

## **SIGNIFICANT CHANGES TO ANIMAL ACTIVITIES**

### **Background:**

It is Institutional Animal Care and Use Committee (IACUC) and Lab Animal Research Core (LARC) policy to meet or exceed all federal, state and local regulations and guidelines and comply with all institutional policies and procedures as they apply to the IACUC review process.

### **Purpose:**

The PHS Policy on Humane Care and Use of Laboratory Animals (Policy) ([IV.C.1.](#)) and Animal Welfare Regulations ([9 CFR 2.31 \(d\) \(1\) \(i\)-\(iv\)](#)) define the responsibilities of the IACUC regarding review and approval of proposed significant changes to animal activities. Changes to approved research projects must be conducted in accordance with the institution's Assurance, the US Department of Agriculture (USDA), Animal Welfare Act, Animal Welfare Regulations, and must be consistent with the [Guide](#) unless an acceptable justification for a departure is presented. Additionally, IACUCs are responsible for assuring that the changes to approved animal activities meet the requirements described in the PHS Policy [IV.C.1.a.-g.](#)

IACUC approval of proposed animal activities or significant changes to previously approved animal activities is granted after full committee review (FCR), designated member review (DMR), or as established by policies for the conduct of animal activities. This Significant Changes to Animal Activities Policy is established to ensure that all research activities have a standardized method, and administrative guidelines are established and meet the goals of the UMKC IACUC.

The IACUC has some discretion to use IACUC-reviewed and -approved policies to define what it considers a significant change, or to establish a mechanism for determining significance on a case-by-case basis in accordance with the PHS Policy [IV.C.1.a.-g.](#) It is the IACUC's responsibility to clearly define and communicate its policy for determining significance to investigators.

### **Procedures**

***Exception:*** Category E protocol requests **MUST** be reviewed at Full Committee Review (FCR). Any minor change to an E protocol that **does not** alter the reasoning of the "E" category work **does not** need FCR, including but not limited to:

- *change in personnel*
- *addition of non-category E animals*
- *addition of an AVMA approved method of euthanasia*
- *addition of a genetic background or strain*
- *changes that don't significantly impact animal care and husbandry needs*

Significant changes include changes that have, or have the potential to have, a negative impact on animal welfare (see paragraph 1, below). In addition, some activities that may not have a direct impact on animal welfare are also considered to be significant (see paragraphs 2. and 3, below).

In support of the use of performance standards and professional judgment and to reduce regulatory burden, IACUC-reviewed and -approved policies (e.g., guidance documents, standard operating procedures, drug formularies) for the conduct of animal activities may be used for the administrative handling of some significant changes according to the following considerations:

### **Class I Amendment**

Significant changes described below, must be approved by one of the valid IACUC approval methods described in the PHS Policy [IV.C.2.](#), that is FCR or DMR, including changes:

1. from non-survival to survival surgery;
2. resulting in greater pain, distress, or degree of invasiveness;
3. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
4. in species;
5. in study objectives;
6. in Principal Investigator (PI); and
7. that impact personnel safety.

### **Class I Amendment Procedure**

The Principal Investigator makes changes to originally approved protocol using the amendment feature in eCompliance. The amendment submitted for review in eCompliance and follows the standard IACUC review process.

### **Class II Amendment**

The protocol changes described below may be handled with the submission of a Class II Amendment to the IACUC:

1. a change anesthesia, analgesia, and tranquilizing drugs listed in our formulary, or experimental substances that do not pose a greater risk than those already approved in the protocol;
2. a change in euthanasia to any method approved for the species in the [AVMA Guidelines for the Euthanasia of Animals](#);
3. a change in experimental protocol as it relates to timing, dose, route of administration and/or specific chemical composition (change may not increase the invasiveness of the procedure, scientific objectives or scientific rationale)
4. addition/Change Animal Genetic Background or Strain;
5. new transgenic rodent strains may be added only if the project already includes transgenic rodents and the new strain does not involve a) any pathogenic vector, b) the expression of any biotoxin, or c) any gene that would require more than a Biosafety Level 1 (BSL-1) containment; and
6. change in location to perform procedures already approved in this protocol (including procedures performed in your laboratory which will be subjected to semi-annual IACUC laboratory inspections).

7. an increase in previously approved animal numbers (PHS Policy [IV.D.1.a.](#)).
  - a. can be greater than 10% of originally approved number
  - b. can include USDA covered and non-covered species
  - c. the requested change must keep with the original rationale for the number of animals approved
  - d. must include a detailed description of why the additional animals are needed but stay within the experimental group parameters on the approved protocol.

## **Class II Amendment Procedure**

The Principal Investigator makes changes to originally approved protocol using the amendment feature in eCompliance. Administrative Staff reviews application and forwards to the IACUC for review. Any IACUC member has 3 business days to request FCR. If FCR is not requested, the Chair appoints himself (or designee in writing) and the Attending Veterinarian as DMRs to review the amendment. The Chair (or designee) or AV may require FCR or modifications to secure approval. Final approval is not granted until both the Chair (or designee) and AV determine that FCR and no further modifications are required to approve the amendment.

### **Class II Amendment with Administrative Approval**

A significant change that may be handled administratively according to an existing IACUC reviewed and approved policy without additional consultation or notification:

1. change 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.)
2. change in Project Title or Funding Source

Changes that may be handled administratively without IACUC-approved policies, consultations, or notifications include:

- a. correction of typographical errors;
- b. correction of grammar; and
- c. contact information updates.

### **Class II Amendment with Administrative Approval Procedure**

The Principal Investigator makes changes to originally approved protocol using the amendment feature in eCompliance. IACUC Administrative Staff reviews to secure approval.

Investigators may use fewer animals than approved. This does not require IACUC approval, notification, consultation, or administrative handling.

The USDA Animal and Plant Health Inspection Service has reviewed and concurs with this guidance.

## **References**

- [NOT-OD-14-126](#): Guidance on Significant Changes to Animal Activities
- eCompliance: <https://umkc.ecompliance.umsystem.edu/acuc>
  - [Guidance on submitting a protocol amendment](#)

## **Applicable To:**

All personnel involved in the care or use of animals owned by the UMKC, or in UMKC facilities.

## **Revisions to the Policy:**

This policy is intended to be flexible and readily adaptable to changes in regulatory requirements. 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.