

TITLE: Institutional Animal Care and Use Committee Policy on the Protocol Amendment Process

PURPOSE: To ensure that all minor and major protocol changes are approved by the Institutional Animal Care and Use Committee (IACUC) prior to implementation by the investigator. The requested amendment must fit within the original objectives of the protocol.

REVIEW/REVISIONS: Permanent amendment/revisions to this policy must be presented to the IACUC for review before implementation and should be developed by the Office of Animal Welfare Assurance (OAWA) staff and/or IACUC membership.

EFFECTIVE DATE: 11/6/2008

PERSON(S) RESPONSIBLE: Principal Investigators, IACUC Membership and Staff

POLICY/PROCEDURES:

1. The Principal Investigator (PI) submits a Protocol Amendment form any time they wish to make a change to a currently approved protocol. *Exception – personnel additions or deletions may be submitted via email to the OAWA staff by an active member of the protocol without the use of a Protocol Amendment form.*
2. Most protocol amendments are reviewed at an IACUC committee meeting and appropriate action taken such as approval, requirement of modifications to secure approval or withhold approval if unfit for the amendment process and must submit a *de novo* protocol.
 - a. Examples of common protocol amendment requests reviewed in committee:
 - i. Addition of animal numbers, species, strains, or procedures
 - ii. Changes to anesthetic regimen, post-operative care, palliative treatment, euthanasia, research or housing location
 - iii. Modification of surgical and non-surgical procedures
 - iv. Request for 12 hours (or more) housing in a laboratory space
 - v. Request to transfer protocol ownership between PIs
 - vi. Request to transfer an animal between surgical protocols, where the animal has already been involved in a surgical procedure
 - b. Examples of minor protocol amendment requests processed directly by a designee of the Office of Animal Welfare (OAWA) manager, and reported to the IACUC committee at the next scheduled meeting:
 - i. Addition of personnel (must meet minimum requirements for inclusion on protocol)
 - ii. Deletion of personnel
 - iii. Changes to the protocol title

JUSTIFICATION:

The **National Institutes of Health (NIH)**(*Public Health Service Policy on Humane Care and Use of Laboratory Animals*; Health Research Extension Act of 1985, Public Law 99-158) and **United States Department of Agriculture (USDA)**(*Animal Welfare Act: Title 9, Part 2, Subpart C*) provide operating standards for Institutional Animal Care and Use Committees. Both the Public Health Policy and the Animal Welfare Act require that the IACUC review and approve proposed modifications to ongoing activities using animals prior to initiation.

The University of Arizona is registered as an animal research facility with the NIH and USDA. In addition, the University of Arizona is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).