



Title: Guidelines for Changes in the Use of Therapeutic Drugs on Approved IACUC Protocols

SOP #	AV 40-407
Version #	1
Implementation Date	11/12/2016
Next Review Date	11/12/2019

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Standard Operating Procedure

1. Purpose

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

2. Scope

This policy deals with drug regimens that are often explicitly defined in IACUC protocols for procedures and research related conditions. Changes to these regimens may be required to ensure animal welfare.

3. Responsibilities

Changes to drug regimens can be made on a case-by-case basis by clinical veterinarians without prior IACUC approval to ensure animal welfare. However, the Principal Investigator (PI) must submit an amendment for the change in drug as soon as possible. Amendment approval is required prior to applying the change to subsequent experiments.


4. Procedure

These guidelines allow clinical veterinarians to change a drug proposed for use in the approved IACUC protocol, as well as the dosage, frequency, duration, and course of therapy that is given.

Such changes may arise due to the following:

- A drug approved on the protocol has become permanently or temporarily unavailable.
- New drugs have become available since the protocol was approved.
- New information has become available about a species-specific drug reaction that was not available when the protocol was approved.
- New information about drug interactions has become available since the protocol was approved.
- Clinical judgement 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 PI, unless the PI is unavailable and the clinical veterinarian determines the changes are critical due to

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significant animal welfare issues. Every attempt will be made to contact the PI in advance to ensure that all are in agreement with the approach and that the changes would not negatively impact the research protocol and studies in progress.

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

5. *References*

1. Institute of Laboratory Animal Resources: Guide for the Care and use of Laboratory Animals, National Academy Press, Eighth Edition (http://www.nap.edu/catalog.php?record_id=12910).
2. Animal Welfare Act and Animal Welfare Regulations. United States Department of Agriculture, 2013 (https://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf).
3. National Institutes of Health: Public Health Service Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/phspol.htm>).
4. The Federation of Animal Science Societies: Guide for the Care and Use of Agricultural Animals in Research and Teaching, 3rd Edition, 2010 (http://www.fass.org/docs/agguide3rd/Ag_Guide_3rd_ed.pdf).

6. *Definitions*

1. AV – Attending Veterinarian – responsible for the health and well-being of all laboratory animals used at the institution
2. AVMA – American Veterinary Medical Association – a not-for-profit organization for advancing the science and practice of veterinary medicine to improve animal and human health
3. SOP – Standard Operating Procedure – established or prescribed methods to be followed routinely for the performance of designated operations or in designated situations
4. IACUC – Institutional Animal Care and Use Committee – responsible for assessment and oversight of the institution’s animal care program components and facilities
5. Chair – Chairperson of the IACUC
6. PI – Principal Investigator – a Central Oregon Community College employee having the background and training in scientific and administrative oversight necessary to conduct and manage the proposed study



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7. AUP – Animal Care and Use Protocol – protocol created by the principal investigator of the proposed research, testing, or educational study
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9. COCC – Central Oregon Community College
10. Guide – the *Guide for the Care and use of Laboratory Animals*
11. AWA – Animal Welfare Act – requires that minimum standards of care and treatment be provided for certain animals bred for commercial sale, used in research, transported commercially, or exhibited to the public
12. PHS – Public Health Service – establishes guidelines for the proper care of animals to be used in research
13. Clinical veterinarian – the Attending Veterinarian or designee

Revision	Author	Revisions Made	Effective Date	Approval
1	Cindy Elston	<ul style="list-style-type: none">• New SOP	11/12/16	Cindy Elston (AV)
		<ul style="list-style-type: none">•		