

Washington State University

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

DETERMINATION AND APPROVAL OF AMENDMENTS TO ANIMAL ACTIVITIES PREVIOUSLY APPROVED BY THE IACUC

A. Purpose:

This policy describes the determination and review process for amendments made to previously approved animal care and use protocols. Amendments may be handled by the following methods per PHS OLAW notice NOT-OD-14-126

1. Classic IACUC review and approval
2. Administrative review and approval as described in this policy
3. Veterinary verification and consultation (VVC) review and approval as described in this policy

B. Principle

The PHS Policy on Humane Care and Use of Laboratory Animals (Policy) ([IV.C.1.](#)) and Animal Welfare Regulations ([9 CFR 2.31 \(d\) \(1\) \(i\)-\(iv\)](#)) define the responsibilities of the IACUC regarding review and approval of proposed significant changes to animal activities. Changes to approved research projects must be conducted in accordance with the institution's Assurance, the US Department of Agriculture (USDA) Animal Welfare Act and Animal Welfare Regulations, and must be consistent with the [Guide](#) unless an acceptable justification for a departure is presented. Additionally, IACUCs are responsible for assuring that the changes to approved animal activities meet the requirements described in the PHS Policy [IV.C.1.a.-g.](#)

PHS OLAW notice NOT-OD-14-126 Guidance on Significant Changes to Animal Activities permits the administrative handling of some significant changes to animal activities as described below.

C. Significant Amendments requiring IACUC review (classic review)

The significant changes described below **must** be approved by full committee review (FCR) or designated member review (DMR) as described in PHS Policy IV.C.2. Refer to the WSU IACUC policy #2 Protocol Review and Post-Approval Review at https://iacuc.wsu.edu/documents/2016/06/policy_2.pdf for the review process for new protocols, protocol renewals and amendments that do not qualify for administrative or VVC amendments.

- Addition of new animal activities and procedures
- 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 impacts personnel safety

D. Administrative Amendments

Review Process for Administrative Amendments

- This level of amendment may be reviewed and approved by the IACUC Coordinator
- The approval will be immediate upon their sending the official approval letter by IACUC Coordinator
- All approvals will be reported to the IACUC at the next scheduled meeting
- Any approved activity may be called for reconsideration by the IACUC if any member determines that such a review of an approved amendment is necessary

The following amendments may be approved by Administrative Amendment

- Increase in animal numbers of less than 10%
- Change in typographical errors or grammar
- Change in personnel other than the Primary Investigator
- Change in administrative information such as funding agency, contact information, title & client-owned animal consent forms.

E. Veterinary Verification and Consultation (VVC) Amendments

The veterinarian is not conducting a designated member review, 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 will be documented by having the veterinarian send an email approving the change to the IACUC coordinator. This email will be appended to the protocol for which the change is authorized and the protocol will be updated by the IACUC Coordinator. The **veterinarian may refer any request to the IACUC** for review by FCR or DMR for any reason and **must** refer any request that does not meet the parameters of WSU IACUC policies or that would constitute an exception to the Guide or Animal Welfare Act.

Review Process for Veterinary Verification and Consultation Amendments

- This level of amendment may be reviewed and approved by the OCV veterinarians
- The approval will be immediate upon the veterinarian's written approval
- Written description of VVC approved amendment must be provided to the IACUC office within two working days and the IACUC office has **30** working days to add the change to the protocol
- All approvals will be reported to the IACUC at the next scheduled meeting
- Any approved activity may be called for reconsideration by the IACUC if any member determines that such a review of an approved amendment is necessary

- In the event that a proposed amendment is not accepted for VVC review then the amendment must be submitted to the IACUC coordinator as defined in WSU IACUC policy #2 on Protocol Review available at https://iacuc.wsu.edu/documents/2016/06/policy_2.pdf

The following amendments may be approved by Veterinary Verification and Consultation.

- Changes in anesthesia, analgesia and sedation *protocols*
 - Anesthesia, analgesia, or sedation protocols that use referenced dosages for the species. Reference material may include textbooks (such as Harkness and Wagner's Biology and Medicine of Rabbits and Rodents; Flecknell's Laboratory Animal Anesthesia; Plumb's Veterinary Drug Handbook; Hawk and Leary's Formulary for Laboratory Animals; Fowler's Zoo and Wildlife Medicine; Lumb and Jones Veterinary Anesthesia and Analgesia; Quesenberry and Carpenter's Ferrets, Rabbits and Rodents Clinical Medicine and Surgery; Fish and Danneman Anesthesia and Analgesia of Laboratory Animals); journal publications (peer reviewed from PubMed and CAB database) and personal communications with OCV veterinarians or veterinary anesthesiologists at WSU
- Changes in experimental substances that are known to not increase invasiveness or expected adverse outcomes or increase hazards to personnel.
 - Change of drug that does not create a new change in animal health status
 - Change of diet that does not create a new change in animal health status
 - Change to a similar or less invasive method of drug administration including frequency (no greater than three times per day) & route (limited to SC, IP, IV, PO)
 - Change of volume within the guidelines described in Diehl et al, Journal of Applied Toxicology 21: 15-23 and Turner et al, Journal of the American Association for Laboratory Animal Science 50 (5): 600-613, or personal communication with OCV veterinarians
- Change in euthanasia to a method approved in the AVMA Guidelines for the Euthanasia of Animals as either "Acceptable" or "Acceptable with Conditions" as long as the AVMA-stipulated conditions are met for that species
- Changes in the duration, frequency, type, or number of procedures performed as long as those procedures are approved in the protocol. For example:
 - Change in humane endpoints which reduce the potential level of pain or distress
 - Modifications to previously approved surgeries that do not increase the invasiveness or expected adverse outcomes; includes changing from survival to non-survival surgery
 - Change to a similar or less invasive method of blood collection (route, frequency, volume) if within the referenced values in Diehl et al, Journal of Applied Toxicology 21: 15-23.
 - Change to a similar or less invasive method of tissue collection for genotyping according to the WSU IACUC SOP #2 "Rodent Tissue sampling guidelines" (not including toe clips)

- Change in method of sterilization of materials or instruments. Refer to WSU IACUC Sterilization of Instruments and Supplies for Aseptic Surgery SOP #3 at https://iacuc.wsu.edu/documents/2016/06/wsu_sop_3.pdf for guidelines.
- Change between animal housing locations approved by the IACUC
- Change in site of non-surgical animal procedures as long as animals are maintained there for less than 12 hours
- Addition of sources of animals. Please refer the WSU IACUC Acquisition and Disposition Policy #5 at https://iacuc.wsu.edu/documents/2016/09/5_acquisition-and-disposition-policy-final.pdf for guidelines on animal acquisition.
- Change in the final disposition of animals at conclusion of use, including change from euthanasia to adoption, or transfer to another protocol. Transfer to invasive protocols such as terminal, surgery or infectious disease studies require IACUC review. Please refer the WSU IACUC Acquisition and Disposition Policy #5 at https://iacuc.wsu.edu/documents/2016/09/5_acquisition-and-disposition-policy-final.pdf for guidelines on animal disposition and WSU IACUC Multiple Survival Procedures Policy #10 at https://iacuc.wsu.edu/documents/2016/06/policy_10.pdf for guidelines on transfer to other protocols.

If any of the above changes increase hazard to personnel or pain, distress or degree of invasiveness to the animal, the amendment will have to be approved through classic IACUC review by DMR or FCR.

References

PHS OLAW notice NOT-OD-14-126 Guidance on Significant Changes to Animal Activities
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html>

OLAW Webpage Significant Changes: http://grants.nih.gov/grants/olaw/significant_changes.htm

AVMA Euthanasia Guidelines - <https://www.avma.org/KB/Policies/Documents/euthanasia.pdf>

Diehl et al (2001). A good practice guide to administration of substances and removal of blood, including routes and volume. *Journal of Applied Toxicology* 21: 15-23.

Turner et al (2001). Administration of substances in laboratory animals: routes of administration and factors to consider. *Journal of the American Association for Laboratory Animal Science* 50 (5): 600-613