



# INDIANA UNIVERSITY

## Office of Research Compliance (ORC)

### Institutional Animal Care and Use Committee (IACUC)

## Review of Changes to an Approved IACUC Protocol

### FULL POLICY CONTENTS

#### Policy Statement Background Policy

Effective: 4.2015  
Last Updated: 8.2019

**Responsible University Office:**  
Office of Research Compliance IACUC Office(s)

**Responsible University Administrator:**  
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### 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

Examples of Significant Amendments
Change from non-survival to survival surgery
Changes 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
Change in the impact of personnel safety
Change in sex of animal to be used
Other changes not listed above may fall into this category
<b><u>DMR or FCR Review Timeframe</u></b>
24 hours to call for FCR
2 weeks for IACUC review

Examples of Minor Amendments
Request to repeat an experiment
Addition of a minor surgery (if already approved for Survival Surgery)
Addition of a procedure to be performed on an already anesthetized animal
Addition of non-invasive sampling
Addition of sample collection times or change in timing of sample collection
Change in administration of treatment/observation as it relates to timing, dose, route of administration, and/or specific chemical composition
Addition of testing compound of similar drug class as previously approved
Refinement in techniques
Addition of another strain or genetic background of the same animal species that is not exempt from IBC review.
Change in final disposition (on same protocol)
Other changes not listed above may fall into this category
<b><u>DMR Review Timeframe</u></b>
24 hours to call for FCR
72 hours for IACUC review
Note: Addition of several Minor Changes may cause amendment to become Significant.
Note: At any time during the Minor Amendment review, the Reviewer(s) can call for the amendment to be reviewed by FCR.

Administrative Amendments	
<b><u>Veterinary Consult Review</u></b>	
Change in anesthesia, analgesia or sedation	Changes in title of protocol
Change in euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals	Change in funding source
	Addition of a qualified student or technician
Change in duration, frequency, type, or number of procedures (already approved in the protocol) performed on an animal	Addition of faculty collaborator
Change in veterinary recommended medication for animal health purpose	Small increase (less than or equal to 10%) in the number of animals used
Other changes not listed above may fall into this category	Change in animal use area outside of Laboratory Animal Resource/Center (LARC) animal facility, provided that the area has been approved by the IACUC/AV.
	Change in Vendor
<b><u>Veterinary Consult Review Timeframe</u></b>	Clarification of nomenclature
36 hours for review	Addition of Co- Principal Investigator
	Other changes not listed above may fall into this category
Note: At any time during the Veterinary Consult review, the Veterinarian can call for the amendment to be reviewed by either DMR or FCR.	Addition of another strain or genetic background of the same animal species that is exempt from IBC review. (after conformation from the IBC office the strain is exempt.)
	<b><u>IACUC Office Timeframe</u></b>
	24 hours for review