



<b>Internal Regulation Title</b>	IACUC Amendment Review Types				
<b>Date Last Revised</b>		<b>Date Created</b>	01/25/2024	<b>Revision #</b>	1.0
<b>Regulation Number</b>	25	<b>Required by:</b>	<input type="checkbox"/> OHRP	<input type="checkbox"/> Funding Agency	<input checked="" type="checkbox"/> OLAW
<b>Applicability</b>	<input checked="" type="checkbox"/> RGC Internal	<input type="checkbox"/> Researcher	<input type="checkbox"/> Institutional		
<b>Subgroup</b>	<input type="checkbox"/> NKU Compliance	<input type="checkbox"/> IRB	<input checked="" type="checkbox"/> IACUC	<input type="checkbox"/> IBC	

### 1.0PURPOSE

The purpose of this internal regulation is to describe the amendment review types for approved Institutional Animal Care and Use Protocols (IACUC).

### 2.0GENERAL INFORMATION AND SCOPE

The IACUC has a responsibility to review and approve changes to approved protocols. In accordance with OLAW notice NOT-OD-14-126 acceptable methods of amendments are explained below.

### 3.0 REVIEW TYPES

#### A. SIGNIFICANT CHANGES

Amendments considered significant include changes that may have the potential to negatively impact animal welfare and must be approved by one of two valid methods of IACUC review: (1) Full Committee Review (FCR) by a convened quorum of the members of the IACUC or (2) Designated Member Review (DMR) by a designated member of the IACUC.

The following require FCR or DMR:

- change from non-survival to survival surgery;
- methods that lead to 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;
- change in species;
- change in study objectives;
- change in Principal Investigator (PI);
- methods that impact personnel safety;
- greater than 50% increase in the number of animals originally approved.

## B. MINOR AMENDMENT – EXPEDITED REVIEW

Certain amendments qualify for expedited review. This means the amendment needs to be reviewed only by the IACUC Chair or the IACUC Veterinarian (referred to as Veterinary Verification and Consultation (VVC)). An amendment undergoing expedited review will typically be reviewed within five business days.

Amendments qualifying for expedited review must include one of the following:

- addition of animals that exceed 10% of original approval numbers;
- changes or additions of veterinary therapeutic drugs;
- addition of drugs to induce a transgene expression;
- changes or additions to anesthesia monitoring methods;
- change in tissue collection method for genotyping;
- changes or additions to environmental enrichment methods;
- addition of non-invasive procedures similar to ones currently approved in the protocol;
- changes or additions to identification methods;
- changes in blood draw techniques;
- changes or additions to sterilization/disinfection methods;
- changes in experimental drug route or dose of an approved drug;
- changes or additions to supportive care (i.e. supplemental heat, IV fluids, etc.);
- changes in non-standard diets or addition/deletion of supplements;
- changes or additions to the anesthetics or analgesic regimen;
- changes in strain, sex, source, or age of animals;
- changes or additions to the euthanasia methods that are AVMA acceptable;
- changes in surgery length;
- changes to wound closure type, technique, or removal date;
- increasing the number of collections for tissue or fluid collections currently listed in the protocol.

## C. MINOR AMENDMENT – ADMINISTRATIVE REVIEW

Amendments that qualify for administrative review may be reviewed by the IACUC Administrator or any member of the IACUC, if necessary. The following items may be approved via administrative review:

- administrative changes (changing titles, contact information, etc.);
- changes in delegation of the provision of care or husbandry;
- changes in funding source;
- changes in housing or facility;
- addition or removal of personnel (other than Principal Investigator);

- removal of a species, agents, or experimental procedures from a protocol;
- addition of animals that do not exceed 10% of the original study numbers (reviewed by the IACUC Chair).

#### 4.0 REFERENCES

[OLAW Guidance on Significant Changes to Animal Activities NOT-OD-14-126](#)

#### 5.0 FORMS OR ATTACHMENTS

#### 6.0 DEFINITIONS

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Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	01/25/2024	<input type="checkbox"/>
IACUC Chair	<input checked="" type="checkbox"/>	01/25/2024	<input type="checkbox"/>
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>

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Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	<input type="checkbox"/>		<input type="checkbox"/>	
IACUC Chair	<input type="checkbox"/>		<input type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input type="checkbox"/>	