

**University of Cincinnati
Animal Care and Use Program**

Protocol Review

University of Cincinnati has several mechanisms for the review and approval of Animal Care and Use protocols and modifications to those protocols. All animal work for research, testing, or teaching must occur under an approved IACUC protocol. Protocols are approved for a maximum of 3 years. Prior to the 3-year expiration date, a triennial (*de novo*) review is required.

All documents requiring IACUC review must be submitted through the Research Administration Portal (RAP) system.

The types of review are:

1. **Full Committee Review (FCR):** Reviewed by all members and deliberated at a scheduled IACUC meeting by a quorum of the IACUC members.
2. **Designated Member Review (DMR)** The IACUC Office will assign the protocol to at least one reviewer as directed by the IACUC Chairperson. DMRs are typically given a minimum of 5 business days to review. Concurrently, IACUC members are given a three day grace period to access and review the proposal/changes, and request full committee review. Note that any IACUC member may elect to review the protocol and submit questions or comments to the PI without calling for FCR. If no member requests to send to full committee the DMRs are authorized to act on the submission. DMRs must be unanimous. DMRs subsequent to FCR follow the same process.
3. **Veterinary Verification and Consultation (VVC):** Certain significant changes may be handled administratively according to this IACUC reviewed and approved policy in consultation with an IACUC member veterinarian (Attending Veterinarian or designee); provided that these changes do not:
 - a. change procedures from non-survival to survival surgery
 - b. result in greater potential pain, distress, or degree of invasiveness
 - c. change species, study objectives, Principal Investigator
 - d. affect personnel safety

The veterinarian is not conducting DMR, but is serving as a subject matter expert to verify that compliance with this IACUC reviewed and approved policy is appropriate for the animals in this circumstance. Review and verification by 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 this IACUC reviewed and approved policy. The VVC process may not be used to add new procedures to a previously approved protocol.

4. **Administrative Review:** A process where the IACUC office reviews and has the authority to approve or send to committee.

Ancillary Reviews-Chemical, Biological and Radiation safety, Training, and Satellite reviews must be completed prior to IACUC approval.

Level of review guidelines-These guidelines are for the use by the IACUC Office for initial categorization of submissions.

Administrative-IACUC office review (amendments only)

1. Change in personnel, other than the PI (There will be an administrative check to ensure mandatory training requirements and Occupational Health and Safety enrollment is complete prior to approval).
2. Changes in animal use sites (May require safety review)
3. Changes in funding source, sponsor or title of grant
4. Correction of typographical errors and grammar
5. Contact information updates

Veterinary (VVC) review (amendments only)

1. Change in anesthetic, analgesic, tranquilizing drugs or addition of reversal agent
2. In additions of the method of euthanasia that is considered “acceptable” or “acceptable with conditions” (if the appropriate conditions are met) as approved in the AVMA Guidelines for the Euthanasia of Animals.
3. Change in blood collection, substance administration routes, and/or volumes
4. Changes in nutritionally complete diet formulations, diet form (liquid/solid), or the addition of nutritional supplements or treats
5. Increase of animal numbers up to 10% or 1000 (whichever is lower) for non-USDA regulated species (limit 1 per year)

Designated Member Review (all submissions)

1. Annual progress report (regulatory required)
2. Category C or D
3. Survival surgery – single major or multiple minor (on a single animal)
4. Change of Principal Investigator
5. Addition of >10% of number of animals used
6. Change in the species
7. Addition or change in the duration, frequency, or number of procedures performed on an animal
8. Change in monitoring due to adverse consequences more severe than anticipated
9. Change or addition of a surgical procedure, change from non-surgical to surgical, from minor to major surgery, from non-survival to survival surgery
10. Change or addition of the use of new hazardous agents (e.g., biological, chemical, radiologic) to animal procedures
11. Previously approved Guide or Policy Exceptions (typically occurs with triennials with minimal changes)

Full Committee Review (all submissions)

1. New Guide or Policy Exceptions
2. Category E
3. Multiple Major Survival Surgical Procedures (on a single animal)

IACUC Approved Reference Materials for Veterinary Verification and Consultation (VVC) include the current editions of the following:

IACUC approved policies, guidelines, and standard procedures.