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UNIVERSITY STANDARD

Title

UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL STANDARD ON SIGNIFICANT CHANGES TO PROTOCOLS: STANDARD ON VETERINARIANS ACTING AS REVIEWERS IN ADMINISTRATIVE HANDLING OF SELECTED CHANGES TO PROTOCOLS (VETERINARY VERIFICATION)

Introduction

PURPOSE

This document describes the type of procedures and parameters that the IACUC uses to determine which significant IACUC-approved changes can be handled via veterinary review. This review mechanism ensures that changes made to the IACUC protocol are properly monitored by a veterinarian, while facilitating a rapid turnaround of certain amendments.

SCOPE OF APPLICABILITY

This standard applies to IACUC members and staff reviewing amendments, as well as veterinary reviewers of IACUC protocols and amendments. This document identifies the type of procedures and parameters that the IACUC uses to determine which significant IACUC-approved changes can be handled via this mechanism.

The UNC-CH IACUC expects that anyone involved in animal work at the University will comply with this Standard. Requests for exceptions to this Standard must be reviewed and approved by the IACUC.

Standard

A specific set of significant changes “may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. The veterinarian is not conducting DMR [Designated Member Review], but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animals in this circumstance. Consultation with the veterinarian must be documented. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies.” It is required



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that these policies be reviewed by the IACUC at appropriate intervals of no less than once every three years to ensure they are appropriate and accurate.

The following is a list of the significant changes to a protocol that have been described in IACUC-approved policies and can be reviewed by a designated veterinarian serving as an expert:

- Laboratory location or surgical suite (non-USDA covered species only)
- Rodent strain and sex (providing no significant health phenotypes)
- Tissues Harvested
- Utilizing a core to perform the work described in protocol
- Blood draw frequency or method
- Approved anesthetics
- Approved analgesics
- Approved methods of euthanasia
- IACUC approved changes in rodent tumor size (below 2.0 cm for mice, 4.0 cm for rats)
- Route of drug administration (IM, SC, IP, IV, IC)
- Drug dose (doses must be below those known to produce toxicity)
- Identification procedures (tattoo, ear tag, toe clip, microchip, ear punch)
- Genotyping procedures
- Breeding strategy (single adult after mating, two adults, trio)
- Rationale for changes to social housing (non-USDA covered species only)
- Body weight loss (not to exceed 20%)
- Adjuvant (not including the addition of Complete Freund's)
- Addition of Body Conditioning Score to assess an animal's health status
- Post-operative care

EXCEPTIONS

Requests for exceptions to this Standard must be reviewed and approved by the IACUC.

Definitions

IACUC: Institutional Animal Care and Use Committee

DLAM: Division of Laboratory Animal Medicine, now called DCM

DCM: Division of Comparative Medicine

University Standard: The minimum acceptable limits or rules used to achieve Policy implementation, enforceable by the IACUC.

IACUC Protocol: The animal use application which describes research activities in detail and is reviewed and approved by the IACUC.



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Related Requirements

EXTERNAL REGULATIONS AND CONSEQUENCES

UNIVERSITY POLICIES, STANDARDS, AND PROCEDURES

For more detailed guidance, please refer to the [University Policy on the Care and Use of Vertebrate Animals for Research, Training and Teaching Purposes](#).

Contact Information

Subject	Contact	Telephone	Email
IACUC Protocol	OACU	919-966-5569	iacuc@med.unc.edu
Veterinary Services	DCM/ DLAM	919-966-2609	

Important Dates

- Effective Date and title of Approver: 2/01/2016; UNC IACUC
- Revision and Review Dates, Change notes, title of Reviewer or Approver:07/07/2017; UNC IACUC

Approved by: UNC IACUC

Dr. Mitchell Picker
UNC IACUC Chair

7/2017