

Clemson University
Institutional Animal Care and Use Committee (IACUC)

Policy Number: 2.6

Policy Title: Changes to Animal Activities Previously Approved by the IACUC (Amendments to AUPs)

Section 1: Purpose

The purpose of this policy is to outline the procedure for making changes to an approved animal use protocol (AUP) as set forth in the PHS Policy at IV.C. and how those changes are reviewed and approved.

Section 2: Scope

This policy applies to all approved and active AUPs.

Section 3: Policy

Procedure

Often, changes to an approved AUP are needed to improve project outcomes, include additional personnel, change the PI of the AUP, increase animal numbers to reach research objectives or statistical significance, improve animal welfare, or address unforeseen issues. To address this need, a PI should follow the procedures below to amend their AUP:

PI Procedures Change of Principal Investigator

1. Ensure the new PI has completed all training requirements outlined in policy 2.2.
2. If the new PI was not already listed on the protocol, contact the IACUC office, iacuc@clemson.edu, for access.
3. Complete an amendment to the protocol via InfoEd.
4. Submit the change of PI amendment eform. Be sure to include a justification for the change, the qualifications of the new PI.
5. Personnel may not act as PI of a protocol until approval of the Change of PI amendment is complete.

Personnel Changes (Other than PI)

1. Ensure all personnel being added to a protocol have completed all training requirements outlined in Policy 2.2.
2. Complete an Amendment in InfoEd. In the form, include each person's qualifications, procedures to be performed, and who will provide additional training if needed.
3. The form will be approved if personnel are qualified to perform tasks assigned and the completion of all training requirements is confirmed. Personnel are not allowed to perform any procedures with animals until amendment approval is complete.

Changes to Procedures, Animal Numbers, or Other Changes

1. Discuss the proposed changes with the AV.
2. Complete the AUP Amendment form. Describe the current approved procedure, number of animals, or other area of the AUP and the proposed change. Include a justification for the change.
3. Submit the completed AUP amendment in InfoEd. Changes may not be implemented until approval of the amendment is received by the PI.

IACUC Procedures

The review of amendments to approved AUPs may occur by one of three methods: review by the committee, review by veterinary verification and consultation, or administrative approval. Selection of review method depends on the changed proposed. A member of the Committee can call for the review of any amendment by the full committee.

1. Review by the Committee

The significant changes described below, must be approved by either Full Committee Review (FCR) or Designated Member Review (DMR):

- a. change from non-survival to survival surgery
- b. change resulting in greater pain, distress, or degree of invasiveness
- c. change in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
- d. addition or change in species
- e. change in study objectives
- f. change in Principal Investigator (PI)
- g. change that impact personnel safety
- h. an increase in animal numbers greater than 10% of the number of animals originally approved.

The review process will be conducted the same as the review of a new protocol for each review type. At the end of the 5-business day review period, the reviewer will complete the review in InfoEd and the PI will be notified of the decision and if modifications are required to secure approval.

2. Veterinary Verification and Consultation (VVC)

The changes listed below may be approved by the Attending Veterinarian and documented administratively without review by the Committee. The veterinarian is not conducting a Designated Member Review but is serving as a subject matter expert. The Veterinary Verification and Consultation (VVC) Policy, IACUC Policy 2.9, describes the specific changes that may be made through VVC review.

3. Administrative

Personnel changes other than the PI may be approved by the IACUC administrator after the completion of all personnel training requirements.