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COMMITTEE ON RESEARCH

15-16 CR 2  
February 2, 2016

**TO:** Executive Committee & Academic Senate  
**FROM:** The Committee on Research  
**SUBJECT:** 15-16 CR 2: Animal Care and Use Policy Amendment  
**ACTION REQUESTED:** Approval by the Academic Senate; effective upon signature of the President

**BACKGROUND INFORMATION:**

The CSUEB Animal Care and Use Policy needs to be updated to remain in compliance with changes in federal regulations covering activities involving vertebrate animals. Such regulations include the National Institute of Health's (NIH's) Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals and the United States Department of Agriculture (USDA) Animal Welfare Act.

The attached summary of changes, edited policy document with changes marked up, and edited policy document with changes accepted were developed by the CSUEB Animal Care and Use Committee, and reviewed and approved by the Committee on Research on January 14, 2016.

## ORSP Summary of CSUEB IACUC policy changes 12/10/15:

- Change in policy title to “Animal Care and Use Policy”
- **“Purpose”** subheading changed to “Background” and now includes delineated reference to NIH’s PHS policy re: Humane Care and Use of Lab animals.
- **“Role of the IACUC”** subheading now includes additional language that outlines the duties of the IACUC, which now include program oversight, program evaluations, facilities inspections, and etc.
- **“Membership”** subheading now includes additional language that references National Research Council’s Guide for the Care and Use of Lab Animals. This section also decreases the minimum number of IACUC members from eight to six by more closely aligning required membership to law and includes a provision to allow dual membership in cases was a member satisfies more than one membership requirement. This section also defines what a properly constituted IACUC consists of. Lastly, this section explicitly defines the roles and responsibilities of members.
- **“Reporting”** subheading provides guidance for semi-annual reports that are due by IACUC.
- **“Protocol Review”** subheading provides guidance for the review of new protocols and existing protocols.
- **“Ongoing Protocol Review”** subheading provides guidance for annual reviews in which no changes have been made and references “de novo” approval.
- **“Institutional Official”** subheading now provides language that allows for Institutional Official to take administrative action when violations of policy arise. Reinstatement clause also included.

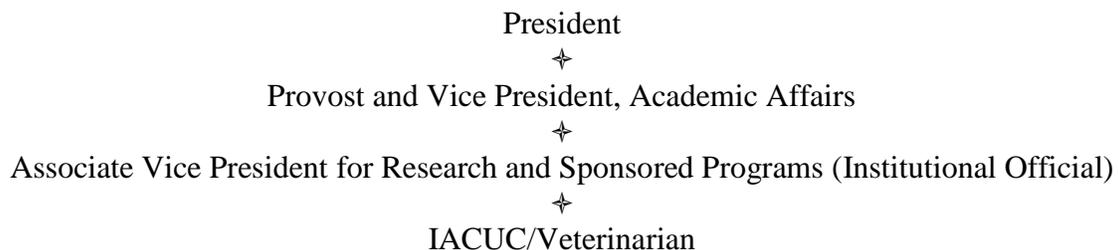
Note: Strikethrough indicates removal from amended policy. Yellow highlights indicate additional language added to the amended policy.

**California State University, East Bay**  
~~Institutional Animal Care and Use~~ **Policy** ~~Committee~~  
(IACUC)

I. ~~INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) POLICY~~

**Purpose:** **Background:** This policy is implemented in order to assure CSU East Bay's continued compliance with federal regulations covering activities involving vertebrate animals. Such regulations include the National Institute of Health's (NIH's) Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ~~Public Health Service (PHS) Policy~~ and the United States Department of Agriculture (USDA) Animal Welfare Act.

**Line of Authority:** At CSU East Bay, the lines of authority and responsibility for administering the animal care program and ensuring compliance with the Policy are:



**Role of the IACUC:** The Institutional Animal Care and Use Committee (IACUC) at CSUEB promotes and ensures the humane and ethical treatment of vertebrate animals used in teaching and research by members of the CSUEB community; advises the Institutional Official regarding program requirements; and may recommend program changes. **IACUCs are charged with program oversight and as such are responsible for program evaluations, facilities inspections, reviews of protocols, reporting noncompliance, ensuring that individuals who work with animals are appropriately trained and qualified, and addressing concerns involving the care and use of animals at the institution. The veterinarian with program authority and responsibility for animal activities, along with the animal care and technical staff, add another important level of program supervision.**

The main responsibilities of the IACUC are to:

1. Maintain current knowledge of applicable federal regulations governing the use of animals in research and teaching.
2. Make written recommendations to the Institutional Official (the Associate Vice President for Research and Sponsored Programs (AVP ORSP)) to ensure that campus policy and procedures are in compliance with applicable federal and state laws regarding the humane care and use of animals in teaching and research.
3. Seek to inform all faculty, staff, students, contractors and volunteers using animals at CSUEB about their legal scientific and ethical obligations with respect to the care and use of those animals.

4. Help to inform personnel about occupational health and safety hazards posed by working with animals.
5. Review protocol applications for the use of vertebrate animals in research and teaching at CSU East Bay and approve the protocol, require modifications to the protocol, or deny approval before the work is initiated.
6. Suspend approval for activities involving vertebrate animals that violate the campus policies or federal regulations.
7. Review the institution's program for humane care and use of animals every six months.
8. Inspect the institution's animal facilities for adherence to PHS and USDA guidelines every six months.
9. Report findings from the program semi-annual reviews and facilities inspections to the Institutional Official.
10. Receive and investigate reports of concerns about the care and/or use of animals at CSUEB or associated with CSUEB activities.

**Membership:** Consistent with the *National Research Council's Guide for the Care and Use of Laboratory Animals (Eighth Edition)*, the IACUC shall be composed of a minimum of six members appointed by the President of the University or the Institutional Official that has been delegated the authority for animal care matters. The term of service will be by mutual agreement and can be terminated by the University or the individual. ~~The IACUC shall be composed of at least eight members appointed by the President of the University or his/her designee, and two ex-officio members.~~ If an appointed member who fulfills one of the required specified positions (i.e., scientist, nonscientist, veterinarian, environmental health and safety, or unaffiliated) leaves the committee so that that position is no longer filled, the IACUC is not properly constituted and may not conduct official business until a member who fulfills the required position is appointed by the Chief Executive Officer or the Institutional Official who has been delegated such authority. The term of service will be by mutual agreement and can be terminated by the University or the individual. The IACUC membership is composed as follows:

- ~~1. A veterinarian~~
- ~~2. Four faculty members, at least one of whom is from the department of Biological Science and one is from the department of Psychology, who are knowledgeable regarding the care and use of animals used in research.~~
- ~~3. One non-scientist (e.g. ethicist, lawyer, member of the clergy)~~
- ~~4. An individual not associated with CSUEB who is familiar with the use, care and welfare of laboratory animals. This member may not be a member of the immediate family of a person who is affiliated with CSUEB, either as student, staff or faculty.~~
- ~~5. A member of the Committee on Research~~
- ~~6. A representative from the Office of Research and Sponsored Programs (non-voting, ex-officio)~~
- ~~7. Campus environmental officer (or designee) (non-voting, ex-officio)~~

1. One Doctor of Veterinary Medicine, with training or experience in laboratory animal

science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution.

2. At least two practicing scientists, both of whom shall be experienced in research involving vertebrate animals.
3. One member whose primary concerns are in a nonscientific area (e.g. ethicist, lawyer, member of the clergy).
4. One individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.
5. One individual from campus Environmental Health and Safety department.

An individual who meets the requirements of more than one of the categories detailed above may fulfill more than one requirement. Therefore ~~However~~, the committee may consist of fewer than six members. In addition, a science student may be appointed as a member of the IACUC.

A quorum for this Committee will consist of a majority of ~~be five~~ appointed members meeting the qualifications described above. A Chair for this Committee will be appointed by the Institutional Official ~~elected from the Committee membership by the Committee members.~~

**Reporting:** The semi-annual reports are documents prepared by the IACUC and submitted to the Institutional Official. The report will include any deficiencies identified during the semi-annual program review or facilities inspection, departures from the Guide for Care and Use of Laboratory Animals, and minority reports.

**Protocol Review:** All new protocols, and significant changes to existing protocols, are reviewed by Full Committee Review (FCR, i.e. a convened meeting of the IACUC with quorum). Designated Member Review (DMR), by a minimum of two voting IACUC members, can be used after FCR.

**Ongoing Protocol Review:**

All protocols are reviewed annually. Annual reviews with no change can be reviewed without change from the original submission. Every three years each protocol must be reviewed “de novo” according to PHS policy.

Minor changes to approved protocols, including adding of new staff, can be done by DMR.

**Institutional Official:**

The Associate Vice President, Research and Sponsored Programs, is the Institutional Official for the NIH Office of Laboratory Animal Welfare (OLAW) and the U.S. Department of Agriculture (USDA). The Institutional Official (or another authorized official) may unilaterally halt, terminate, or impose sanctions on any animal activity that is not prohibited by the PHS Policy. However, the AVP may not approve or reinstate any animal activity without IACUC approval.

The Institutional Official is responsible for filing the required annual and semi-annual reports to the OLAW and USDA.

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**H. POLICY ON TRAINING REQUIREMENTS FOR ANIMAL USERS**

**BACKGROUND:**

~~U.S. Animal Welfare Act Regulations (AWAR)<sup>1</sup> and Public Health Service (PHS)<sup>2</sup> policy require institutions to provide training for all personnel engaged in animal research. This includes Principal Investigators (PIs), technicians and laboratory personnel. The content of this general training is specified by federal regulations and policy and must include, as applicable:~~

- ~~\_\_\_ Appropriate species specific housing methods, husbandry procedures, and handling techniques~~
- ~~\_\_\_ Proper use of anesthetics, analgesics and tranquilizers for any species of animal used by PIs, technicians and laboratory personnel.~~
- ~~\_\_\_ Research and testing methods that minimize the number of animals required to obtain valid results and minimize animal distress~~
- ~~\_\_\_ Proper use of hazardous biological, chemical, or physical agents and to assess potential dangers and select and oversee the implementation of appropriate safeguards~~
- ~~\_\_\_ Institutional procedures for reporting deficiencies in animal care and treatment~~

~~The CSUEB Institutional Animal Care and Use Committee (IACUC) is charged, in its review of animal use protocols, with determining that all personnel conducting procedures using animals are appropriately qualified and trained.~~

**~~POLICY:~~**

~~The IACUC has established the following policy on training requirements for animal users.~~

- ~~1. Prior to the start of any animal activity, all faculty, staff, students and research personnel who use live vertebrate animals in research or instruction must receive training as applicable in the five subjects bulleted above.~~
- ~~2. It is the responsibility of the PI to ensure that all personnel listed on the PI's animal care and use protocol receive the required training in animal care and use. Successful completion of this training must be documented in writing, with a copy of such documentation sent to the IACUC to be kept in the protocol file.~~
- ~~3. All IACUC members, PIs, staff, students and research personnel who use live vertebrate animals are required to update their animal care and use training at least once every three years to ensure that they remain current on laws, regulations, guidelines and policies. Successful completion of the renewal training must be documented in writing, with a copy of such documentation sent to the IACUC.~~

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<sup>1</sup>~~Code of Federal Regulations, Title 9 (Animals and Animal Products), Chapter 1, Subchapter A (Animal Welfare), Part 2 Regulations, Subpart C Research Facilities, §2.32 Personnel Qualifications.~~

<sup>2</sup>~~Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), "Public Health Service Policy on Humane Care and Use of Laboratory Animals," revised August 2002, page 10.~~