Title: **Review and Approval of Continuing Reviews and Amendments**
Effective Date: **October 21, 2010** **Revision # 08**
Standard Operation Procedure Number: **IACUC-RVW-028** Last Committee Review: September 21, 2018

Purpose/Scope

The purpose of this Standard Operating Procedure (SOP) is to outline the IACUC's policy regarding review and approval of continuing review and amendments to approved animal care and use protocols. The continuing review process will evaluate if the study remains in compliance, if the activities have been conducted in accordance with the approved protocol, and if any new requirements of PHS, USDA, AAALAC or the institution should be transmitted to the investigator.

References

PHS policy IV, C,2 and IV,C,5
AWAR §2.31,d,2 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.research.usf.edu/cm/docs/Formulary_for_Lab_Animals_3rd_ed.pdf

Procedure

Investigators may request changes to protocols via the myProtocol electronic submission system. Continuing reviews are required of all protocols. Continuing reviews with no changes or non-significant changes are eligible for Administrative Review, which means they can be reviewed by the Animal Care & Use Program Officer (ACUP) or the Assistant Compliance Administrator. . Amendments with non-significant changes are also eligible for Administrative Review by either the ACUP, Assistant Compliance Administrator or by the ULAV and/or IACUC Chair, if needed, depending on the extent of the non-significant change. Continuing reviews or 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 VVC. The IACUC Chair may grant an exception to this general review policy as he deems appropriate. Continuing reviews and amendments via VVC may not be disapproved under administrative review or VVC; they must be referred to full committee review. Veterinary verification and consultation (VVC) is a method for approving significant changes by a veterinarian authorized by the IACUC (ULAV or Designee) to a previously approved protocol. It may not be used to add a new procedure that was not previously approved on the protocol.

Administrative review is a method for approving changes by the Animal Care and Use Program Officer, Assistant Compliance Administrator or ULAV and/or IACUC Chair that are not considered to be 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;
- change in animal strain or type used (ULAV)
- transfer of animals from one approved protocol to another (ULAV)
- change in an approved location of an already approved procedure (ULAV)

Examples of significant changes that must be approved by the IACUC 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; and
- an increase in previously approved animal numbers

The Office of Research Compliance will notify investigators approximately 90 days prior to the Continuing review due date and again every 30 days. Failure to submit a Continuing review/Amendment by the required date (within 365 days of most recent approval) will result in a Past Due notice indicating that the project is expired and research must stop immediately. Research may not reconvene until a Continuing review is completed and approved. The investigator has 30 days past the expiration date to submit the Continuing review. After the 30 day period, 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 a Continuing review by the required date and animal work continues and/or 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

Research Compliance Director Date