

INSTITUTIONAL ANIMAL CARE & USE COMMITTEE IACUC PROTOCOL REVIEW PROCEDURES

A. Purpose

The Institutional Animal Care and Use Committee at The University of Southern Mississippi is charged with overseeing USM's vertebrate animal care and use program as outlined by the Office of Lab Animal Welfare under the Public Health Service and the Animal and Plant Health Inspection Service under the USDA. The IACUC's responsibilities are codified in *PHS Policy for Humane Care and Use of Laboratory Animals*, the *Guide for the Care and Use of Laboratory Animals*, and the *Animal Welfare Act*. This policy describes the IACUC review process.

B. Background

The IACUC oversees the specific care and use of animals by formally reviewing animal protocols and granting approval before any activities may begin. In making this determination, the IACUC shall confirm that the research project will be conducted in accordance with the Animal Welfare Act insofar as it applies to the research project, and that the research project is consistent with the Guide for the Care and Use of Laboratory Animals (8th ed.) unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the research project conforms with the institution's Office of Laboratory Animal Welfare (OLAW) Assurance and meets the following requirements:

1. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
2. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
3. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be humanely euthanized at the end of the procedure or, if appropriate, during the procedure, unless it is justified scientifically when death as an endpoint is needed.
4. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
5. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
6. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

7. Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

IACUC members evaluate the referred protocols for all criteria defined in the federal and institutional animal care and use regulations and policies. Particular attention is paid to the justification of the proposed animal use, the appropriateness of the treatments and animal numbers proposed, and the possibility of modification by application of the 3Rs (Reduce, Refine, & Replace).

C. Types of Protocol Submissions

1. New Protocol: A new application for the use of animals in research, testing, or teaching.
2. Triennial Review: Per Public Health Service (PHS) Policy, a complete resubmission by the Principal Investigator (PI) and a de novo review that must occur after three years of approval.

Important Note: According to the PHS policy, no research or teaching activities should be conducted with the vertebrate animals beyond the protocol's expiration date. It is the PI's responsibility to seek timely renewal and maintain the active status of their protocols. If needed, the ORI Staff will send three reminders at three, two, and one month before the protocol expires. Upon a protocol's expiration, the PI, the PI's unit director, and the animal facility manager will be notified through email. The animals must be returned to holding protocols, and the PI is responsible for all related costs of animal care and housing.

3. Modification: Any changes to an already approved protocol, for example, changing personnel or adding new procedures. If a modification fundamentally changes the aim of the study, the PI is encouraged (and may be required by the IACUC) to submit a new protocol.

D. Types of Review

1. Administrative Review: For modifications, some minor changes, and reviews can be handled administratively by Office of Research Integrity (ORI) staff and the chair. Examples include:

- A change in the project title
- A change in funding source
- A change in personnel
- A change in the animal source, provided the new source is either from an IACUC-approved protocol or from an approved vendor
- A change in animal strain/line will be reviewed and approved by the IACUC Chair and the attending Veterinarian
- A change in location for housing and use will be reviewed and approved by the IACUC Chair and the attending Veterinarian

- Reuse of animals previously used in experimental procedures will be reviewed and approved by the attending Veterinarian
 - A change in animal numbers (for non-USDA-regulated species only), provided the change is 10% or less than the approved number since the last IACUC protocol review
2. Veterinary Verification and Consultation: Significant changes must be reviewed and approved by the IACUC through Designated Member Review (DMR) or Full Committee Review (FCR), but some changes may be reviewed by the attending Veterinarian.
 3. Designated Member Review (DMR): May occur only after all IACUC members have been provided with the protocol(s) to be reviewed and have an opportunity to call for FCR. If an FCR is not requested, the Chair designates at least one member of the IACUC qualified to conduct the review. DMR should be anonymous to the PI. DMR may result in approval, revisions to secure approval, or a request for an FCR. DMR may not result in disapproval.
 4. Full Committee Review (FCR): May only be conducted at a convened meeting with a quorum (simple majority) of members present. A majority vote of the quorum present is needed to approve, require revisions (to secure approval), or withhold approval of a protocol. When substantive revisions are required in a protocol to secure approval, the resubmitted protocol must be reviewed using either FCR or DMR.

D. Protocol Submission and Review Process

All PIs must complete the applicable forms available [here](#) and email them to iacuc@usm.edu. All correspondence throughout the review process will occur by email. All proposed activities must be approved by the IACUC before animals can be acquired, and any activities may begin.

1. Pre-review: All protocols submitted to the IACUC will be subject to pre-review by the Office of Research Integrity (ORI) staff before submission to the IACUC for review.
 - a) ORI staff will check for the completion of mandated [CITI](#) training certificates for all personnel listed on the protocol, the approval of biosafety protocols if required, inclusion of appropriate appendices, compliance with IACUC, and consistency in the submission.
 - b) For protocols that involve painful and/or distressful procedures, like surgery, a veterinarian must be consulted in the planning of such procedures. The veterinarian will review the protocol to ensure that the planned procedures minimize any potential pain or distress and adhere to best practices for animal welfare.
 - c) The PI should prepare the proposal in good-quality writing. Staff may return the protocols to the PI for editing or clarification as needed. Any pre-review questions raised by the ORI Staff or the veterinarian will be returned to the PI via email to revise the application before the IACUC reviews it.

2. IACUC Review

- a) After the pre-review is completed, the protocol will be sent to the IACUC for review. A protocol may be approved through Administrative Review, reviewed through a designated member review (DMR), or reviewed through a full committee review (FCR). Typically, fish and herptile protocols or those involving animals in USDA pain categories B or C may be reviewed by any member of the IACUC. The IACUC chair assigns each protocol to a DMR. This designated reviewer has the authority to approve, require revisions (to secure approval), or request a full committee review of a protocol. Any IACUC voting member may request an FCR of any protocol or modification. If requested, protocols nominated for FCR will be discussed at the next convened IACUC meeting.
- b) Designated Member Review (DMR):

DMRs act on behalf of the IACUC to evaluate the referred protocols. The DMR may approve, request revisions to secure approval, or request FCR. The DR will communicate any questions or concerns to the IACUC Chair and ORI Staff. The IACUC Chair will send the requests to the PIs, and the PI will make those changes and resubmit the revised protocol to iacuc@usm.edu.
- c) Full-Committee Review (FCR)
 - 1) Protocols involving animals in the USDA pain categories D and E or requested by any IACUC member, including the DMR, will be reviewed by the entire committee. During a convened meeting, following careful review of the protocol under evaluation for all the criteria defined in the federal and institutional animal care and use regulations and policies, the IACUC discusses/deliberates, and each committee member may vote to approve, abstain from voting, withhold approval, or request revisions to secure approval of the proposed activities. Protocols are approved by a majority vote of IACUC voting members at an IACUC meeting with a quorum of members in attendance. Any objections or abstentions to a protocol are recorded in the IACUC meeting minutes.
 - 2) If additional information is required to secure approval, the IACUC may elect one of the following options:
 - a. DMR subsequent to FCR: A quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when revisions are required to secure approval. However, any member of the IACUC may, at any time, request to review the revised protocol and/or request the FCR for the protocol.
 - b. Tabling: Request that the protocol be deferred/tabled until the next convened IACUC meeting. This often occurs when significant additional information/revisions are needed regarding the proposal before a decision can be made. The PI will be notified and requested to make revisions.
 - c. Withhold Approval (Rejection): If the IACUC votes to withhold approval, the PI will be provided with written notification of the IACUC's decision along with the reasons for denial.

F. Conflict of Interest

For Full-Committee reviews, IACUC members who are the PI or have another potential conflict (spouse, affiliated with the grant, etc.) will be recused from the meeting room during consideration of those protocols and cannot contribute to the constitution of a quorum.

For DMR reviews, IACUC members with a potential conflict will not be assigned to review those protocols.

If a member is inadvertently assigned to a protocol for which they have a conflict of interest, it is their responsibility to notify the IACUC Chair and/or the ORI staff and recuse themselves from review of that protocol.

G. Protocol Review Timelines

1. Protocol submitted to iacuc@usm.edu
2. ORI Staff:
 - a) Pre-reviews the submission for completeness and follows up with the PIs with any questions or revisions. Should a protocol modification be minor, it will be approved administratively by the ORI Staff and the IACUC Chair.
 - b) Upon completion of pre-review for submissions, the protocol will be submitted by the IACUC Chair or designee to the IACUC members for review (New Protocols, Three-Year Renewals, and Regular Modifications only).
3. IACUC Review:
 - a) The IACUC Chair submits potential DMR protocols via email to the committee, and any IACUC member may request FCR on any protocol within five business days of submission. If FCR is requested, the protocol is added to the agenda of the next scheduled IACUC meeting.
 - b) If DMR is approved by the committee unanimously, the IACUC Chair will appoint a DMR to proceed with the IACUC review process. DMRs are typically given up to two weeks to submit their review report to the Chair. Regular reminders are provided to DMRs to ensure the timely completion of reviews. If the DMR is unable to complete the review within two weeks, a replacement DMR may be appointed.
 - c) If FCR is requested, the protocols will be submitted to the committee no later than a week before the meeting date. All new protocol submissions classified under the Pain & Distress categories D and E require FCR review and should be submitted two weeks prior to the meeting date to be included on the monthly meeting agenda.
 - d) Any questions and/or revisions requested for the protocol/modification are sent to the PI by the ORI Staff and IACUC Chair. The PI should resubmit the revised protocol within 30 days. A reminder is provided to the PI to ensure timely resubmission. Failure to respond to the reminder and a delayed submission may result in rejection, and the PI may need to resubmit it as a new submission.

- e) Once revised and resubmitted, the protocol and any additional comments from the PI are returned to the DMR (or the full committee for protocols requiring FCR) for re-review. The same timeline as mentioned above is expected from the DMR or PI.

4 Approval

Once finalized, the PI is notified of the approval via an email approval notification from the ORI Staff.

5. Post-approval Review

All approved protocols are subject to Post-approval Review to ensure that the procedures in use are in agreement with the procedures approved in the IACUC-approved protocol. Post-approval reviews may include tabletop exercises, inspection of surgical or animal housing facilities, and/or direct observation of animal procedures, at the discretion of the IACUC.