

ACUC POLICY ON ADMINISTRATIVE APPROVAL OF PROPOSED CHANGES TO APPROVED ANIMAL USE PROTOCOLS

Reapproved April 2006

The Public Health Service Policy¹ and the United States Department of Agriculture Regulations² require the Animal Care and Use Committee (ACUC) to review and approve proposed significant changes in ongoing activities involving animals. However, the word "significant" is not defined. To ensure compliance with this policy, the ACUC requires faculty members to request approval for any proposed changes to an approved animal use protocol by submitting them in writing. The purpose of this policy is to provide guidelines for evaluating the significance of a proposed change and to establish procedures for reviewing and approving proposed minor changes administratively.

CRITERIA FOR EVALUATING THE SIGNIFICANCE OF A PROPOSED CHANGE:

The Chair and the Director of OLAC (or their designees) will evaluate the significance of a proposed change by comparing it to the investigator's currently approved protocol, using the following guidelines:

1. Nature of the Procedure. A proposed change in procedures will be considered minor if it meets all of the following criteria:
 - it involves no increased risk of pain, distress, or discomfort to animals.
 - the technical expertise required to perform it falls within that described for approved procedures, or the proposed procedure will be performed by, or under the direct supervision of, OLAC.
 - the rationale for the new procedure is consistent with the research goals in the approved protocol.

Any proposed change in the method of euthanasia will be considered minor if it meets the above criteria and complies with AVMA guidelines.

2. Number of Animals. A proposed change in animal numbers for an approved species will be considered minor if it does not markedly increase the proportion of that species involved in the project.
3. Species of Animals. A proposed change in the species of animal will be considered minor if it meets all of the following criteria:
 - the proposed rationale for using the new species is consistent with the research goals of the approved protocol.
 - the new species is not classified as threatened or endangered.
 - OLAC is able to meet any special animal husbandry or housing needs of the new species.
 - the potential hazards associated with the use of the new species do not differ from those associated with the previous species.
 - the proposed number of new animals is well justified and does not result in a large proportional increase in the total number of animal involved in the project.

- the anatomy and physiology of the new species resemble those of the approved species closely enough not to require new training or experience for personnel to perform currently approved procedures with no increased risk of pain or distress to animals.
4. New Personnel. A proposal to add new personnel will be considered minor if it is accompanied by evidence that the individuals will be directly supervised by properly trained current personnel until the new personnel have the training and experience required to perform the relevant animal procedures independently.

PROCEDURE FOR APPROVAL OF MINOR CHANGES:

If a proposed change is judged to be minor according to the above criteria, the Chair and the Director of OLAC may grant it administrative approval. Administrative approvals shall be subject to further continuing review, on request, at the next convened meeting of the ACUC, where they shall be listed on the Agenda under the heading of "Administrative Approval." Copies of these Administrative Approvals shall be made available, upon request, to any member of the committee.

1. Office of Laboratory Animal Welfare, National Institutes of Health, "Public Health Service Policy on Humane Care and Use of Laboratory Animals," revised August 2002, page 13.
2. United States Department of Agriculture Regulations (9 CFR, Subchapter A) issued under the Animal Welfare Act, 1998 edition, § 2.31(c)(7).