Institutional Animal Care and Use Committee
Clemson University

POLICY #13: INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) CHANGES TO ANIMAL ACTIVITIES PREVIOUSLY APPROVED BY THE IACUC

Background: 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 projects must be conducted in accordance with the institution’s Assurance, the United States 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.

Significant Changes to Animal Activities Previously Approved by the IACUC

Significant changes include changes that have, or have the potential to have, a negative impact on animal welfare (see paragraph 1., below). In addition, some activities that may not have a direct impact on animal welfare are also considered to be significant (see paragraph 2., below).

1. Significant changes described in 1. a. – g., below, must be approved by one of the valid IACUC approval methods described in the PHS Policy IV.C.2., that is Full Committee Review (FCR) or Designated Member Review (DMR), including changes:
   a. from non-survival to survival surgery;
   b. resulting in greater pain, distress, or degree of invasiveness;
   c. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
   d. in species;
   e. in study objectives;
   f. in Principal Investigator (PI) (See IACUC Policy #10); and
   g. that impact personnel safety.
   h. an increase in animal numbers > 10%

2. The specific significant changes described in 2. a. – d., below, may be handled administratively by the IACUC Administrator according to IACUC-reviewed and-approved policies in consultation with the Attending Veterinarian. The Attending Veterinarian is not conducting DMR, 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 Attending Veterinarian must be processed and documented according to Veterinary Verification and Consultation (VVC) changes to approved protocols. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies. These changes can only be made if the change fits the original rationale and objectives of the study.

This includes:
   a. Changes to compounds or dosage of anesthesia, analgesia, sedation, or experimental substances. Examples of changes which may be approved under this category are:
      1) A change in dosage, route, frequency or duration within acceptable veterinary parameters;
      2) Switching from one analgesic, anesthetic, or sedative agent to another; or
      3) Changing the dosage, timing or route of an experimental substance if the change will not increase the potential for animal pain or distress.
   b. Changing euthanasia method to any method approved in the AVMA guidelines.
c. Changes in duration, frequency, number, and type of procedures performed. Typical examples under this category may include:
   1) Changing the duration, frequency, or number of procedures, if the change will not increase the potential for animal pain or distress;
   2) Changing a surgery from survival to non-survival;
   3) Adding a procedure which will reduce animal discomfort or complications; or
   4) Changing from a more invasive to a less invasive procedure.

d. Increasing the number of animals approved for a study by up to 10% to allow the PI to achieve the original study objectives.

e. In housing and or use of animals in a location or in moving the housing to a new location.

f. In changing the source of animals

g. In changing the acclimation period if there is no impact on the science

Other Changes
3. Changes that may be handled administratively without IACUC-approved policies, consultations, or notifications include:
   a. correction of typographical errors;
   b. correction of grammar;
   c. contact information updates; and
   d. change in personnel, other than the PI.