

September 20, 1993

Assurance of Compliance with PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions

Cal Poly, hereinafter referred to as institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, hereinafter referred to as PHS Policy.

I. Applicability

This assurance is applicable to all research, research training, experimentation, and biological testing activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the sub-granting or subcontracting of a PHS-conducted or supported activity by this institution. "Institution" includes any recognized academic department within the following colleges at Cal Poly: College of Agriculture, College of Architecture and Environmental Design, College of Business, College of Engineering, College of Liberal Arts, and College of Science and Mathematics.

II. Institutional Policy

A. This institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

B. This institution is guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training.

C. This institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this assurance. As partial fulfillment of this responsibility, this institution will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this assurance as well as all other applicable laws and regulations pertaining to animal care and use.

D. This institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

III. Institutional Program for Animal Care and Use

A. The lines of authority and responsibility for administering the program and ensuring compliance with this policy are:

The chief executive officer of this institution, the president of Cal Poly, has responsibility for appointing members of the Institutional Care and Use Committee. Cal Poly's Institutional Care and Use Committee is the Animal Welfare Committee (AWC). The AWC is directly responsible only to the Dean of Research and Graduate Programs who acts as the authorized institutional official. The Veterinarian(s) has direct program responsibility and authority over all activities involving animals at Cal Poly.

B. The qualifications, authority, responsibility, and amount of time contributed by the Veterinarian(s) who will participate in the program are as follows:

Qualifications:

Veterinarian(s) must hold a DVM degree and maintain current licensure with the Department of Consumer Affairs, State of California; current veterinary accreditation with the United States Department of Agriculture; and be currently registered with the Department of Justice, Drug Enforcement Administration.

Veterinarian(s) should be familiar with routine laboratory animal medicine. Veterinarian(s) should regularly consult with specialists in laboratory animal medicine whenever unusual procedures or treatments are required in laboratory animal studies.

Authority:

To assure compliance of federal Public Health Services and Department of Agriculture policies regarding the humane care and use of laboratory animals associated with either teaching or research purposes.

Responsibility:

Review written protocols drafted by the principal investigator or person directly in charge of care, handling and use of animals in either teaching or research programs.

Review of protocols shall include areas of housing, caging, feeding, and watering of laboratory animals. Within areas of applied research, review shall include details of pending use of drugs, chemicals and medications intended for topical, oral or parenteral

administration; security and storage of drugs, chemicals and medications; applications of anesthesia, and euthanasia; disposal of animal tissues.

Provide veterinary consultation to faculty, concerned with the use of animals in teaching or research studies.

Time contributed to duties:

Veterinarian(s) normally will conduct quarterly evaluations of animal subjects, facilities, and standard operating procedures. The amount of Veterinarian time spent in treating and caring for animals will depend upon the number and diversity of animal studies under way. Likewise, the amount of Veterinarian time spent in consulting with faculty members, AWC members, specialists in animal medicine, and animal care technicians will depend upon the number and diversity of animal studies under way. The amount of Veterinarian time spent in program development and review is expected to increase as more animal species and more regulations are incorporated into the Animal Welfare Act and its amendments.

C. This institution has established an Institutional Animal Care and Use Committee (IACUC), the Animal Welfare Committee (AWC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The AWC consists of at least five members, and its membership meets the compositional requirements set forth in the PHS Policy at IV.A.3.b. Attached is a list of the names, position titles, earned degrees, and other credentials of the AWC chairperson and members.

D. The AWC will:

1. Review at least once every six months the institution's program for humane care and use of animals using the Guide as a basis for evaluation.
2. Inspect at least once every six months all of the institution's animal facilities (including satellite facilities) using the Guide as a basis for evaluation.
3. Prepare of reports of the IACUC (AWC) evaluations as set forth in the PHS Policy at IV.B.3 and submit reports to the Dean of Research and Graduate Programs.
4. Review concerns involving the care and use of animals at the institution.
5. Make written recommendations to the Dean of Research and Graduate Programs regarding any aspect of the institution's animal program, facilities, or personnel training.

6. Review and approve, require modifications in (to secure approval) or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C.

7. Review and approve, require modifications in (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C.

8. Notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC (AWC) approval as set forth in the PHS Policy at IV.C.4.

9. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6.

E. The procedures which the AWC will follow to fulfill the requirements set forth in the PHS Policy at IV.B. are:

1. The AWC will meet at least twice annually at a time that is convenient to the majority of the committee members; such date will be determined by the Chairperson of the AWC. Other meetings will be called by the committee chairperson as the need arises.

2. The AWC will conduct semi-annual inspections of all of the authorized facilities for housing laboratory animals at Cal Poly in conjunction with each of the regularly scheduled semi-annual meetings of the AWC as listed in Part III.E.1.

3. Inspection of all facilities by the AWC in Part III.E.2. will be as a group tour conducted by the attending veterinarian.

4. Any concerns or recommendations of the AWC shall be made known in writing to the attending veterinarian and the faculty supervisor of the laboratory animal facility via the minutes of the AWC meetings, a copy of which shall be sent to the institutional official (Dean of Research and Graduate Programs).

5. Applications and proposals for research grants involving the use of laboratory animals are received by the Grants Development Office. The director of that office will send a copy of the proposal to the chairperson of the AWC. The AWC chairperson will call a meeting of the committee to review the proposal and make recommendations. The chairperson of the AWC will transmit these recommendations to the Dean of Research and Graduate Programs with a copy to the Director of the Grants Development Office.

6. All proposals for senior projects, master's theses, instruction-related projects, faculty research, or any other experiments involving

laboratory animals at this institution shall be submitted to the AWC. Only after receiving approval by the AWC shall any experiments be initiated, and then only in strict accordance with the protocol as amended (if needed) and approved by the AWC. After initiation of the experiment, any deviation from the approved protocol shall be immediately reported to the AWC.

7. The AWC will make recommendations, where appropriate, to prospective research proposals concerning alternatives to in vivo studies and testing methods or experimental designs that might minimize the number of animals required to obtain valid results and minimize animal distress.

8. The AWC will provide assistance or instruction in the humane care and use of laboratory animals to anyone requesting same, and will ensure that such assistance is given to any potential animal worker or investigator whom the AWC determines to lack the necessary experience to handle laboratory animals or to conduct animal experiments in accordance with the Guide. The personnel that provide this help will be experienced in laboratory animal care (e.g., the AWC veterinarian or other qualified AWC members, vivarium director, senior animal technician, faculty resource personnel, etc).

F. The individual authorized by this institution to verify AWC approval of those sections of applications and proposals related to the care and use of animals is the Dean of Research and Graduate Programs.

G. The institution does not require routine medical examinations or immunizations of its vivarium workers, but encourages all such personnel to develop their own medical schedules and maintain records of same. Animal caretakers should maintain an active tetanus toxoid immunization as recommended by the American Health Association and the United States Communicable Disease Center as supervised through the Cal Poly Health Center. Because vivarium personnel are only routinely exposed to laboratory rats, mice and rabbits, the AWC does not require health screening or tests. The nature of Cal Poly's vivarium precludes the use of highly pathogenic microorganisms in research projects for which such tests would be necessary. If anyone is scratched, bitten or otherwise possibly infected by a laboratory animal, they should immediately cleanse and flush the wound, and seek medical attention as provided by the Cal Poly Health Center or emergency services of a community hospital. All such accidents should also be reported to the chairperson of the AWC and/or the attending veterinarian.

H. The total gross number of square feet in each animal facility, the species of animals housed therein and the average daily inventory, by species, of animals in each facility are indicated in the attached table.

I. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use are:

Assistance or instruction in the humane care and use of laboratory animals will be provided to anyone requesting same or to anyone that the AWC identifies as lacking the necessary experience to handle laboratory animals or to conduct animal experiments in accordance with the Guide. The assistance or instruction will be provided by qualified members of the AWC, the AWC veterinarian, vivarium director, senior animal technicians, or faculty resource personnel.

As proposals are reviewed, the AWC will make recommendations, where appropriate, for the consideration of alternatives to in vivo studies and testing methods or alternate experimental designs that would minimize the number of animals required to obtain valid results and minimize animal distress.

IV. Institutional Status

As specified in the PHS Policy at IV.A.2 as Category 2, all of this institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the AWC and will be reevaluated by the AWC at least once every six months. The AWC has and will continue to use the Guide as a basis for evaluating the institution's programs and facilities. The report of the AWC evaluation has been submitted to the the Dean of Research and Graduate Programs and a copy of the report is attached. The report contains a description of the nature and extent of this institution's adherence to the Guide. Any departures from the Guide are identified specifically and reasons for each departure are stated. Where program or facility deficiencies are noted, the report contains a reasonable and specific plan and schedule for correcting each deficiency. The report distinguishes significant deficiencies from minor deficiencies. Semi-annual reports of the AWC evaluation submitted to the Institutional Official (Dean of Research and Graduate Programs) will also contain a reasonable and specific plan and schedule for correcting each deficiency and distinguish significant deficiencies from minor deficiencies. Semi-annual reports of the AWC will be maintained by this institution and made available to OPRR upon request.

V. Recordkeeping

A. This institution will maintain for at least three years:

1. A copy of this assurance and any modifications thereto, as approved by PHS.
2. Minutes of AWC meetings, including records of attendance, activities of the committee, and committee deliberations.
3. Records of applications, proposals and proposed significant changes in the care and use of animals and whether AWC approval was given or withheld.
4. Records of semi-annual AWC reports and recommendations as

forwarded to the Dean of Research and Graduate Programs.

5. Records of accrediting body determinations.

B. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the AWC for the duration of the activity and for an additional three years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OPRR or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

A. At least once every 12 months, the AWC, through the Institutional Official, will report in writing to the Office for Protection from Research Risks (OPRR):

1. Any change in the status of the institution (e.g., if the institution becomes accredited by AAALAC or AAALAC accreditation is revoked), any change in the description of the institution's program for animal care and use as described in this assurance (e.g., changes in lines of authority or responsibility of the veterinarian(s) and percentage of time devoted to the program by the veterinarian(s), AWC procedures, occupational health program, training program, number of species of animals, and size of facilities where animals are housed), or any changes in AWC membership. If there are no changes to report, this institution will submit a letter to OPRR stating that there are no changes.

2. Notification of the date that the AWC conducted its semi-annual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to the Dean of Research and Graduate Programs.

B. The AWC, through the Institutional Official, will provide the OPRR promptly with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS Policy.

2. Any serious deviations from the provisions of the Guide.

3. Any suspension of an activity by the AWC.

C. Reports filed under VI.A.2 and VI.B. above shall include any minority views filed by members of the AWC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official

Name: -----
Title: -----
Address: -----

Phone: -----

Signature: -----

B. PHS Approving Official

Name: -----
Title: -----
Address: -----

Phone: -----

Signature: -----

C. Effective date of assurance: -----

D. Expiration date of assurance: -----