

Modifications of Approved Animal Use Protocols

Version 3.0

I. Introduction

The Animal Welfare Regulations and the Public Health Service Policy on Humane Care and Use of Laboratory Animals require that the Animal Care Committee (ACC) review and approve proposed significant changes regarding the use of animals in ongoing activities. In an effort to standardize this process at UIC, the ACC has developed the following guidelines.

II. Guidelines

Definitions

Animal Care Committee (ACC) - The CEO (Chancellor) of UIC has delegated responsibility for appointing the members of the Animal Care Committee to the Institutional Official (Vice Chancellor for Research). The UIC ACC composition is designed to meet the requirements set forth in the Public Health Service Policy and consists (at a minimum) of a chair, the veterinarian with programmatic responsibility, the chairs of the respective subcommittees (scientists), a non-scientist, an unaffiliated member, and an at large representative from the Health Science Center and the East Campus. The ACC is responsible for reviewing and approving, requiring modifications in (to secure approval), or withholding approval of proposed major changes regarding the use of animals in ongoing activities of research, testing and teaching.

Conflict of Interest - The ACC may not have a member participate in the review or approval of a modification in which the member has a conflicting interest, except to provide information requested by the ACC. A conflict of interest is defined as being directly associated with the protocol under review such as Principal Investigator, Co-investigator or other personnel employed in the laboratory of the Principal Investigator or Co-investigator. Moreover, members of the subcommittees may not participate in the initial review process of a modification in which the member has a conflicting interest, except to provide information.

A. Process of Submission and Review

1. In requesting a modification, the Principal Investigator or Co-investigator should complete the Protocol for Animal Use Form D and submit it to the Animal Care Committee Office.

Office of Animal Care and Institutional Biosafety
c/o Office of the Vice Chancellor for Research
206 AOB - M/C 672

The changes should be described in detail. Modifications that would dramatically change the overall purpose or goal of the protocol may require submission of a new protocol. If you are unsure as to what constitutes a modification and/or its level of review, contact the Director of the Office of Animal Care and Institutional Biosafety or a member of the veterinary staff at the BRL. All modifications must be approved prior to initiation of the change(s).

2. Levels of Review

The Chair or the Chair's designee conducts an initial assessment of all modifications to categorize the requested modifications as minor, major level 1 or major level 2 changes. During the initial assessment, the need for additional clarifications will be determined.

- a. *Administrative or Veterinary Review/Administrative Approval -*
Is conducted prior to initiation when the modification request is categorized as a minor change. This review is conducted by the Chair or the Chair's designee. All minor modification requests are included in an administrative approval report, which is submitted by the veterinarian with programmatic responsibility to the ACC.
- b. *Designated Review/Designated Approval -*
Is conducted prior to initiation when the modification request is categorized as a major level 1 change. The ACC office forwards a summary report of those modifications eligible for designated review to all members of the Full Committee on a weekly basis. The report shall include the title, protocol number, modification number, investigator name, department, project overview, modification overview, and requested clarifications based on initial assessment. Full Committee members will have 3 working days to request that a modification undergo full committee review and approval. If full Committee review and approval is not requested by any member within 3 working days and, in addition, a quorum of the full ACC membership has responded to receipt of the summary report, the modification can be reviewed and approved by the Chair or the Chair's designee. If any member of the Committee requests full Committee review and approval, the modification in its entirety will be reviewed as outlined under 2c below. All modifications approved via designated review are included in a designated approval report, which is submitted by the ACC office to the ACC.
- c. *Full Committee Review and Approval -*
Is conducted prior to initiation when the modification request is categorized as a major level 2 change or when a member of the ACC requests a modification eligible for designated review for full committee review. This review process is conducted by a quorum of the ACC at a convened meeting. If substantive corrections are required, the committee may vote to require revisions to secure approval and whether or not the revisions can be reviewed and approved by designated member review or need to be returned to the full committee for review and approval. All members of the committee and all alternative members must have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use designated member review if revisions to secure approval are requested. At any time, any member of the committee may request to see the revised modification and/or request full committee review of the revised modification.

B. Minor Changes – Administrative Approval

The following changes are considered by the ACC to be minor changes and are eligible for administrative approval: protocol title change, change in the effective date of protocol within the three year approval, change in the Co-investigator, change in other staff, the addition of a new strain or stock of animal, an increase in animal numbers of 10% or less for mice or rats only, a decrease in the animal numbers that does not involve a change in the intent, scope, or approved procedures, change in the location site in which a procedure will be performed, and the addition of a procedure that does not result in greater discomfort or in a greater degree of invasiveness as compared to previously approved procedures. Requests for the change in disposition of nonnaïve animals who have not undergone a major operative procedure and other painful procedures, or addition of a funding source might be considered minor changes. Requests of this nature will be considered on a case by case basis.

C. Major Level 1 Changes - Designated Review/Designated Approval

The following changes are considered by the ACC to be major changes that require Designated Review

and Designated Approval: a change in species (this requires a justification of the new species), an increase in animal numbers greater than 10% for mice and rats, any increase in animal numbers for species other than mice and rats, the addition of a breeding colony (requires appendix 1), the addition of a procedure that increases the level of pain or distress experienced and/or invasiveness as compared to previously approved procedures, the addition of a surgical procedure or the upgrade of an acute surgical procedure to a survival surgical procedure, a decrease in the animal numbers that involves a change in the intent, scope, or approved procedures, change in anesthetic/analgesic agents or the withholding of analgesics, change in or the addition of an organ system, additional restraint of more than two hours, change from one drug within a classification to another drug within the same classification, change in or the addition of a new class of drugs, change in method of euthanasia, and an increase in the duration, frequency, or number of procedures performed on an animal. All major level 1 changes will be considered on a case by case basis to determine their eligibility for designated review and the need for a veterinary review.

D. Major Level 2 Changes Requiring Full Committee Review and Approval

The following changes are considered by the ACC to be major changes that require Full Committee Review of the modification request in its entirety: change in Principle Investigator, requests for an exemption from the UIC Environment Enhancement Program for Primates or the UIC Dog Exercise Plan, disposition of animals that have had a major operative procedure besides euthanasia, methods of euthanasia not classified as acceptable or conditionally acceptable, an upgrade from a single major operative procedure to multiple major operative procedure, the addition of a procedure involving prolonged restraint as defined by UIC Policy, the addition of a model system that would cause a significant natural or experimental disease or pathologic condition in which an animal would be maintained for a period of time (e.g. tumor models), the addition of a procedure causing unalleviated pain or distress, and the addition of a fluid or food restriction protocol.