



Institutional Animal Care and Use Committee UNIVERSITY OF GEORGIA

Policy for Changes to Approved Animal Use Protocols

Animal Welfare Regulations state that Institutional Animal Care and Use Committee approval is required for all significant changes to approved animal use protocols (AUP) prior to implementing these changes. All changes to an approved AUP require submission of a modification to the UGA IACUC for review and approval prior to implementation.

Minor Changes and Administrative Approval

Changes in personnel other than the Principal Investigator are not considered significant and will be reviewed administratively. Administrative review ensures that added personnel are appropriately identified, adequately trained and qualified, enrolled in applicable occupational health and safety programs, and meet other criteria as required by the IACUC before participating in animal work. Other minor changes may be eligible for administrative review, for example, increases of a small number of animals (less than 10% cumulative increase over the originally approved number), the addition of alternate titles and/or funding sources, corrections of grammar or typographical errors, contact information updates, or changes or additions of rodent stock, strain, or line that do not present deleterious genetic effects.

Significant Changes

Modifications considered to be significant are not eligible for administrative review. Examples of proposed changes that are considered to be significant and which must undergo either full committee review or designated member review include, but are not limited to, the following:

- Altering the objectives of a study
- Changing from non-survival to survival surgery
- Varying procedures that result in potential for greater distress, pain, or discomfort
- Changes that require a greater degree of invasiveness
- Adding or changing the species
- 10% (or more) cumulative increase over the originally approved number
- Withholding analgesia
- Substituting a new Principal Investigator
- Using different methods of euthanasia that *are not* approved in the AVMA Guidelines for the Euthanasia of Animals

- Changes in the duration, frequency, type, or number of procedures performed on an animal which may increase the potential for pain or distress experienced by the animal
- Changing animal housing from group housing to single housing
- Changes that affect personnel safety

Veterinary Verification and Consultation Process

There are also certain modifications that can be handled simply in consultation with an IACUC-designated veterinarian through a Veterinary Verification and Certification process. The UGA Laboratory Animal Veterinarians (faculty and staff) are the designated veterinarians, and determine at their discretion which modifications meet the criteria for this level of review (described below):

- Changes in anesthesia, analgesia, sedation, or experimental substances
- Changes in euthanasia techniques to any method approved in the [AVMA Guidelines for the Euthanasia of Animals](#)
- Changes in the duration, frequency, type, or number of procedure performed on an animal which *do not* increase the potential for pain or distress experienced by the animal

Amendment Processing

The IACUC has some discretion to define what it considers a significant change, or to establish a mechanism for determining significance on a case-by-case basis. Depending on the extent of the changes, submission of a complete new proposal may be required.

All AUP changes are reviewed and may be subject to further review at any time. Significant changes may not require the same level of review that the original AUP required. The IACUC notifies investigators, the Office of Sponsored Programs, and the directors of animal resources in writing of its decision to approve or withhold approval of modifications. The IACUC provides written notification of failure to approve along with a rationale for non-approval and changes or additional information required for resubmission and reconsideration.

Consultation with the Office of Animal Care and Use or the Attending Veterinarian is recommended for assistance in determining appropriate levels of review.

Source:

[NIH/OLAW Notice NOT-OD-14-126: Guidance on Significant Changes to Animal Activities. August 26, 2014.](#)