

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

Protocol Submission and IACUC Review

The 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 use for research, testing, or teaching must occur under an approved IACUC protocol. The LAMS Holding Protocol temporarily covers care of animals that are not currently covered on an active 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 Principal Investigator (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, 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 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.

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

- IACUC approved policies, guidelines, and standard procedures.

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.

Triennial Reviews

[PHS Policy \(IV, C 5\)](#) requires a complete review of protocols at least every three years. The PI is required to submit an updated protocol for continuing activities prior to the three year expiration of their protocol if they wish to continue work.

1. To avoid protocols expiring with animals in-house, the IACUC strongly recommends the triennial submission of protocol updates 3 months prior to the expiration of the protocol.
2. A properly completed protocol application (including all appropriate safety applications/approvals) requires approximately 30-45 days for processing depending on the complexity of the project.
3. It is the PI's responsibility to ensure that a completed new/triennial submission is submitted in enough time to be reviewed and approved prior to the expiration date.

If the protocol expires:

1. A protocol closure notification will be sent to the PI and LAMS.
2. No research can be conducted on an expired protocol (including but not limited to: breeding, euthanasia, and tissue harvest).
3. Any animals assigned to the protocol will be automatically transferred to a LAMS holding protocol at the PIs expense. Once animals are transferred to the holding protocol, the Attending Veterinarian or designee will decide the care and disposition of transferred animals.
4. Many granting agencies do not allow sponsored monies to be used to pay per diems while on the holding protocol. PIs will need to check with their grant administrator to identify whether alternate funds are needed to support per diems on these animals.

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
6. Up to a 10% increase in animal numbers as long as the study objectives and animal number rationale remain unchanged.

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 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

Designated Member Review (all submissions)

1. All protocol submissions-new or triennial
2. Significant changes (amendments) as described in [OLAW NOT OD 14-126 1a-g](#).
 - a. from non-survival to survival surgery;
 - b. resulting in greater pain, distress, or degree of invasiveness;
 - c. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
 - d. in species;
 - e. in study objectives;
 - f. in Principal Investigator (PI);
 - g. that impact personnel safety.
3. Addition of >10% of number of animals used

Full Committee Review (all submissions)

1. New *Guide* or policy exceptions
2. New Category E (more than momentary, unrelieved pain or distress) protocols
3. Multiple major survival surgical procedures
4. Death as an endpoint
5. Withholding analgesics