

IACUC SOP:	SOP Amendments to Animal Activities Previously Approved by the IACUC	
SOP#110.00	IACUC Approved: 8/11/2022	IO Approval: 8/24/2022

Purpose:

This SOP describes the determination and review process for amendments made to currently 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 processing as described in this SOP.
3. Veterinary Review, Verification and Consultation (VVC) review and verification as described in this SOP.

A. Background

The PHS Policy on Humane Care and Use of Laboratory Animals ([Policy](#)) and [Animal Welfare Regulations](#) 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](#).

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.

Failure to obtain IACUC approval prior to implementing a significant change is considered noncompliance. This generally requires reporting to NIH-OLAW and action by the IACUC in accordance to IACUC Use of Vertebrate Animals [Rule 15.99.07.01](#) and System Regulation for Use of Vertebrate Animals [15.99.07](#)

B. 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.](#)

- 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 location
- 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
- Increases in animal numbers that do not fit the criteria for administrative approval

C. Administrative and Minor Amendments

Review Process for Administrative and Minor Amendments

- This level of amendment may be reviewed and approved by the IACUC Staff.
- The approval will be provided in writing after administrative review by IACUC staff.
- Administrative 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

D. Criteria for Approval of Administrative Amendments

The following amendments may be approved by Administrative Amendment

- Increase in animal numbers of less than 10%. This can be used for experiments/teaching activities already approved in the protocol. For example, adding animals to replace animals that needed to be excluded from the study for various reasons (shipping issues, health issues, animals did not meet study criteria, etc.). It cannot be not used for new experimental groups (these requests would fall under classic amendments).
- 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, etc.
- Changes in IACUC approved housing locations with Vet consultation.
- Addition or change in carcass disposal method with Biosafety Office consultation

E. Veterinary Verification and Consultation (VVC) Amendments

The Attending Veterinarian may administratively verify changes through Veterinary Verification and Consultation. 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 policies is appropriate for the animals in this circumstance. The following significant changes to a previously approved IACUC protocol, guidelines, SOP and formularies may be handled administratively without review by the FCR or DMR:

- Changes in anesthesia, analgesia, sedation or other clinically relevant medications that use referenced dosages for the species. Reference materials may include:
 - Flecknell's Laboratory Animal Anesthesia
 - Plumb's Veterinary Drug Handbook
 - Harkness and Wagner's Biology of Medicine of Rabbits and Rodents
 - Hawk and Leary's Formulary for Laboratory Animals
 - Fowlers Zoo and Wildlife Medicine
 - Lumb and Jones Veterinary Anesthesia and Analgesia
 - Peer reviewed journal publications
 - ACLAM e-Formulary
- Veterinary communications with veterinary anesthesiologists
 - Changes in experimental substances that are known to not increase 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, ID, IN, 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.
 - Change in euthanasia to a method approved in the AVMA Guidelines for the Euthanasia of Animals as either “Acceptable” or “Acceptable with Conditions” so long as the AVMA-stipulated conditions are met for that species
 - Replacement strain, stock or breed of the same species that does not increase the risk of adverse events
 - Addition or change of animal source.
 - Change in the final disposition of animals at the conclusion of use, including change from euthanasia to transfer to another protocol or to private ownership if the animals underwent minimally invasive procedures (B or C category animals).
 - Changes in the duration, frequency, type, or number of procedures performed as long as those procedures are approved in the protocol or covered by and IACUC approved SOP, guideline or SOP.
- 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 change from survival to non-survival surgery
 - Change of diet that does not create a new change in animal health status.
 - Change to a similar or less invasive method of blood collection, including the route used or amount collected.
 - Change to a similar or less invasive method of drug delivery, including frequency and route.
 - Change in method of sterilization of materials or instruments.
 - Change in site of non-surgical animal procedures as long as animals are maintained there for less than 12 hours.

F. Review Process for Veterinary Verification and Consultation Amendments

1. The Veterinarian may approve changes to the protocol as described in section E.
2. The change will be immediate upon the veterinarian’s verbal and written confirmation, or the request will be denied and referred for regular amendment process to the IACUC.
3. Written description of VVC change must be provided to the IACUC office within two working days by the veterinarians and the IACUC office has 30 working days to add the change to the protocol. The PI is responsible for submitting amendment to IACUC.
4. All changes will be reported to the IACUC at the next scheduled meeting.
5. Any amendment activity may be called for reconsideration by the IACUC if any member determines that such a review of a verified amendment is necessary.

References

1. 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.htm>
2. OLAW Webpage Significant Changes: http://grants.nih.gov/grants/olaw/significant_changes.htm
3. AVMA Euthanasia Guidelines - <https://www.avma.org/KB/Policies/Documents/euthanasia.pdf>
4. USDA Inspection Guide, Ch. 7.1.7 - https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-InspectionGuide.pdf



History:

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