

**University of Colorado at Boulder
Institutional Animal Care and Use Committee
SOP # 36**

Significant and Administrative Changes

Effective Date: 2/18/2015 Revised date: N/A Version: 1

A. PURPOSE

This SOP describes the IACUC policies for reviewing changes to an animal protocol.

B. BACKGROUND

IACUC is responsible for assuring that the changes to approved animal activities are in accordance with the CU Boulder Assurance filed with the Office Laboratory Animal Welfare (OLAW), the United States Department of Agriculture (USDA) Animal Welfare Act and Animal Welfare Regulations and consistent with the *Guide for the Care and Use of Laboratory Animals 8th Ed. (Guide)* unless an acceptable justification for a departure is approved by the IACUC.

IACUC approval of proposed significant changes to previously approved animal activities is granted only after full committee review (FCR) or designated member review (DMR). The IACUC also reviews standard operating procedures at least every three years to ensure they are appropriate and accurate.

C. Tiers of changes

- Tier I -- administrative changes
- Tier I with Veterinary consult -- significant changes that can be reviewed by the veterinarian
- Tier II -- significant changes that do not affect the health and welfare of the animals
- Tier III -- significant changes that have, or could have a negative impact on animal welfare

D. Tier I, Administrative Changes include the following:

- Adding a funding source provided there are no other changes
- Correcting typographical errors and grammar
- Changing an animal strain or variety.
- Changing contact information updates
- Changes in personnel, other than the PI
- Tier I Change in animal numbers
 - Increases in animal numbers may be handled administratively in the IACUC office in up to 15% of the originally approved animal numbers.
 - Investigators may use fewer animals than approved without IACUC consultation or administrative handling.

E. Tier I with veterinary consult -- Specific significant changes may be handled administratively in consultation with the Attending Veterinarian. The Attending Veterinarian is not conducting DMR, but is serving as an expert to verify that any changes are appropriate for the animals with the following stipulations:

- Consultation with the Attending Veterinarian must be documented in writing.
- At any time, the Attending Veterinarian or another IACUC member may decide that the changes need to be reviewed through a DMR or FCR.

Tier I with veterinary consult includes:

- Changing anesthesia, analgesia, sedation, or experimental substances;
- Changing euthanasia to any method approved or conditionally approved in the [AVMA Guidelines for Euthanasia of Animals: 2013 Edition](#).

- Changing the duration, frequency, type, or number of procedures performed on an animal that will not further negatively impact the health and welfare of the animal and are justified for scientific reasons (excludes teaching protocols).
- Adding or changing the type of pain category D or E procedures provided that they have been peer-reviewed that are time-sensitive, scientifically justified (excludes teaching protocols), and may reduce number of animals needed for the study (reduction). This could be an interim measure until the review by the IACUC can take place through DMR or FCR.
- Transferring of animals from one protocol to another that have undergone pain category C procedures provided that the previously conducted procedures will not negatively impact the results on the second protocol, and that the animals will be used solely for training or equipment testing, or data collection when the previous procedures are determined by the PI to not affect the research results. Training and/or equipment testing must be listed on the approved protocol if this is the reason for the transfer.

F. Tier II and III -- Significant changes must be approved through FCR or DMR, and include the following :

- Changing from non-survival to survival surgery
- Procedures resulting in greater pain, distress, or degree of invasiveness
- Changing housing or use of animals in a location that is not part of the animal program overseen by the IACUC
- Changing species
- New or revised study objectives.
- Different Principal Investigator (PI);
- Changes in procedures that impact personnel safety;
- Increases in animal numbers greater than 15% of the originally approved number.

See more at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html#sthash.d5e4DQE2.dpuf>