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 live, vertebrate 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) website.

Types of Review
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 three business days to access and review the proposal/changes and request full committee review. 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 FCR, 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 (PI), or
   d. affect personnel safety.

   The veterinarian is not conducting DMR but is serving as a subject matter expert to verify compliance with current editions of IACUC approved policies, guidelines, and standard procedures. 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 VVC.

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

5. **Ancillary Reviews:** Safety (biological, chemical, physical, radiological), training, and satellite location reviews must be completed prior to IACUC approval when applicable.
Levels of Review
These guidelines are used by the IACUC Office for initial categorization of submissions.

Administrative-IACUC Office review (amendments only)
1. Personnel additions or removals, other than the PI (training ancillary reviews will be completed to ensure protocol team have completed appropriate required training)
2. Changes in satellite 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. Change in 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 route, volume, and/or frequency of blood collection
4. Change in route, volume, frequency, and/or formulation of substance administration
5. Change in nutritionally complete diet formulations, diet form (liquid/solid), or the addition of nutritional supplements or treats
6. Increase of animal numbers up to 10% or 1000 (whichever is lower) for non-USDA regulated species

Designated Member Review (all submissions)
1. Category C or D, or new Category E animals to approved Category E protocol
2. Survival surgery – single major or multiple minor (on a single animal)
3. Change of PI
4. Addition of >10% of number of animals used
5. Change in the species
6. Change in or addition to the duration, frequency, or number of procedures performed on an animal
7. Change in monitoring due to adverse consequences more severe than anticipated
8. Change or addition of a surgical procedure, change from non-surgical to surgical, from minor to major surgery, from non-survival to survival surgery
9. Change or addition of the use of new hazardous agents (e.g. biological, chemical, radiological) to animal procedures
10. 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. New Category E protocols
3. Multiple major survival surgical procedures (on a single animal; exceptions for existing triennial renewals at IACUC veterinarian discretion)
4. Death as an endpoint
5. Withholding analgesics

IACUC Approved Reference Materials for Veterinary Verification and Consultation (VVC) include the current editions of the following:
IACUC approved policies, guidelines, and standard procedures.