



**POLICY AND PROCEDURES FOR THE PROTECTION OF
ANIMALS IN RESEARCH AND EDUCATION
CALIFORNIA STATE UNIVERSITY, BAKERSFIELD**

April 2022

- I. The authority under which the Institutional Animal Care and Use Committee (IACUC) at the California State University, Bakersfield (CSUB), is established and empowered to act is based upon the following documentation:
 - A. *Guide for the Care and Use of Laboratory Animals: Eighth Edition (Guide)*, an update of the 1996 Seventh Edition, released by the National Academy of Sciences Institute for Laboratory Animal Research (ILAR) in 2011. Institutions with PHS Animal Welfare Assurances implemented the Eighth Edition of the Guide during 2012.
 - B. *The Code of Federal Regulations. Title 9, Animal Welfare, Parts 1,2, and 3, Definitions, Regulations, and Standards* (March 3, 2022). Animal and Plant Health Inspection Service, U.S. Department of Agriculture (USDA).
 - C. *Institutional Administrator's Manual for Laboratory Animal Care and Use*. Prepared by the Editorial Committee of Institutional Administrators and Laboratory Animal Specialist for the Henry M. Jackson Foundation, Advancement of Military Medicine, Uniformed Services University of the Health Sciences. NIH Publication No. 88-2959.
 - D. *Institutional Animal Care and Use Committee Guidebook*. Prepared by the Council of the Applied Research Ethics National Association (ARENA), Public Responsibility in Medicine and Research (PRIM&R), and Office of Protection from Research Risks (OPRR). NIH Publication No. 92-3415.
 - E. *On February 26, 2013, the American Veterinary Medical Association (AVMA) Panel on Euthanasia released the AVMA Guidelines for the Euthanasia of Animals: 2013 Edition (Guidelines)*. PHS Assured institutions implemented the 2013 AVMA Guidelines during the period from March 1, 2013, to September 1, 2013.
- II. Definition of "Animal"
 - A. The U.S. Department of Agriculture (USDA) defines animal as follows: "Animal" is generally defined as any warm-blooded animal used for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. Excluded from this definition are birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, horses not used for research purposes, and other farm animals used for food, fiber, or production purposes. This term includes all dogs used for hunting, security or breeding purposes. (Section 1.1)



- B. The Public Health Services (PHS) defines animal as follows: any live vertebrate used or intended for use in research, research training, experimentation, biological testing, or for related purposes.
- III. Federally Mandated Functions for the CSUB IACUC
- A. Review, at least once every 6 months, CSUB's animal program, using USDA Regulations and *Guide*.
 - B. Inspect, at least once every 6 months, all of CSUB's animal facilities, including animal study areas and satellite facilities, using USDA Regulations and *Guide*.
 - C. Prepare reports of IACUC evaluations and submit the reports to the Institutional Official--Provost and Vice President for Academic Affairs.
 - D. Review and investigate legitimate concerns involving the care and use of animals at CSUB resulting from public complaints and from reports of non-compliance received from facility personnel and employees.
 - E. Make recommendations to the Provost and Vice President for Academic affairs regarding any aspect of CSUB's animal program, physical equipment and facilities, and/or personnel training.
 - F. Review and approve, require modification in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.
 - G. Suspend an activity involving animals when necessary; take corrective action and report to the appropriate funding agency and to the USDA.
- IV. Membership of the CSUB IACUC
- A. Federally-mandated membership requirements
 - 1. The USDA requires the membership to be no fewer than three (3) persons, which includes at least one Doctor of Veterinary Medicine (DVM), at least one person who is not affiliated in any way with CSUB or a member of the immediate family of a person affiliated with CSUB and who represents public community interests in the proper care and use of animals, and at least one person who is a practicing scientist experienced in research involving animals. When more than three person form the membership, no more than three (3) can be from the same administrative unit (academic department) of CSUB.
 - 2. The PHS requires the membership to be no fewer than five (5) persons, which includes at least one Doctor of Veterinary Medicine (DVM), at least one person who is not affiliated in any way with CSUB or a member of the immediate family of a person affiliated with CSUB, at least one person who is a practicing scientist experienced in the use of laboratory



animals for research, and at least one person whose primary concerns are in a nonscientific area.

- B. CSUB membership requirements. The CSUB IACUC membership shall be composed of at least five (5) members:
 - 1. One (1) Doctor of Veterinary Medicine (DVM).
 - 2. CSUB Safety Officer/Hazardous Materials Coordinator.
 - 3. One (1) or more persons who are not affiliated in any way with CSUB or a member of the immediate family of a person affiliated with CSUB and who represent public community interests in the proper care and use of animals.
 - 4. One (1) or more faculty who are practicing scientists experienced in the use of laboratory animals for teaching and research.
 - 5. One (1) or more faculty whose primary concerns are in a nonscientific area.

- V. Management of the CSUB IACUC
 - A. Chairperson and Vice-Chairperson
 - 1. In consultation with the IACUC committee members and the Provost and Vice President for Academic Affairs, the Associate Vice President for Grants, Research, and Sponsored Programs shall select and appoint the Chairperson and Vice-Chairperson of the CSUB IACUC.
 - 2. The nominal length of service shall be three (3) years. By mutual agreement, the Chairperson and Vice-Chairperson may be appointed to additional three-year terms.
 - 3. The Chairperson and Vice-Chairperson may be removed from office by the Provost and Vice President for Academic Affairs, after consultation with the IACUC committee members and the Associate Vice President for Grants, Research, and Sponsored Programs, if there are significant and/or repeated "failures" to comply with the policies and procedures outlined in this document.

 - B. Committee members
 - 1. In consultation with the Associate Vice President for Grants, Research, and Sponsored Programs and the Provost and Vice President for Academic Affairs, the current sitting IACUC members will recommend individuals to appoint to the committee of the CSUB IACUC in accord with the requirements specified in IV.B. above.
 - 2. The nominal length of service shall be three (3) years. By mutual agreement, committee members may be appointed to additional three-year terms.



3. Appointment for the first year shall be a one-year term of service. Thereafter, all terms shall be three (3) years. By mutual agreement, a committee member completing an initial one-year term may be appointed to a full three-year term.
 4. All members are expected to attend all meetings convened by the Chairperson. Repeated failure to attend meetings shall be grounds for removal from the IACUC.
 5. Any committee member may be removed from IACUC service by the Provost and Vice President for Academic Affairs, after consultation with the IACUC committee chair and the Associate Vice President for Grants, Research, and Sponsored Programs if there are significant and/or repeated "failures" to comply with the policies and procedures outlined in this document.
- C. Voting Requirements.
1. A quorum shall be required for the CSUB IACUC to take formal action at any convened meeting. At least five (5) members must be present for a quorum.
 2. Decisions regarding a protocol shall be based upon majority of those members of the CSUB IACUC present at the meeting.
 3. Only members of the CSUB IACUC in attendance of a convened meeting shall have full voting rights on a protocol, unless a member has a "conflict-of-interest" with a specific protocol (see subsection "F" below).
 4. No proxy votes from non-attending members of the CSUB IACUC shall be counted in the judgement of a protocol.
 5. Persons invited by the CSUB IACUC for assistance or consultation, including the investigator(s), are prohibited from voting on any protocol.
- D. Use of consultants. In accord with USDA and PHS policy, the CSUB IACUC may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the committee. Such consultants may not vote with the IACUC.
- E. Support of the CSUB IACUC. The Dean for Graduate Studies and Research shall be responsible for identifying, justifying the need for, and providing/acquiring needed resources to support the functions of the CSUB IACUC. These resources include, but are not limited to, required Federal and State documents regarding the use of animals in research, secretarial/administrative support, computer access for information, reproduction/duplicating of minutes and other required documents, meeting area and refreshments for meetings, filing space for IACUC minutes and research protocols, educational materials for committee members, and travel necessary to keep committee members current.



- F. Conflict of interest. No member of the CSUB IACUC may participate in the review of any project in which the member has a conflicting interest, e.g., the member is the principal investigator, the project director or co-director, the faculty sponsor for a student project, or a consultant or subcontractor, nor may that person contribute to the establishment of the quorum.

VI. Types of Review by the IACUC

- A. Initial review of all projects using animals prior to initiation by the investigator(s).
- B. Continuation/annual review of all projects to confirm that no changes have taken place in the approved activity that might require further consideration by the IACUC.
- C. Modification review of all projects in which a change in the approved activity must be made by the investigator(s);
- D. Review of concerns of noncompliance of all projects in which the IACUC becomes knowledgeable of problems or noncompliance.

VII. Federal Criteria for Granting Approval by the IACUC

- A. Activities will be in accord with USDA Regulations and PHS Policy.
- B. Housing/Living Conditions must be consistent with standards of housing, feeding, watering, and providing activity and must be directed by a veterinarian or scientist with appropriate knowledge and skill. Facilities must be maintained for cleanliness and sanitation and have procedures for waste disposal and vermin control.
- C. Rationale and Methods for the use of animals must be submitted to the IACUC in writing. The number of animals to be used should be the minimum number necessary to produce reliable and valid results.
- D. Assurance must be provided that a non-animal substitute is not available or feasible and that the proposed activities do not unnecessarily duplicate previous efforts.
- E. Personnel using animals must have appropriate training for the proper care and use of animals and for personal safety in handling animals and using equipment/facility.
- F. Deviations from Requirements or Approved Procedures must be justified for scientific reasons and must be submitted to the IACUC in writing.
- G. Surgery must meet requirements for sterile surgery and pre/post operative care. The use of animals for multiple major operative procedures must be fully justified and approved by the IACUC.



- H. Pain/Distress/Discomfort must be avoided, if at all possible, and minimized otherwise. If pain/distress is caused, appropriate sedation, analgesia, or anesthesia will be used. An attending veterinarian must be involved in the planning. The use of paralytics without anesthesia is prohibited, unless fully justified and approved by the IACUC. Animals with chronic/severe unrelievable pain will be painlessly euthanized.
 - I. Alternatives must be considered for any painful procedures proposed; alternatives considered by the investigator(s) must be documented if animals are likely to experience pain, suffering, or distress as a result of the proposed activity.
 - J. Euthanasia must be consistent with USDA Regulations/AVMA recommendations.
- VIII. Approval and Disapproval of Animal Protocols by the IACUC
- A. All proposals for the use of animals must be submitted in writing to the IACUC and must include the following information:
 - 1. Complete description of the activities in the proposed project.
 - 2. Reason/justification for the proposed use of animals.
 - 3. Appropriateness/justification of the species and number of animals proposed. Whenever possible, the number of animals proposed should be justified statistically.
 - 4. Appropriateness/availability of less-invasive procedures, other species, isolated organ preparations, cell or tissue cultures, or computer simulations.
 - 5. Unnecessary duplication of experiments.
 - 6. Reason/justification for the conduct of multiple major operative procedures.
 - 7. Unusual housing and/or husbandry requirements.
 - 8. Description of procedures for limiting discomfort, distress, and pain, including criteria and process for timely intervention, removal of animals from the study, or euthanasia if painful or distressful outcomes are anticipated.
 - 9. Description of use of analgesics, anesthetics, and/or tranquilizers.
 - 10. Description of post procedure care.
 - 11. Description of euthanasia methods used and/or methods for disposal of animals at the conclusion of the study.
 - 12. Adequacy of training and experience of all personnel involved with the study.



13. Safety of the "working environment" for personnel, including precautions for potential exposure to viral and bacterial infectious diseases, allergies, bites and scratches, and musculoskeletal injuries.
- B. As a result of their review, the IACUC may make one of the following judgments:
1. Unqualified Approval - all significant points have been addressed by the investigator(s) and no questions has been raised by any elements of the proposed activity.
 2. Deferral - usually the result of insufficient information for the IACUC to make a judgment.
 3. Approval Pending Clarification - no major problems with the proposed activity, but clarification is required on specified minor points.
 4. Qualified or Conditional Approval - no major problems with the proposed activity, but specified areas are judged to be inappropriate or problematic.
 5. Limited Approval - serious concerns with the proposed activity, usually due to complexity of the study and/or to the use of new untried procedures.
 6. Disapproval - limited largely to those cases where the investigator(s) refuse to make requested modifications and/or supply requested information.
- IX. Record Keeping Requirements for the IACUC
- A. Minutes of all IACUC meetings, with records of attendance, activities, deliberations, requested changes in protocols, and final judgements.
 - B. Protocols describing proposed activities using animals. Protocols must be maintained on file for the duration of the activity plus three (3) additional years.
 - C. Basic documents, such as semiannual IACUC reports and recommendations.
 - D. Animal records, depending upon the type of animals used.
- X. Procedures for Consideration of Allegations of Noncompliance
- A. IACUC determines if a complaint has sufficient substance to be investigated further.
 - B. An Investigative Committee of the IACUC is formed, and the Committee informs the alleged violator of the nature of the complaint and the investigative procedures that will be followed. The Investigative Committee shall have a minimum of four (4) members:
 1. DVM or CSUB Safety Officer, depending on the nature of the complaint;



2. One (1) community member not affiliated with the university;
3. One (1) faculty member who is practicing scientist experienced in the use of laboratory animals for teaching and research; and
4. One (1) faculty member whose primary concerns are in a nonscientific area.

The faculty member who is a practicing scientist shall serve as the chair of the Investigative Committee.

- C. The Investigative Committee examines all pertinent documents, animals, procedures, personnel, etc.
- D. The Investigative Committee presents its findings to the IACUC for endorsement with appropriate recommendations to the Provost and Vice President for Academic Affairs.
- E. The Institutional response will be dictated by the nature of the findings, current legal requirements, and current policies of CSUB. Grievance procedure shall be in accord with current policies of CSUB.

XI. Reporting Requirements for CSUB:

1. Semi-annual IACUC report, filed every six (6) months.
 - Describing adherence to Animal Welfare Act
 - Identifying departures from Animal Welfare Act
2. Suspension/Noncompliance report for serious deviation from the *Guide* and/or serious or noncompliance with PHS policy, as necessary.

XII. USDA Reporting (Contingent on federal funds for animal research). This reporting is only required when federal funds are procured for animal research.

1. Annual report, filed on or before December of each calendar year.
 - Assuring that professionally acceptable standards for care, treatment and use of animals were followed.
 - Assuring that alternatives to painful protocols were considered.
 - Assuring that facilities adhere to requirements of the Animal Welfare Act.Assuring that all exceptions to standards and regulations have been explained by the investigator(s) and approved by the IACUC.

XIII. Federal Requirements for an Institutional Training Program for Personnel Handling Animals

A. Humane methods of animal maintenance and experimentation, including but not limited to the following:

1. Basic needs of each species of animal used in the facility.



2. Proper handling and care of each species of animal used in the facility.
 3. Proper pre- and postprocedural care of each species of animal used in the facility.
 4. Aseptic surgical methods and procedures.
- B. The concept, availability, and use of research or testing methods that limit the use of animals or minimize pain/distress in animals.
- C. Proper use of anesthetics, analgesics, and tranquilizers for each species of animal used in the facility.
- D. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies reported by any employee of the facility. No facility employee, IACUC member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of regulations or standards under the Animal Welfare Act.
- E. Utilization of services (e.g., National Agricultural Library, National Library of Medicine, etc.) available to obtain information for any of the following;
1. Appropriate methods of animal care and use.
 2. Alternatives to the use of live animals in research.
 3. Unintended and unnecessary duplication of research.
 4. Intent and requirements of the Animal Welfare Act.
- XIV. Components for an Occupational Health Program for Personnel Handling Animals
- A. Pre-placement medical examination should be conducted (1) to ensure that all individuals handling animals are capable of the demands and exposure of the job and (2) to provide a medical reference baseline. Although specific tests will depend on the species of animals used, the medical examination generally should include:
- clinical history
 - physical examination
 - spirometry
 - appropriate immunizations
 - baseline tests such as TB test and serum sample analysis
- B. Periodic medical examinations should be conducted (1) to allow for detection of early stages of any disease, (2) to update immunizations, and (3) to re-evaluate any medical restrictions.
- C. Orientation and education to inform individuals of the health and safety risks in handling animals and of the precautions necessary to minimize those risks.



- D. Provisions for reporting and treating any illness or injury, with special attention to allergies, viral and bacterial infectious diseases, bites and scratches, and musculoskeletal injuries.
- E. Provisions for consultation with other professional staff from both on-site and off-site facilities.