Station/Galveston: Revision to allow for additional modifications to clinical drugs and experimental compounds. Inclusion of CMP equivalent unit within COD animal program.
01/21/2020	002	Dallas: New Document; partial replacement of CD-108
03/24/2022	003	College Station/Dallas/Galveston: Merging of Dallas animal care and use program with College Station/Galveston
11/01/2022	004	College Station/Dallas/Galveston/Kingsville: Renewal; incorporation of Kingsville campus, updates to scope, responsibility, and definitions, clarification to changes in euthanasia. Reviewed and approved via email.