

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Administrative Review

Policy/Procedure ID: 17-08-002

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. This includes:

- a. An increase in the previously approved number of animals allowed for use on a protocol, up to 10% over the previously approved number;
- b. Correction of typographical and/or grammatical errors;
- c. Contact information updates; and
- d. Changes in personnel, other than the PI (There must be an administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.)

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

B. Changes Approved for Administrative Review at BGSU

(See Appendix I for further details)

1. **Increase in Animal Numbers:** An increase in the previously approved number of animals allowed for use on a protocol, up to 10% over the previously approved number, may be handled administratively. The requested animals must be the same strain, species and sex as previously approved.
2. **Correction of typographical and/or grammatical errors:** Spelling and grammatical corrections, along with clarification or minor modifications of proposed changes, may be requested by the IACUC and addressed through the administrative review process. Any significant concerns or questions raised through the administrative review process will result in referral of the renewal or modification request to DMR or FCR.
3. **Contact information updates:** Changes to the PI's contact information (e-mail address, office location, etc) may be made administratively.

4. **Changes in personnel (other than the PI):** Personnel additions or deletions may be handled administratively. Personnel additions will require administrative review to confirm the completion of all necessary enrollment requirements as identified in BGSU IACUC policies (e.g., CITI training, enrollment into Occupational Health and Safety program).

C. The Administrative Review process

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

1. All applicable documents (personnel additions, etc.) are submitted by the PI through the IRBNet electronic submission process.
2. The Office of Research Compliance will evaluate the request and determine if it is eligible for Administrative Review. If it is not, the submission will be sent back to the PI for Attending Veterinarian pre-review and re-submission for FCR or DMR.
3. If the submission is eligible for Administrative Review, then the request will be processed and an approval letter will be issued to the PI.

APPENDIX I

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

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; pertains to 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 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; 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; 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 $\leq 10\%$ of the number of animals over the original authorized number in protocols; pertains to protocols involving all species (USDA regulated AND non-regulated)				X