



Issuing Office(s)

___ OACU ___

Responsible University Officer(s)

___ IACUC ___

UNIVERSITY STANDARD

Title

UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL STANDARD FOR AMENDMENTS AND OTHER PROTOCOL CHANGES

Introduction

PURPOSE

The standards described below provide guidance to IACUC members and UNC researchers/investigators on changes and amendments to UNC approved IACUC protocols. Investigators may wish to make changes to approved applications during the three-year protocol approval time. These changes are handled in a variety of ways and depend on the type of change being requested. Some changes are handled via an email to the Office of Animal Care and Use (OACU), while others require the submission of an amendment or review by an authorized veterinarian.

SCOPE OF APPLICABILITY

All personnel, including animal handlers and Principal Investigators (PI) involved in the writing, revising, and amending of IACUC protocols. The standards described in this document apply to changes and amendments to all IACUC approved protocols.

The UNC-CH IACUC expects that all individuals 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

Amendments requesting the addition of personnel, a change in an individual's role on the protocol (other than change in PI) or the addition of specific techniques are handled directly by the OACU staff and are not sent to the IACUC for review. Significant changes to an IACUC approved protocol, defined as changes that negatively impact animal welfare, or have the potential to negatively impact animal welfare, are sent electronically for Designated Member Review (DMR) to a Designated IACUC reviewer, a DCM veterinarian (for consultation), and all members of the IACUC. Any IACUC member can request a Full Committee Review (FCR) of the amendment to be conducted at the next



Issuing Office(s)

___ OACU ___

Responsible University Officer(s)

___ IACUC ___

convened IACUC meeting or the submission of a new protocol instead of an amendment. Alternatively, some significant changes are handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. 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.

1. Application Changes Handled by Email

Principal Investigator (PI) submits an **email** to iacuc@med.unc

- Termination of protocol(s)
- Removal of personnel [include full name, PID number and relevant protocol number(s)]
- Change in animal housing location - between buildings only, not rooms within same building [indicate new housing location, old location and protocol number(s) for which changes are requested]

2. Significant Changes to an Approved Application Requiring the Submission of an Amendment

Significant Changes handled by DMR

- Addition of new procedures
- Change in specific study objectives
- Addition of rodent strains that have significant health phenotypes
- PI transfer from one qualified UNC-CH faculty member to another
- Change(s) in the degree of invasiveness of a procedure or in the degree of pain or distress an animal may experience (Note: changes to painful/distressful procedures involving USDA covered species require an updated literature search)
- Unanticipated or marked increase in clinical signs or animal deaths
- Addition of a non-survival or survival surgery when the original application does not include surgery (assessed case-by-case to determine need for FCR)

3. Significant changes to an Approved Application Which Requires Administrative or Veterinary Review and Inclusion in the Application

Significant changes handled by the OACU staff or IACUC Chair

- Addition of qualified personnel (other than change in PI)



Issuing Office(s)

___ OACU ___

Responsible University Officer(s)

___ IACUC ___

- Addition of a qualified UNC-CH faculty collaborator
- Addition of personnel technique(s)
- Addition of a specific role for already approved personnel (e.g., Laboratory Animal Coordinator, surgeon, etc.)
- Increase in animal numbers not exceeding 25% of originally approved number (does not apply requests for a change in animal species or for amendments with changes in study objectives or health status of the animals or for which additional procedures are included)

Significant Changes handled administratively according to IACUC-reviewed and -approved policies in consultation with an authorized veterinarian

- Changes in the use of anesthetics, analgesics, sedatives/tranquilizers (drugs must be listed in the IACUC-approved drug formulary), or experimental compounds
- Changes in euthanasia to any method approved in the 2013 AVMA Guidelines for the Euthanasia of Animals
- Changes in the duration, frequency, type, or number of procedures performed on an animal
- Addition or change of a collaborator or an approved core facility and any associated changes in housing location, or location where procedures will be performed

4. Significant Changes Requiring Submission of a New Protocol

Changes that require the submission of new protocol and FCR by the IACUC at a convened meeting

- Change in animal species (exception: when multiple species [e.g., fish, wild birds] are described in the protocol, additional species can be requested via an amendment)
- Change in overall purpose of a study
- Greater than 25% increase in the number of animals indicated in the original approved application (handled on a case-by-case basis)

EXCEPTIONS

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

Definitions

IACUC: Institutional Animal Care and Use Committee



Issuing Office(s) ___ OACU ___
Responsible University Officer(s) ___ IACUC ___

DLAM: Division of Laboratory Animal Medicine
DCM: Division of Comparative Medicine, formerly DLAM
OACU: Office of Animal Care and Use
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.
Amendment: Changes to the IACUC protocol which require IACUC review prior to implementation.

Related Requirements

UNIVERSITY POLICIES, STANDARDS, AND PROCEDURES

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	919-966-2609	

Important Dates

- Effective Date and title of Approver: August, 2002; UNC IACUC
- Revision and Review Dates, Change notes, title of Reviewer or Approver: July, 2017.

Approved by: UNC IACUC

Dr. Mitchell Picker
UNC IACUC Chair

6/2017