

IACUC Policy #:	340
Policy Title:	<i>Protocol Review</i>
Date Approved:	September 21, 2022
Date Reviewed:	

Purpose:

This document describes the IACUC review process for protocol submissions and amendments to IACUC-approved protocols at Southern Illinois University Carbondale.

Policy:

Animal Care and Use Protocols and amendments are prepared by the principal investigator and submitted to the IACUC Administrative Office (IAO) electronically for IACUC review. Under [PHS Policy IV.C.1-3](#) and Animal Welfare Regulations [9 CFR 2.31](#), the IACUC is empowered to approve, require modifications (to secure approval), or withhold approval of each proposal, including those for PHS and NSF-supported activities, related to the care and use of animals.

Investigators are notified in writing when approval is granted. Animal work may not commence until a protocol or protocol amendment receives IACUC approval.

Review Types

New protocol review occurs through Full Committee Review (FCR) or Designated Member Review (DMR). Amendments to approved protocols containing significant changes are reviewed using DMR, FCR, or Administrative Veterinary Verification and Consultation (VVC). Minor amendments to approved protocols may occur through administrative review in consultation with the IACUC chair. Any IACUC member may request FCR for any submission at any time.

New or Renewed Protocol Review

In accordance with [PHS Policy IV.C.2](#), the IAO distributes electronic copies of new protocols to all IACUC members. If no member calls for FCR, the IACUC chair appoints two qualified members to conduct a Designated Member Review (DMR) of the proposed animal care and use activities. A member with a conflicting interest in a protocol cannot participate in the approval process except to provide information to the assigned reviewers. New protocols may be approved or require modifications (to secure approval) by agreement of both designated member reviewers or referred to FCR by either reviewer at any time. For FCR reviewed protocols, a majority vote of the quorum present at FCR is required to approve a protocol.

The IACUC may require modifications of a protocol to secure approval. The principal investigator is notified in writing of the modifications necessary to secure approval and a

revised protocol incorporating these modifications is requested. If FCR requires modifications, the IACUC may use FCR or DMR to review the revision response provided by the PI.

If the IACUC unanimously agrees to DMR of the modified protocol, the Chairperson appoints two committee members present at the meeting as designated reviewers to conduct a DMR of any resulting modifications. The designated reviewers may also request additional modifications to the revised protocol to secure final approval. DMR can result in approval or referral to the full committee for further review of the modified protocol. Both designated reviewers must agree on approval. The entire IACUC is apprised of all decisions resulting from DMR. If the DMR of a modified protocol ends without approval by the designated reviewers, the modified protocol is referred to the full IACUC for review at a convened meeting of the IACUC with at least a quorum present.

The IACUC may withhold approval by a formal majority vote for protocols involving serious or multiple animal care issues (e.g., lack of justification for multiple survival surgeries, lack of justification for physical euthanasia without anesthesia, etc.). These protocols are returned to the principal investigator with written IACUC comments. The principal investigator may respond in writing or in-person to the IACUC comments and may also submit a modified protocol to the IAO. The modified protocol is distributed to the entire IACUC and reviewed in the same manner as new protocol submissions.

Amendment Review

Modifications (amendments) to approved research protocols must be requested in writing by the principal investigator. Amendment requests are initially reviewed by the IACUC Chairperson, with input from the Attending Veterinarian. The amendments are categorized as major or minor by the IACUC Chairperson, with input from the Attending Veterinarian. Any IACUC member may request FCR for any submission at any time.

Amendments considered minor are administratively reviewed and may include:

- Change in personnel other than the principal investigator.
- Contact information updates for personnel.
- Title changes as long as it does not change the original objectives.
- Addition of another strain of the same species.
- Addition of animals (10% or less of same species).
- Change in the supply source of animals.
- Changing housing location between facilities that are already inspected and approved by the SIU IACUC.
- Correction of grammar or typographical errors that do not substantially change the protocol methods.
- Other changes categorized as minor by the IACUC Chairperson.

Significant amendments/modifications are approved through FCR or DMR, as described above for new or renewed protocols, and may include:

- Principal investigator change.
- Significant increases in animal numbers (10% or more).
- Any increase in animal numbers for USDA-regulated species.
- Addition of experimental groups.
- Major changes in experimental designs.
- Addition of new surgeries.
- Changes resulting in greater discomfort, pain, or in a great degree of invasiveness.

Administrative Veterinary Verification and Consultation (VVC)

As provided for in OLAW guidance ([NOT-OD-14-126](#)), IACUC reviewed and approved policies may be used in conjunction with consultation by the Attending Veterinarian to administratively authorize certain significant changes or modifications which do not unduly impact animal welfare or alter study objectives. During VVC review, the veterinarian is not conducting designated member review, but is serving as a subject matter expert to verify compliance with IACUC reviewed and approved reference documents appropriate for the circumstance.

Reference documents may include but are not limited to: [The Formulary for Laboratory Animals](#) (Hawk & Leary, 2005), [AVMA Guidelines for the Euthanasia of Animals](#) (2020), and internal guidance documents on [sedation, tranquilization, anesthesia and analgesia](#).

PIs must still follow the standard amendment procedure and request the modification in writing to the IACUC Administrative Office. The IAO distributes electronic copies of the proposed amendment to all IACUC members. If no member calls for FCR or DMR, the protocol is assigned to VVC review. Amendments approved through VVC are reported to all IACUC members. 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 policy. Any IACUC member may request FCR for any submission at any time.

Modifications that may be reviewed under VVC include:

- Changes to anesthetics, analgesics, sedatives, antimicrobials, and contrast agents using referenced dosages, routes, durations, and frequencies for the species and within acceptable and known veterinary parameters.
- Switching Euthanasia to any method approved in the AVMA Guidelines
- Addition of a drug or compound used routinely in veterinary practice and/or the laboratory animal medicine field at referenced dosages, routes, durations, and frequencies for the species and within acceptable and known veterinary parameters.
- Changes in duration, frequency, type, or number of already approved procedures performed on an animal provided the changes do not result in greater pain, distress, or degree of invasiveness.