

## 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:

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->