

VVC – What is it? And how can it help you?

VVC: Veterinarian Verification and Consultation is an expedited process you can use to make minor changes to your AUP without having to submit an Amendment. If you would like to make a change in one of the following areas: Anesthesia, Analgesia, Antimicrobials, Sedation, (some) Experimental substances, Euthanasia, and (some) minor procedural changes, speak with one of the CMP/ARU veterinarians. They reference one of the IACUC approved documents (includes several different formularies and AVMA guidelines). If the change is approved under these guidelines and does not result in a change in study objectives or greater pain, distress, or degree of invasiveness, they can allow you to immediately implement changes to your AUP. The veterinarians and IACUC Office staff will incorporate these changes into your AUP for you.

Anesthesia, Analgesia, Antimicrobials and Sedation

The AV or their designee may verify changes to:

- 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.
- Modify the dose, route, concentration, volume, and/or duration of an approved anesthetic, analgesic, antimicrobial, or sedative drug.
- 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.
- Note: The addition of a non-pharmaceutical grade anesthetic, analgesic, antimicrobial, or sedative drug is not eligible for the VVC process.

Experimental Compounds or Substances

The AV or their designee may verify changes to:

- 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.
- Modify the timing, frequency, dose, route, concentration, volume, and/or duration of an approved experimental substance.
- 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.
- Note: The addition of an experimental compound or substance that requires review and approval by either Biosafety/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.

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:

The AV or their designee may use his/her discretion to verify minor procedural changes provided that in the judgment of the VVC veterinarian the change will not unduly impact animal welfare (i.e., 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 specifically addressed in IACUC procedure or guidance. Common examples include:

- Changes related to blood collection (e.g.: frequency, volume, vessel of access)
- Change in sample collection method to a method with equal or lesser pain, distress or degree of invasiveness.
- Revision of sample collection intervals or total samples collected.
- Change in route of administration for an approved compound.

- Additional peri-mortem tissue collection or tissue collection from a new organ system or anatomical site when the animal is under terminal anesthesia.
- Substitution of one accepted biopsy method for another for tissue or DNA analysis (e.g.: tail snip vs ear notch)
- Altering the duration or interval between procedures (e.g.: lengthening an imaging episode or the time between episodes).
- Changing an identification means (e.g.: ear tag vs microchip).
- Adding or altering behavioral testing methods providing they do not involve greater pain and distress or degree of invasiveness.
- Change in other protocol time-points not addressed above
- Note: The addition of anesthesia where anesthesia is not currently used for an approved procedure is not eligible for the VVC procedure.

Modification to sex of previously approved animal species

- The AV or their designee may verify the appropriateness of:
 - The addition of the opposite sex from what is approved in the protocol, e.g., addition of females when males are approved
 - Change in sex to the opposite sex
 - If additional animals are requested, the increase in animals must be congruent with IACUC guidelines.

Changes related to surgery

The AV or their 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).

Source of Animals

The AV or their designee may verify a change in the source of animals as long as the new source is a previously approved **CMP/ARU** vendor or barrier.

Increase in previously approved animal numbers

Limits on animal numbers are for the protocol approval period and are not cumulative. Modifications to protocol activities must meet the description for VVC as described on this SOP or AR as described on TAMU-S-005.

The AV or their designee may verify an increase in animal numbers for the following:

- Non-rodent USDA-regulated species:
 - Replacement of animals lost as a result of reported adverse events
 - No more than the number of animals listed in a reported adverse event
 - Additional animals associated with another VVC classification
 - One animal or up to 5% of the number originally approved within that pain category

USDA-regulated rodents and non-USDA regulated species:

- Replacement of animals lost as a result of reported adverse events
 - No more than the number of animals listed in a reported adverse event
- Additional animals associated with another VVC classification
 - No more than 30% of the number originally approved within that pain category

Final Disposition of the Animal

The AV or their 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 invasive protocols such as terminal surgery or infectious disease studies require IACUC review.

Euthanasia

The AV or their designee may verify a change in euthanasia to any method approved in the current AVMA Guidelines for the Euthanasia of Animals.