

**California State University, Stanislaus
Institutional Animal Care and Use Committee
SOP: IACUC Submission and Committee Review Process**

PURPOSE

The IACUC must review and approve all proposed components of a protocol involving the care and use of vertebrate animals or significant changes to previously approved protocols either through Full Committee Review (FCR) or Designated Member Review (DMR).

Types of Protocols:

- New Protocols
- Annual Review
- Amendment to an Existing Protocol

The IACUC has established the following operating procedures concerning protocol submission and review.

Protocol Submission: The Investigator/Instructor submits the signed protocol application to the IACUC Administrator (IA) at least six weeks prior to the IACUC meeting. The IA reviews the protocol to ensure administrative completeness, assigns a protocol number and logs the protocol into the tracking system. The protocol is then sent to the Attending Veterinarian (AV). The AV is responsible to review procedures concerning surgery, pain, and anesthesia on the protocol. Should any changes and/or corrections be required, the IA will communicate them to the Investigator/Instructor. At least one week prior to the scheduled meeting, the IA will send the protocol to the members of the IACUC for their review. Protocols are discussed and voted on at the monthly IACUC meeting. The Investigator/Instructor will be invited to attend the IACUC meeting.

Approved Protocols: The Investigator/Instructor will receive approval notice via an email notification containing a PDF of the approval letter.

Protocol Renewal Notification: A reminder email will be sent to the Investigator/Instructor at least two months in advance of the annual renewal or three-year review due date of the protocol. The Investigator/Instructor is responsible for submitting the renewal application at least six weeks prior to the protocol expiration date in order to ensure appropriate time for IACUC review.

Procedures for Full Committee Review (FCR)

1. Protocols shall be reviewed at a convened meeting of the IACUC. The PHS and USDA Animal Welfare policy require that proposals reviewed by the full committee receive approval vote of a majority (> 50%) of the quorum present in order to receive protocol approval.
2. Review of proposals by the full committee method invokes a deliberative process and federal regulations require that minutes of the IACUC meetings reflect committee deliberations. Minutes shall include record of attendance, a summary of the issues discussed and the resolution of those issues, and results of the vote.
3. Investigators/Instructors shall be invited to the meeting in which their proposal is being reviewed. The presence of the Investigator/Instructor during the protocol review will allow for the immediate clarification of questions and gives the Investigator/Instructor the opportunity to give a broad overview of the proposal under review.
4. Under a Full Committee Review, the IACUC has the authority to:
 - Approve
 - Require modifications to secure approval.
 - Withhold approval

Procedures for Designated Member Review (DMR)

1. DMR is a procedure in which the IACUC chair designates at least one qualified member of the IACUC to review a protocol or amendment and make a recommendation regarding approval to the full committee. A "qualified member" of the IACUC is one who does not have a conflict of interest with the particular protocol.
2. The DMR method can be used for review of new protocols, renewals, and amendments. In such instances, the protocol will be distributed to all IACUC members to give them the opportunity to call for a FCR. A full committee review can be called by any IACUC member at any time during the review.
3. A DMR is not allowed in cases where a protocol or amendment includes any of the following:
 - Major survival surgery
 - Death as an endpoint
 - Unrelieved pain and distress
4. The DMR has the authority to:
 - Approve
 - Require modifications (to secure approval)
 - Request a Full Committee Review.

DMRs cannot withhold approval of a protocol.

Procedures for DMR subsequent to a FCR

1. DMR subsequent to a FCR is a procedure in which the IACUC designates one or more members to review information provided by the Investigator/Instructor in response to a FCR of a protocol application.
2. A quorum of members present at a convened IACUC meeting may decide by unanimous vote to use a DMR subsequent to FCR when modifications are needed to secure approval.
3. Any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.
4. Minor changes of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by the IACUC administrator.

Procedures for Review of Changes to Approved Protocol

1. Significant changes to an IACUC-approved protocol must be reviewed and approved by the IACUC before they occur. The following are examples of changes that would require additional review:
 - change in objectives of study
 - proposals to switch from nonsurvival to survival surgery
 - change in degree of invasiveness of a procedure or discomfort to an animal
 - change in species or in the approximate number of animals used
 - change in anesthetic agent(s) or in the use or withholding of analgesics
 - change in methods of euthanasia
 - change in duration, frequency, or number of procedures performed on an animal
2. Review of significant changes may be conducted using either the full committee review or the designated member review method as described above.

Outcomes of IACUC Actions

1. If the protocol is approved, the approval letter will be sent to the Investigator/Instructor indicating that the research covered by the protocol may begin. A protocol is approved for a maximum of 3 years and requires yearly renewal.
2. If the protocol is approved pending modification:
 - The IACUC administrator will notify the investigator in writing.
 - Upon receipt of the revised protocol or amendment, the response will be reviewed and determined that it is adequate and approved, or requires further modifications.