

UCAR Animal Care and Use Protocol Review Process

New protocol review or 36 Month Review – UCAR reviews, and approves, requires modifications in (to secure approval), or withholds approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3.

The UCAR procedures for protocol review are as follows:

Animal Use Protocols must be submitted to the UCAR for any use of vertebrate animals in research or teaching. There are several different forms used, depending on the animal model proposed for use and the type of protocol. Projects that will not be receiving scientific peer review from a funding agency or an established peer review committee must receive approval from the University of Rochester's internal Dean's Research Advisory Committee (DRAC) before they can be initiated.

All protocols must be submitted using our on-line submission and review system (Topaz Protocols from Topaz Technologies, Inc.)

Once a week, a list of protocols for Committee Pre-Review is sent by email to all committee members, requesting that they review the protocols to determine whether any should be reviewed at a meeting of the Full Committee. The Committee members have access to the protocol from the time it is assigned until five (5) days after the notice is sent. The Committee members may also enter review comments and questions at this time. Committee meetings are normally held once a month. A quorum must be met before voting on protocols or any other issues.

If any committee member request Full Committee Review (FCR) for a protocol, it is placed on the agenda for the next meeting. A notice is sent to committee members telling them that the protocol will undergo FCR, and requesting that they review it and submit any questions and comments. All questions and comments submitted by reviewers are returned to the PI, who then has an opportunity to revise the protocol before the meeting. If a revision is submitted, it is assigned to FCR and the committee members are notified that the protocol has been revised. The protocol and any responses from the PI are then discussed at the meeting. Additional questions or clarification may be required by the committee. During the committee meeting, a quorum of the full committee may vote to:

- Approve the protocol
- Require modification(s) to obtain approval
- FCR at the next meeting
- Withhold approval

If the vote is to require modifications to secure approval, a quorum of the full committee may further vote to require the protocol to return for full committee review, or be assigned to Designated Member Review (DMR). The information that the protocol has been assigned to DMR will be available in the meeting minutes. Any member wishing to review the modified protocol, may at any time request to see the revised protocol and will be added to the list of reviewers in the online review group, but they will not be considered designated reviewers. At any time, those members reviewing the protocol can call for it, or the modifications to it, to be reviewed at a meeting of the full committee.

If no member of the committee requests full committee review during the five-day period of Committee Pre-review, the protocol is assigned to the DMR process. Designated reviewers submit any questions or clarification required from the investigator using the on-line system. Reviewer comments and questions are summarized by the UCAR Chair or the UCAR office staff. The protocol is then returned to the PI with all the summarized comments and questions. The PI edits the protocol to address all issues that have arisen during the review, and

resubmits the protocol. The resubmitted protocol is assigned for review to the original designated reviewers (and to any other committee member who wishes to see it). Designated reviewers can approve the protocol, request additional information, or request that the protocol be reviewed at a full committee meeting.

The procedure at the University for DMR requires that 2 UCAR members review each protocol. The protocol cannot be approved unless both designated reviewers agree to its approval. If either designated reviewer requests FCR, the DMR process is suspended until FCR takes place. If either designated reviewer requests modification to obtain approval, the resubmitted, modified protocol must be reviewed by both designated reviewers, who again, can approve, request FCR, or require modification to secure approval. This procedure continues until either the protocol is reviewed by the full committee, or both designated reviewers agree to approve. Members who have a conflict of interest with a protocol are not allowed to vote on the protocol at a meeting of the full committee and are not assigned to be designated reviewer.

Modification of UCAR protocols - UCAR procedures for reviewing proposed significant changes in ongoing research are as follows: Review and approval of significant changes will be handled in the same manner as a new submission or 36 Month Review (described above) according to PHS Policy IV.C .

Examples considered to be significant include changes, but not limited to:

- In the objective of a study or Principal Investigator
- From non survival to survival;
- Resulting in greater pain/discomfort or in a greater degree of invasiveness
- In the species or in approximate number of animals used;
- Anesthetic agent(s) or the use or withholding analgesics;
- In the duration, frequency, or number of procedures performed on an animal; and
- Any changes deemed significant by one or more reviews

Twice a week, a summary of each modification is distributed to all members of the committee, who then have two business days to request FCR at a meeting. If FCR is requested, it is handled in the same manner as FCR and approval of protocols. If FCR is not requested, UCAR has delegated review of the modification to the UCAR Chair and one other member of the committee designated by the Chair. The two reviewers can approve the modification, seek additional information from the investigator, or request FCR of the modification.

Veterinary Administrative Approval for Significant Protocol Changes (Veterinary Verification and Consultation or VVC).

Significant changes to a protocol must be approved either by a majority vote of a convened quorum of the UCAR (FCR) or by DMR. However, in the following specific circumstances (a-c below), administrative approval may be obtained by consultation with and approval of any DLAM veterinarian RESTRICTED WITHIN THE CONTEXT OF THE UCAR APPROVED REFERENCE RESOURCES LISTED BELOW.

Changes in:

- a. anesthesia, analgesia, or sedation;
- b. euthanasia to any method approved in the [AVMA Guidelines for the Euthanasia of Animals](#); and
- c. duration, frequency, type, or number of procedures to be performed on an animal as long as those procedures are either approved in the protocol or are approved UCAR or DLAM SOPs.

The veterinarian is not conducting DMR, 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 will be documented by having the veterinarian send an email approving the change to UCAR.

This email will be appended to the protocol for which the change is authorized and the protocol will be updated by the UCAR Chair or Research & Training Coordinator.

The **veterinarian may refer any request to UCAR** for review for any reason and must refer any request that does not meet the parameters of the UCAR reviewed and approved policies.

AVMA Euthanasia Guidelines - <https://www.avma.org/KB/Policies/Documents/euthanasia.pdf>

DLAM tail biopsy: <http://www.urmc.rochester.edu/MediaLibraries/URMCMedia/ucar/policies/documents/DLAM-tail-biopsy.pdf>

Euthanasia Methods:

<http://www.urmc.rochester.edu/medialibraries/urmcmedia/ucar/policies/documents/euthanasia5-10.pdf>

Rodent Identification:

<http://www.urmc.rochester.edu/MediaLibraries/URMCMedia/ucar/policies/documents/Rodent-Identification-Methods.pdf>

Rodent & bird surgery/formulary:

<http://www.urmc.rochester.edu/MediaLibraries/URMCMedia/ucar/policies/documents/Policy-on-Aseptic-Surgery-on-Rodents-and-Birds-8-1-14.pdf>

USDA Regulated Species surgery/formulary:

<http://www.urmc.rochester.edu/medialibraries/urmcmedia/ucar/policies/documents/aseptic-surgery-usda-regulated.pdf>

AAALAC Int. Reference document:

A Good Practice Guide to the Administration of Substance and Removal of Blood, Including Routes and Volumes

<http://www.aaalac.org/accreditation/RefResources/BloodRemoval.pdf>

DLAM SOPs:

D-2 Rodent colony management

D-39 Anesthesia for Primate MRI procedures

D-81 Rodent Anesthesia Machine Rental (e.g. training on equipment)

D-52 Monkey Perfusion

D-69 Cat castration

D-74 Protocol for Rabbit Immunization and Polyclonal Antibody Production

D-87 Rodent Cardiac Exsanguination

D-88 Retro-orbital Injection in Mice