



# The University of Georgia

Office of the Vice President for Research

## **UGA IACUC Policy for Significant Changes to Approved Research Protocols**

*Approved by the UGA IACUC*

*Effective September 17, 2009*

*Revised November 19, 2009*

Animal Welfare Regulations state that Institutional Animal Care and Use Committee approval is required for all significant changes to approved animal research protocols prior to implementing these changes.

Significant changes to an approved animal protocol require submission of a modification to the UGA IACUC for review and approval prior to implementation.

Examples of proposed changes considered to be significant 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 discomfort
- Changes that require a greater degree of invasiveness
- Adding or changing the species
- Increasing animal numbers in excess of 10% from the originally approved number
- Changing anesthetic agents or withholding analgesia
- Substituting a new Principal Investigator
- Using different methods of euthanasia
- Any changes in the duration, frequency, or number of procedure performed on an animal or any other changes that have the potential to increase distress or pain

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 significant changes are reviewed and are subject to further review at any time in the same manner as the original proposal. The category of the AUP dictates whether significant changes are reviewed by the full committee or through the designated member review process. 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.

Changes in personnel other than the Principal Investigator need not be considered significant provided that an appropriate administrative review mechanism is in place to ensure that all such 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. Other minor changes may be eligible for administrative review, for example addition of non-invasive procedures, increases of a small number of animals (less than 10% increase over originally approved number), or change or addition of rodent stock, strain, or line.

Consultation with the IACUC Coordinator or the Attending Veterinarian is recommended for assistance in determining appropriate levels of review.