

Procedure: IACUC-41
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**UC Davis
Institutional Animal Care and Use Committee (IACUC)**

Title: *Therapeutic Drug Changes on Approved IACUC Protocols*

I. Purpose:

To provide guidance for changing preventive or therapeutic drug regimens described in IACUC approved protocols.

II. Background:

This policy deals with drug regimens that are often explicitly defined in IACUC protocols for procedures and research-related conditions. However, changes to these regimens may be required to ensure animal welfare. Such changes can be made on a case-by-case basis by the Attending Veterinarian or designee responsible for the clinical care of animals without prior IACUC approval to ensure animal welfare. However, an amendment for the change in drug must be submitted as soon as possible. Amendment approval is required prior to applying the change to subsequent studies.

Animals that are being treated for an injury or illness can be prescribed any drugs that are deemed necessary by the clinical veterinarian.

III. Policy:

These guidelines allow the Attending Veterinarian or veterinary designee to change a drug proposed for use in an approved IACUC protocol, as well as the dosage, frequency, duration, and course of therapy that is given.

Such changes that may arise may be due to the following:

- A. A drug approved on the protocol has become permanently or temporarily unavailable.
- B. New drugs have become available since the protocol was approved.
- C. New information has become available about a species-specific drug reaction that was not available when the protocol was approved.
- D. New information about drug interactions has become available since the protocol was approved.

- E. Clinical judgment indicates that a different drug is more appropriate for the given situation than the IACUC approved drug.

No changes will be made to a research protocol without the prior approval of the Principal Investigator (PI), unless the PI is unavailable and the Attending Veterinarian or designee determines the change(s) are necessary to best meet the animal and study needs. Every attempt will be made to contact the PI in advance to ensure that all are in agreement with the approach and that the change would not negatively impact the research protocol and studies in progress.

IV. Resources:

1. Animal Welfare Act and Regulations
<https://www.nal.usda.gov/awic/animal-welfare-act>
2. ILAR, Guide for the Care and Use of Laboratory Animals
<http://nap.edu/12910>
3. PHS Policy
<https://olaw.nih.gov/policies-laws/phs-policy.htm>