BGSU
BOWLING GREEN STATE UNIVERSITY
Office of Research Compliance

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Veterinary Verification and Consultation (VVC)

Policy/Procedure ID: 17-08-001 **Effective: August 16, 2017**

A. Background

The Office of Laboratory Animal Welfare (OLAW) published NOT-OD-14-126 "Guidance on Significant Changes to Animal Activities" on August 26, 2014. This document allows for flexibility in the evaluation of certain proposed changes to animal protocols, and outlines the specific significant changes which may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. The Attending Veterinarian (AV) is not conducting DMR, but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animal activity in this circumstance. This includes changes in:

a. Anesthesia, analgesia, sedation, or experimental substances;
b. Euthanasia to any method considered acceptable or acceptable with conditions in the AVMA Guidelines for the Euthanasia of Animals
c. Duration, frequency, type, or number of procedures performed on an animal.

In order to take advantage of this flexibility in whole or in part, BGSU's IACUC has established criteria that address significant changes eligible for VVC.

B. Approved VVC activities at BGSU

(*See Appendix I for further details)*

1. **Euthanasia:** The AV may use his/her discretion to authorize the use of any currently acceptable AVMA method including those acceptable with conditions (providing the conditions are met). Note that Principal Investigators are responsible for assuring that personnel who may conduct euthanasia on the approved Animal Use Protocol have received training and certification in the new method of euthanasia. PI's should contact the AV or University Animal Facilities Director regarding euthanasia training for personnel in their labs.
2. **Anesthesia, Analgesics and Sedatives:** The AV may use his/her discretion to authorize changes to the dose, route, concentration, volume, and/or duration of any anesthetic, analgesic or sedative agents already approved on the protocol. Changes to other agents not previously approved on the existing protocol may also be authorized under this mechanism under the discretion of the AV. In addition, training on the new drug changes may be required; for example, a change that might require additional training would include changing from an injectable to an inhalant anesthesia.

3. **Experimental Substances:** The addition or deletion an experimental substance, adjustment in dose, alternate formulation, or less invasive route of administration may also be authorized under this mechanism. This includes special diets and medicated/special water. Note that the addition of a non-pharmaceutical grade drug, or a change from a pharmaceutical grade to a non-pharmaceutical grade drug requires additional justification and will not be authorized under this mechanism.
4. **Duration, frequency, type, or number of procedures performed on an animal:** The AV may use his/her discretion to authorize minor procedural changes providing, in the judgment of the AV, 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 or other policy. Examples include:
    a. Changes related to blood collection (e.g., frequency, volume, vessel of access)
    b. Revision of sample collection intervals or total samples collected.
    c. Addition of a non-invasive sampling method.
    d. Additional perimortem tissue collection or tissue collection from a new organ system or anatomical site when the animal is under terminal anesthesia.
    e. Substitution of one accepted biopsy method for another for tissue or DNA analysis.
    f. Altering the duration or interval between approved procedures (e.g., lengthening the time between doses).
    g. Changing an identification means.
    h. Adding or altering behavioral testing methods providing they do not involve unrelieved pain or distress.

5. **Increase in Animal Numbers:** The AV may use his/her discretion to authorize an increase in the previously approved number of animals allowed for use on a protocol, up to 50% over the previously approved number. The AV may also use their judgement to approve the addition of a different strain of the same species to be added to the protocol, as well as the addition of the same strain but different sex.

C. Responsibilities of the Veterinarian during the VVC process

Only the AV approved by the IACUC may conduct VVC. The responsibilities of the AV are as follows:

1. Ensure that the requested change is eligible for VVC
2. Determine if the change is appropriate under the specific circumstances. If so, the change may be authorized. If not, the following actions are appropriate under VVC:
    - Recommend revision to the existing request if it is within the scope of the policy and is appropriate for the conditions of the experiment;

    OR
    - Defer the request to DMR (Designated Member Review) or FCR (Full Committee Review)

D. Documentation of the VVC process

The following process must be followed in regard to conduct and subsequent documentation of the VVC process:

1. All amendment requests are submitted by the PI through the IRBNet electronic submission process. If the PI believes the amendment qualifies for the VVC method of review, the PI checks the "VVC" box and provides reasons why the submission is eligible for the VVC method of review.
2. The Office of Research Compliance will evaluate the request and determine if it is eligible for VVC.
    a. If the request is not eligible for VVC review, the PI is notified to submit the amendment to the AV for pre-review and to resubmit the amendment for FCR or DMR.
    b. If the submission is eligible for VVC, the AV will then be assigned to the protocol amendment.
3. If the request is deemed to be urgent, the Research Compliance Officer may contact the AV via email or phone call to alert them of the situation, so as to expedite the request.
4. If the AV verifies that the request can be authorized via VVC, this will be noted in the review process in addition to all other review notes and documentation in IRBNet. The approval will be processed through IRBNet. An approval letter will be sent to the PI.
5. If the AV feels that the request does not fit within the established policies and procedures for VVC, then the AV will document this in the review notes, and the amendment will be reassigned for DMR or FCR as appropriate.

APPENDIX I

Please refer to this chart for details on which amendment requests are eligible for Full Committee Review (FCR) vs. Designated Member Review (DMR) vs. Veterinary Verification and Consultation (VVC) vs. Administrative Review.

Amendment Requests	FCR	DMR	VVC	Admin
All Studies involving Exceptions to "The Guide"	X			
All studies involving exemptions or exceptions from established IACUC policy.	X			
Addition of another strain of the same species in protocols involving USDA regulated species		X		
Changes to the PI		X		
Addition of faculty collaborator (co-PI)		X		
Change in species used on a protocol; pertains to protocols involving all species (USDA regulated and non-regulated)		X		
Addition of >50% of the number of animals over the original authorized number in protocols involving all species (USDA regulated AND non-regulated)		X		
Addition of a minor surgery; pertains to protocols involving all species (USDA regulated AND non-regulated)		X		
Addition of >10% but ≤50% of the number of animals over the original authorized number; pertains to protocols involving all species (USDA regulated AND non-regulated)			X	

Amendment Requests	FCR	DMR	VVC	Admin
Reducing or eliminating previously approved water or feed restrictions in protocols; pertains to all protocols involving all species (USDA regulated AND non-regulated)			X	
Addition of or change in diet (special food, water, bedding) or dosage of an experimental drug in the same class as one previously approved; pertains to protocols involving all species (USDA regulated AND non-regulated)			X	
Addition of non-invasive sampling in protocols; pertains to protocols involving all species (USDA regulated AND non-regulated)			X	
Substitution of one AVMA acceptable euthanasia method for another acceptable euthanasia method; pertains to protocols involving all species (USDA regulated AND non-regulated)			X	
Adding additional perimortem tissue collection when the animal is under terminal anesthesia; pertains to protocols involving all species (USDA regulated AND non-regulated)			X	
Substitution of one accepted biopsy method for another for tissue or DNA analysis in protocols; pertains to protocols involving all species (USDA regulated AND non-regulated)			X	
Addition of or change in dosage of an experimental drug in the same class as one previously approved; pertains to protocols involving all species (USDA regulated AND non-regulated)			X	
Addition of another strain of the same species in protocols; pertains to protocols involving all species (USDA regulated AND non-regulated)			X	
Change of sex in the animal to be used in protocols; pertains to protocols involving all species (USDA regulated AND non-regulated)			X	
Addition of sample collection times, not exceeding standard limits, in protocols; pertains to protocols involving all species (USDA regulated AND non-regulated)			X	
Addition of or change in dosage of an experimental drug in the same class as one currently approved; pertains to protocols involving all species (USDA regulated AND non-regulated)			X	
Deletion of animal usage location approved in protocols; pertains to protocols involving all species (USDA regulated AND non-regulated)			X	
Changes to contact information or training updates of the PI or study personnel for all protocols				X
Addition of lab personnel (students, technicians, etc) for all protocols				X
Corrections in spelling/grammatical errors; minor clarifications				X
Changes to funding (addition or deletion) in all protocols				X

Amendment Requests	FCR	DMR	VVC	Admin
Changing the title of an approved protocol				X
Addition of <10% of the number of animals over the original authorized number in protocols NOT involving USDA regulated species				X