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
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 Freunds)
- 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.
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

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<thead>
<tr>
<th>Subject</th>
<th>Contact</th>
<th>Telephone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>IACUC Protocol</td>
<td>OACU</td>
<td>919-966-5569</td>
<td><a href="mailto:iacuc@med.unc.edu">iacuc@med.unc.edu</a></td>
</tr>
<tr>
<td>Veterinary Services</td>
<td>DCM/ DLAM</td>
<td>919-966-2609</td>
<td></td>
</tr>
</tbody>
</table>

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