Policy Statement

This policy applies to changes made to a protocol and the approval process. Any changes to an already approved IACUC protocol must be approved by the IACUC prior to implementation. If a change is implemented prior to approval, it is considered protocol non-compliance.

Background

NIH released a Notice on August 26, 2014, which provides guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs), on significant changes to animal activities.

The USDA Animal and Plant Health Inspection Service has reviewed and concurs with the guidance provided in the NIH Notice.

Policy

The IU Bloomington and School of Medicine IACUC have adopted the direction provided in the NIH Guide Notice NOT-OD-14-126 for review of proposed changes to a previously approved animal study.

Significant changes must be approved by one of the valid IACUC approval methods described in the PHS Policy IV.C.2., that is FCR or DMR. These review process are described in the IACUC SOP.

The specific significant changes described below, may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. The veterinarian 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 animals in this circumstance. Consultation with the veterinarian must be documented. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies.

This includes changes in:
- anesthesia, analgesia, sedation, or experimental substances;
- euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals; and
- duration, frequency, type, or number of procedures performed on an animal.

Other changes considered by the IACUC to be Minor or Administrative are defined in the IACUC SOP. The following chart summarizes the type of review and categories of changes.
# Type of Amendment Reviews

## IACUC Committee Reviews

### Significant Changes:
- Change from non-survival to survival surgery;
- Change resulting in greater pain, distress, or degree of invasiveness;
- Change in housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC;
- Change in species;
- Change in study objectives;
- Change in Principal Investigator (PI);
- Change that impact personnel safety; or
- Other changes not listed above may fall into this category.

### Minor Changes:
- Addition of a minor surgery;
  - (This Guide states that a "minor survival surgery does not expose a body cavity and cause little or no physical impairment..."
- Addition of another strain or genetic background of the same animal species;
- Change in administration of treatment/observation as it relates to timing, dose, route of administration, and/or specific chemical composition;
- Change in sex of animal to be used;
- Change in final disposition (on same protocol);
- Duration, frequency, type, or number of procedures performed on an animal, which are not listed under Vet Consultant Review, or
- Change in veterinary recommended medication for animal health purposes.

### DMR or FMR Review
- 24 hours to call for FCR
- 2 weeks for IACUC review

### ILR Review
- 72 hours for IACUC review
- see flowchart for ILR

## Administrative Reviews

### Veterinary Consultant
- Change in approved anesthesia, analgesia, or sedation;
- Change in euthanasia to any method approved at IU;
- Duration, frequency, type, or number of procedures performed on an animal, which are limited to the following:
  - Addition of a procedure to be performed on an already anesthetized animal;
  - Addition of non-invasive sample collection methods;
  - Addition of sample collection times or change in timing of sample collection;
  - Addition of testing compound of similar drug class as previously approved;
  - Refinement in techniques; or
  - Change in food/dosing type.

### Administrative (Office Staff)
- Changes in title of protocol;
- Changes in funding source;
- Addition of qualified student or technician;
- Addition of faculty collaborator;
- Small increase (<10%) in the number of animals used; or
- Change in animal use area outside of Laboratory Animal Resource Center (LARC) animal facility.

### Administrative Review
- Follow flowchart for Vet/Admin Review

Please Note: At any time during the Vet Consultant review, the Vet can call for the amendment to be reviewed by either of the process under IACUC Committee Review.