ANIMAL EYE CONSULTANTS OF IOWA

Animal Eye Consultants of Iowa ***Instituti mittee***	
Policy #24	**"Determination and Approval of Amendments to Animal Activities Previously Approved by the IACUC"**
Approval Date: 2/20/2026 (Replacing Version 7/30/2025)	

A. Purpose

This policy 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 policy
3. Veterinary Review, Verification and Consultation (VVC) review and verification as described in this policy

B. 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 Animal Welfare Assurance, the Animal Welfare Act and Animal Welfare Regulations, and must be consistent with the *Guide* unless an acceptable justification for a departure is presented.

PHS OLAW notice NOT-OD-14-126 Guidance on Significant Changes to Animal Activities, OLAW permits the administrative handling of some significant changes to animal activities as described in the policy 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 with IACUC Policy 27.

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 AEC IACUC Policy #2 "Protocol and Amendment Review" 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 that are not already approved in the protocol or covered by an IACUC-approved policy, guideline, or SOP
- Change from non-survival to survival surgery
- Change resulting in greater pain, distress, or degree of invasiveness
- Addition of a new experimental drug or chemical that may increase expected adverse outcomes or hazards to personnel.
- 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
- Increases in animal numbers

  ***Increases in animal numbers of less than 10% may be handled administratively by the Animal Welfare Program Assistant Director or Animal Welfare Program Specialists without additional consultation or notification, provided they do not change objective, add new experimental groups, or impact animals welfare (e.g., replacement animals due to shipping issues, health issues, or animals not meeting study criteria). Animal number increases that involve adding new experimental groups or changes to study objectives, increases of 10% or more, and/or increases that may result in a negative impact on animal welfare must be reviewed by the IACUC. The AWP staff can defer any request to the IACUC for review.*

D. Administrative Amendments

Review Process for Administrative Amendments

1. This level of amendment may be reviewed and approved by the Animal Welfare Program Staff.
2. The approval will be immediate upon receipt of the official approval letter by Animal Welfare Program Office.

The following amendments may be approved by Administrative Amendment:

- 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 or use locations with AEC consultation.
- Addition or change in carcass disposal method with Biosafety Office consultation

E. Veterinary Verification and Consultation (VVC) Amendments

The Attending Veterinarian (AV) or designated AEC Veterinarians may handle administratively certain significant 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 Full Committee or Designated Member Review:

- 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
- AEC formularies
- ACLAM e-Formulary
- Veterinary communications with veterinary anesthesiologists

▪ Changes in compounds and drugs that are known to not increase expected adverse outcomes or increase hazards to personnel.
  - Change of drug or diet that does not create a new adverse 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, AEC IACUC guideline #10: Drugs and Chemical Administration or personal communication with AEC veterinarians

- 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
- 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:
  - A change from euthanasia to transfer to another protocol or to private ownership if the animals were not used or only underwent minimally invasive procedures (B or C category animals). Animals can only be transferred to protocols within the same or lower pain category. Increases in pain category require IACUC review.
- Changes in the duration, frequency, type, or number of procedures performed if those procedures are approved in the protocol and covered by an IACUC-approved policy, 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 to a similar or less invasive method of blood collection, including the route used or amount collected.
- Change in method of sterilization of materials or instruments.

Review Process for Veterinary Verification and Consultation Amendments

1. Contact the AV or any of the veterinarians within the Office of the Campus Vet (AEC) at 319-826-6217 or animaleyeiowa@gmail.com.
2. The proposed significant change will be reviewed and verified as appropriate by the AEC veterinarians.
3. 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.
4. A written description of VVC change must be provided to the IACUC office within two working days by the veterinarian(s). The IACUC office has 30 working days to add the change to the protocol.
5. All changes will be reported to the IACUC at the next convened IACUC meeting.
6. 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.

F. 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.html
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-Inspection-Guide.pdf
5. AEC IACUC Policies and Guidelines at https://animal-eye-iowa.com/forms/resources/