VETERINARY VERIFICATION AND CONSULTATION (VVC) STANDARD OPERATING PROCEDURE (SOP)

Background:

The Veterinary Verification and Consultation (VVC) is designed to provide a structured and targeted review for specific changes on approved animal use protocols. The VVC process can only be used to modify previously approved procedures, techniques, or experiments that remain within the scope of the currently approved IACUC protocol. The VVC does not authorize the addition of new procedures or activities not previously approved by the IACUC in the current protocol.

Policy:

The VVC process allows the Attending Veterinarian (AV) to verify that the requested changes are consistent with IACUC policies, allowable parameters, guidance documents, drug formularies, and references listed in this policy.

The veterinarian will verify that the proposed changes and justifications are appropriate for the animals in each specific situation. The AV may refer any request to the IACUC for review for any reason and must refer any request that does not meet eligibility criteria for Designated Member Review (DMR) or Full Committee Review (FCR).

What is Permitted by VVC?

1. **Change in pre-anesthetic, anesthetic, analgesic, sedative, antibiotic, and other clinical or veterinary products may be approved if:**
    - Replacing an already approved anesthetic, analgesic, antimicrobial, or sedative drug; or providing an alternate drug that may be used due to shortages in supply.
    - Changes to the dose, administration route, volume and/or frequency of administration if the change does not increase the potential for pain or distress.
2. **Change in euthanasia method (to another AVMA-approved method for the species)**
    - The alternative method is listed as acceptable or acceptable with conditions in the most recent AVMA Guidelines for the Euthanasia of Animals, for the species, age, size, and/or developmental stage of the animals involved.
3. **Change in experimental compounds or substances:**
    - Modify the timing, frequency, dose, route, concentration, volume, and/or duration of an approved experimental substance.
    - Addition of an experimental substance comparable to one already included (example: addition of a different cell line of the same cell type)
    - Adding 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.
    - Additions or modifications may occur if the change does not result in a change in study objectives or greater pain, distress, or degree of invasiveness.

i. *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.*

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:**
    - A modification to an existing IACUC-approved procedure and,
    - Does not result in greater pain, distress, degree of invasiveness, and/or a change in study objectives and is consistent with current standards of veterinary practice or specifically addressed in IACUC procedure or guidance. This includes:
        i. Change in blood collection method (site, frequency, volume),
        ii. Change in genotyping procedures,
        iii. Change in sample collection method to a method with equal or lesser pain, distress or degree of invasiveness,
        iv. Altering the duration or interval between procedures,
        v. Modification of a previously approved non-surgical procedure,
        vi. Modification of a previously approved surgical procedure that does not increase invasiveness, induce additional risk, pain or distress to the animal (e.g., performing ovariectomy using a different incisional approach, such as flank vs midline; or change in suture type/incision closure method),
        vii. Addition of a new strain or stock (without adverse phenotype).
5. **Changes that increase supportive care (fluids, thermoregulation, nutrition, etc.)**
    - The change improves or maintains animal well-being and does not introduce new experimental variables or procedures.
6. **Increase in animal numbers up to 10% of the originally approved number for non-USDA-regulated species if:**
    - The increase does not change the study objective, statistical design, or endpoints,
    - Does not introduce new procedures, techniques, treatments, or experimental conditions, and
    - The justification is consistent with previously approved scientific aims.

Please refer to Table 1 (below) for the appropriate review mechanism for types of modifications.

What is Not Permitted by VVC?

1. Change from non-survival to survival surgery,
2. Changes causing greater pain, distress, or invasiveness,
3. Change in species,
4. Change in study objectives or scientific rationale,
5. Change in housing or use of animals outside IACUC oversight,

6. Change in personnel (including PI),
7. Adding new procedures not described in the approved protocol,
8. Changes that impact personnel safety,
9. Any changes that require additional or new approval from other oversight committees (e.g., additional tumor or cell line; see 3.i above).

Procedure:

The Principal Investigator must review the VVC policy to determine if the proposed changes fall within the scope of the policy, then make changes to the originally approved protocol using the VVC Amendment feature in eCompliance.

The amendment submitted for review in eCompliance will be reviewed by IACUC Administrative Staff to affirm that the changes may fall within the scope of this policy. Administrative Staff forwards the amendment to the AV for review. The AV will have 3 business days to confirm the proposed changes are within the scope of this policy. The AV may:

- approve the amendment,
- require modifications to secure approval,
- request that the amendment be reviewed under the Class II Amendment procedure as outlined in the Significant Changes to Animal Activities Policy,
- or refer the amendment to FCR.

The PI will be notified in eCompliance of the AV's determination. VVC changes will be documented in eCompliance as a VVC protocol amendment. These amendments will be available to IACUC members and for auditing purposes.

Policy Violations

Any policy violations may constitute noncompliance and will be brought before the IACUC to determine reporting requirements to OLAW, AAALAC, the IO, and other agencies as appropriate. This may require the protocol amendment to undergo de novo review through the appropriate review process.

Applicable To:

All UMKC faculty, staff, employees, and students involved in the care or use of animals owned by the UMKC.

Revisions to the Policy:

This policy will be updated as changes in regulatory requirements and guidance evolve. The UMKC IACUC has the authority to amend this policy as needed. The UMKC Institutional Animal Care and Use Committee has reviewed and approved this policy.

References:

Request for Information (RFI) on Flexibilities for Streamlining IACUC Review of Protocols and Significant Changes. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-152.html

A Word from the USDA and OLAW: The Pain and Distress of VVC.
https://olaw.nih.gov/guidance/commentary/lab-animal-2023-5212.html

A Word from OLAW. Making changes: when is VVC appropriate?
https://olaw.nih.gov/guidance/commentary/lab-animal-2017-4603.html

Table 1. Review Process Overview

Modification Request	DMR/FCR	VVC	Admin
Change from non-survival surgery to survival surgery	X		
Change resulting in greater pain, distress, or degree of invasiveness	X		
Change in housing or use of animals in a location not overseen by the IACUC	X		
Change in species	X		
Change in study objectives	X		
Change in PI	X		
Change that impacts personnel safety	X		
Addition of a new procedure to the protocol	X		
Increase in animal numbers (USDA species)	X		
Increase in animal numbers >10% (non-USDA)	X		
Addition of a strain with an adverse phenotype	X		
Change in anesthetic/analgesic (within policy)		**X**	
Change in euthanasia method (AVMA-approved)		**X**	
Change in blood collection (within policy limits)		**X**	
Change in genotyping method (approved method)		**X**	
Change to a pharmaceutical-grade drug of the same class		**X**	
Change in dosing method or site (per policy)		**X**	
Addition of strain with no adverse phenotype (non-USDA)		**X**	
Minor change in diet (approved diet types)		**X**	
Increase in animal numbers <10% (non-USDA)			X
Change to personnel other than PI			X
Change in funding			X
Addition of animal housing/procedure rooms (IACUC-approved)			X
Removal of animal usage location (already approved)			X
Correction of grammar or typographical errors			X
Update contact information			X
Change the title of the approved protocol			X