

**University of California, Merced
Institutional Animal Care and Use Committee Policy**

Version No. 1

Policy No. 112

Significant Changes to Approved Research Protocols

I. Purpose:

Animal Welfare Regulations require that investigators receive IACUC approval for all significant changes to approved animal research protocols. However, federal regulations provide little guidance with respect to actual criteria to be used in determining what constitutes a significant change to an approved research protocol.

II. Definition:

Significant changes to a protocol include, but are not limited to:

- Changes in animal species
- Requests for additional animals (representing an increase greater than 10% of total animals originally approved)
- Changing from non-survival to survival surgery
- Changes in method of euthanasia or anesthesia
- Significant Changes to study objectives

III. Policy:

The IACUC has defined a Significant Change as any deviation from the protocol that substantially alters or affects the overall study objectives/rationale, specific approved procedures, or the potential for pain, distress and discomfort in the animals. The following guidelines have been developed to help investigators determine what qualifies as a significant change to an approved protocol for animal use and has set forth procedures to assist in the timely review and approval of such changes. Significant changes must not be implemented without review and approval by the IACUC. In general, the addition of a new procedure that increases the invasiveness or the amount of pain or distress an animal experiences requires a full committee review. Additionally, if the study objective changes significantly, a new protocol may be required. Consultation with the Attending Veterinarian or the IACUC Administrator is recommended for assistance in determining appropriate levels of review.

IV. Procedure:

Requests to make significant changes to an approved protocol must be submitted to the IACUC staff office. These are distributed to all IACUC members in a timely fashion. Significant changes are reviewed and discussed at the next scheduled IACUC meeting. The IACUC may vote to approve, request modifications to secure approval, or not approve significant changes, similar to the protocol review process. At the discretion of the IACUC chair, significant changes may be approved by designated member review. Designated reviewers will be selected by the IACUC chair. IACUC members will have three business days to review the significant changes. If no

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IACUC member (including a designated reviewer) calls for full committee review, significant changes may be approved by unanimous vote of the designated reviewers or sent for full committee review. A non-unanimous vote by the designated reviewers or request for full committee review by any IACUC member will supersede approval of the requested significant changes.

V. Related Policies:

- Policy 100 Research and Instruction Using Animal Subjects

VI. References:

- Institutional Animal Care and Use Guidebook (OLAW 2nd edition)
- Guide for the Care and Use of Laboratory Animals (Eight Edition)
- PHS Policy on Humane Care and Use of Laboratory Animals