

Title: **Review and Approval of Amendments**

Effective Date: **October 21, 2010**

Revision # 09

Standard Operation Procedure Number: **IACUC-RVW-028** Last Committee Review: **December 4, 2024**

Purpose/Scope

The purpose of this Standard Operating Procedure (SOP) is to outline the IACUC's policy regarding review and approval of amendments to approved animal care and use protocols.

References

PHS policy [IV, C.1](#)

AWAR [9 CFR §2.31,d,1 and d,5](#)

OLAW Webpage– Significant Changes to Animal Activities

http://grants.nih.gov/grants/olaw/significant_changes.htm

Veterinary Verification & Consultation (VVC) - NIH Guide Notice NOT-OD-14-126 (08/26/14)

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html>

AVMA Guidelines for the Euthanasia of Animals

<https://www.avma.org/KB/Policies/Documents/euthanasia.pdf>

Formulary for Laboratory Animals, 3rd Ed.

<https://www.aclam.org/publications>

Procedure

Investigators may request changes to approved protocols via the protocol electronic submission system. Amendments with significant changes will be reviewed by the Designated Member Review process (B and C pain category animals) or by a convened quorum of the members of the IACUC (D and E pain category animals) or by Veterinary Verification and Consultation (VVC). The IACUC Chair may grant an exception to this general review policy as deemed appropriate. Amendments may not be disapproved under Administrative review, DMR, or VVC; they must be approved or referred to full committee review. VVC is a method for approving certain significant changes by a veterinarian authorized by the IACUC (ULAV or Designee) to a previously approved protocol. VVC may not be used to add a procedure that was not previously approved on the protocol.

Administrative review is a method for approving changes by the ORC&S staff that are considered to be non-significant.

Examples of non-significant changes include:

- changes that are only clerical in nature (typographical errors and grammar);
- addition/modification of funding source;
- changes in the title of the protocol;
- changes in contact information and updates;
- changes in personnel other than the Principal Investigator provided that all such personnel are appropriately identified, adequately trained and qualified, enrolled in the occupational health and safety program, and meet other IACUC criteria as necessary.

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Examples of significant changes include but are not limited to:

- change in objectives of a study;
- proposals to switch from non-survival to survival surgery;
- increase in pain, distress, or degree of invasiveness of a procedure or discomfort to an animal
- change in species
- change in the Principal Investigator;
- change that impacts personnel safety; and
- change in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC.

Examples of significant changes that can be handled by VVC include:

- anesthesia, analgesia, sedation, or experimental substances;
- euthanasia to any method approved in the [AVMA Guidelines for the Euthanasia of Animals](#);
- duration, frequency, type, or number of procedures performed on an animal, as long as the change does not result in a change in study objectives or greater pain, distress, or degree of invasiveness.
- an increase in previously approved animal numbers, as long as the increase is justified in the protocol; and
- final disposition clarification (adoption, euthanasia, transfer to other protocols).

The Office of Research Compliance & Security will notify investigators approximately 90 days prior to the protocol expiration date and again every 30 days. Failure to submit a new protocol by the required date will result in a Past Due notice indicating that the project is expired and research must stop immediately. A new application must be submitted in order for any research to be conducted or a Protocol Closure Report (PCR) must be submitted.

Failure to submit and receive approval of an Amendment prior to the implementation of changes will constitute non-compliance and SOP IACUC-RVW-011 regarding Investigation of Possible Non-Compliance will be followed.

Reviewed:

IACUC Chairperson

Date

Executive Director, Research Administration

Date