

University of Tennessee at Chattanooga Institutional Animal Care and Use Committee Standard Operating Procedures		
Effective Date: 06/30/2016 Revised Date: 10/06/2020	TITLE: IACUC SOP #1: Significant and Administrative Changes	Page 1 of 3

A PURPOSE

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

B BACKGROUND

IACUC is responsible for assuring that any changes to approved animal activities are in accordance with the University of Tennessee at Chattanooga’s Assurance filed with the Office Laboratory Animal Welfare (OLAW), the United States Department of Agriculture (USDA) Animal Welfare Act and Animal Welfare Regulations and are 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 IA– Administrative changes
- Tier IB– Administrative Changes with Veterinary consult
- 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 IA, ADMINISTRATIVE CHANGES are submitted to the IACUC office and reviewed by the IACUC Chair and incorporated into the protocol. For administrative increase in the number of animals, the IACUC Chair will review the original rationale for the number of animals to be used and determine if the rationale supports the requested change and require an expanded explanation if the original rationale does not. Administrative changes include the following:

- Adding a funding source provided there are no other changes
- Corrected typographical errors and grammar
- Ordering or importing an animal strain
- 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 up to 10% of the originally approved animal numbers
 - Investigators may use fewer animals than approved without IACUC consultation or administrative handling.

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E TIER IB, ADMINISTRATIVE CHANGES 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 and within the scope of this standard operating procedure with the following stipulations:

- Consultation with the Attending Veterinarian must be documented in writing and anything approved in this manner will be listed on the subsequent IACUC meeting agenda.
- At any time, the Attending Veterinarian or the IACUC Office may decide that the changes need to be reviewed through a formal IACUC review process (DMR or FCR).

Tier IB with Veterinary Consult includes:

- Changing anesthesia, analgesia, or sedation
- Changing euthanasia to any method approved or conditionally approved in the [AVMA Guidelines for Euthanasia of Animals: 2020 Edition](#) and the [Association of Zoos and Aquariums \(AZA\) Animal Care Manuals](#)
- Adding procedures or 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 (Pain Category C) and are justified for scientific reasons (excludes teaching protocols).
- 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:

- Impacts animal welfare
- Changing from non-survival to survival surgery
- Procedures resulting in greater pain, distress, or degree of invasiveness
- Adding pain category D or E procedures, or increasing existing procedures to these categorical levels.
- 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 10% of the originally approved number.

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H LINKS

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html>

http://grants.nih.gov/grants/olaw/significant_changes.htm

<http://www.utc.edu/research-integrity/institutional-animal-care-use-committee/>

<http://www.utc.edu/research-integrity/pdfs/iacuc-bylaws.pdf>