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POLICY ON THE USE OF ANIMALS IN RESEARCH AND TEACHING

I. SCOPE

This policy governs University of California, San Diego (UCSD) research, teaching, and service activities involving animals when conducted by University faculty, staff, or students or when using University facilities or equipment.

II. COMMITMENT AND GUIDING PRINCIPLES

UCSD recognizes the importance of the use of animals in its research and teaching programs. Animals are vital both for understanding basic biological processes and in developing treatment for human and animal diseases. UCSD, being committed to maintaining high standards for the care and use of animals in research and teaching, adopts as its own the 'U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training'. UCSD, including its principal investigators and other researchers, accepts responsibility for determining that research and teaching involving the use of animals fulfills these principles.

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training:

"The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires *in vivo* experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:

- I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal laws, guidelines, and policies.
- II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and *in vitro* biological systems should be considered.
- IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

Effective: 6/20/2006

Supersedes: 1/17/86

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- VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must 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. In any case, veterinary care shall be provided as indicated.
- VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
- IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.”

UCSD has based its policies on and fully adheres to all of the following: the Animal Welfare Act as Amended (7 USC, 2131-2159), Code of Federal Regulations, Title 9, Chapter 1, Subchapter A - Animal Welfare; the Institute for Laboratory Animal Research, National Research Council, *Guide for the Care and Use of Laboratory Animals*; the Public Health Service Policy on Humane Care and Use of Laboratory Animals; the Health Research Extension Act of 1985, Public Law 99-158; the Endangered Species Act; the Fish and Wildlife Act; the Report of the AVMA Panel on Euthanasia 2000; and all applicable state and local regulations (see: V. References).

UCSD fully adheres to all UC systemwide policies including the University Policy on the Use of Animal in Research and Teaching 10/15/84 and the UC Research Administration Office Contracts and Grants Manual 1/1/96 sections 18-400 through 18-466.

The University Policy on the Use of Animal in Research and Teaching states that “ facilities in which animals are housed shall be fully accredited by the American Association for the Accreditation of Laboratory Animal Care (AAALAC) or the Chancellor, Vice President, or Director shall take appropriate action to achieve such accreditation.”

III. AUTHORITY

A. Institution (UCSD)

The authority to operate an animal care and use program is derived from the State of California as part of the University of California (UC) mission, with the delegated line of authority going through University of California Office of the President to each individual UC campus. The Chancellors of the campuses, the Directors of the Department of Energy Laboratories, and the Vice President Agriculture and Natural Resources have the authority for their respective institution. The UCSD Chancellor is authorized to maintain a campus animal care and use program and to take appropriate action for those activities under his/her jurisdiction to implement regulations required by all funding and regulatory agencies on the care and use of animals in research and teaching.

Effective: 6/20/2006

Supersedes: 1/17/86

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B. Institutional Official (IO)

At the University of California, San Diego, the Chancellor has delegated the responsibility as Institutional Official to the Vice Chancellor for Research (VCR). The VCR has the legal, administrative and operational authority to commit institutional resources to ensure compliance with the PHS policy and other requirements. The VCR signs UCSD's PHS Assurance, making a commitment on behalf of the institution that the requirements of this Policy will be met.

C. Institutional Animal Care and Use Committee and Animal Welfare Program

The UCSD Institutional Animal Care and Use Committee (IACUC) derives its authority from federal law. These committees are mandated by the Health Research Extension Act (HREA) of 1985 and the Animal Welfare Act. The UCSD Institutional Animal Care and Use Committee is appointed by the Vice Chancellor for Research.

The IACUC, by law, has authority to approve, require modifications before approval, or withhold approval of proposals submitted to it for review. No activity involving animals can begin unless it is first approved by the IACUC. The IACUC has the authority to suspend animal research activities; the IACUC's authority to review and approve protocols is independent of the Institutional Official, who may not overrule an IACUC decision to withhold approval of a protocol.

The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the *Guide for the Care and Use of Laboratory Animals* (the "Guide"), the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.

The UCSD IACUC has the authority to gain access to all facilities used for the care and research of animals and to obtain any records and other relevant information related to the use of animals.

The Animal Welfare Program, through its Director and Compliance Officers is given the authority to act as the agent of the IACUC to conduct unannounced laboratory, satellite facility, and animal facility inspections on behalf of the IACUC, to perform compliance sanctions as authorized by IACUC Policy 11.02, to file required reports to governmental and accrediting agencies on behalf of UCSD, and act as the administrative agency in all matters prescribed by federal law to the IACUC.

D. Attending Veterinarian (Campus Veterinarian) and Animal Care Program

The Attending Veterinarian derives authority from federal legislation, University Policy and IACUC Policy. Federal regulations place authority for the veterinary care program with the attending veterinarian and require the institution (UCSD) to assure the attending veterinarian has appropriate authority and resources to ensure the provision of adequate veterinary care. The provision of care for animals at UCSD is placed under the authority of the UCSD Campus Veterinarian, who reports directly to the UCSD Institutional Official. Federal regulations mandate that the attending veterinarian be appointed as a voting member of the IACUC.

Effective: 6/20/2006

Supersedes: 1/17/86

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The Attending Veterinarian must have unrestricted access to all areas where animals are used or housed (including the vivarium, research laboratories, and research study areas).

The Attending Veterinarian has full authority to treat, suspend and activity, or humanely euthanize animals at his or her discretion. Ideally, this will be done after consultation with the Principal Investigator or responsible members of the research team. However, the attending veterinarian is not required to seek approval from the investigator, the investigator's department chair, or the IACUC in order to treat, suspend and activity, or euthanize animals for humane reasons if such actions are judged prudent by the veterinarian for the welfare of the animal.

The provision of animal care (all basic and extended requirements to provide for the health and well-being of animals) at UCSD is delegated to a centralized department (Animal Care Program) directed by the attending veterinarian, which allows UCSD to meet all applicable regulatory requirements relating to the care and use of animals in research, teaching and testing.

IV. RESPONSIBILITIES

A. Institution (UCSD)

It is the responsibility of the University of California, San Diego (Chancellor's office) to maintain an effective Animal Care and Use Program to support the University's mission of teaching, research and service. The responsibility for compliance with federal, state, county and University regulations also rests with the Chancellor. The UCSD Chancellor has delegated the institutional official responsibilities to the Vice Chancellor for Research (VCR).

B. Institutional Official (VCR)

The VCR, as Institutional Official, has operational responsibility for animal research and teaching and the VCR carries out this responsibility through the centralized Animal Care Program. Compliance with federal, state, county, or University regulations concerning activities involving the care and use of animals is also the delegated responsibility of the VCR, who carries out this responsibility through the IACUC, the Animal Welfare Program, and the Animal Care Program.

The Institutional Official shall ensure compliance with applicable laws, guidelines, and policies; appoint IACUC members and the IACUC chair; perform all necessary reporting requirements; report to the appropriate federal and University officials any serious or continuing noncompliance with applicable laws and policies and any corrective action taken; consult with the Office of the General Counsel in carrying out these responsibilities as appropriate; and participate in monthly meetings of the IACUC and Executive Subcommittee and effectively support the IACUC and the Animal Care and Use Program.

C. Institutional Animal Care and Use Committee (IACUC)

The Committee is responsible for oversight and evaluation of the Animal Care and Use Program and its components described in *The Guide for the Care and Use of Laboratory Animals*. Its functions include inspection of facilities, evaluation of programs and animal-activity areas, submission of reports to responsible institutional officials, review of proposed use of animals in research, testing, or education (i.e., protocols), and maintenance of a mechanism for receipt and review of concerns involving the care and use of animals at the institution.

Effective: 6/20/2006

Supersedes: 1/17/86

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The IACUC must meet as often as necessary to fulfill its responsibilities, but it should meet at least once every month. Records of committee meetings and of results of deliberations are maintained. The committee must review the animal care and use program and inspect the animal facilities and activity areas at least once every 6 months. After review and inspection, a written report, signed by a majority of the IACUC is provided to the Institutional Official on the status of the animal care and use program and other activities as stated and as required by federal, state, or local regulations and policies. Protocols are reviewed in accord with the *Animal Welfare Regulations, Public Health Service Policy, U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (IRAC 1985)*, and *The Guide for the Care and Use of Laboratory Animals*.

The responsibilities of the UCSD IACUC are to review, at least once every 6 months, the research facility's program, using USDA Regulation/Guide as basis; inspect, at least once every 6 months, all of the animal facilities, including animal study areas/satellite facilities, using USDA Regulations/Guide, as basis; prepare reports of IACUC evaluations and submit the reports to the Institutional Official; review and investigate legitimate concerns involving the care and use of animals at the research facility resulting from public complaints and from reports of non-compliance received from facility personnel or employees; make recommendations to the Institutional Official regarding any aspect of the research facility's animal program, facilities or personnel training; review and approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities related to the care and use of animals; review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities; and suspend an activity involving animals when necessary; take corrective action and report to funding agency and USDA.

D. Campus Veterinarian (Attending Veterinarian)

The animal care program is the responsibility of the Campus Veterinarian (also called the Campus Veterinarian or CV), who must be certified by ACLAM, or have equivalent training or experience in laboratory animal science and medicine in the care of the species being used. The CV must be appointed as a member of the UCSD IACUC. The CV directs the Animal Care Program) which is the means by which the responsibilities of the campus veterinarian are met. Additionally, the CV serves as a member of the IACUC and Institutional Biosafety Committees.

The Campus Veterinarian is responsible for supervision of the following components of the UCSD Animal Care Program: animal environment; animal housing; behavioral management; animal husbandry; population management; animal procurement and transportation; preventative medicine; surveillance, diagnosis, treatment, and control of disease (including zoonosis control); management of research-associated disease, disability, or other sequelae; anesthesia and analgesia, surgery and postsurgical care, assessment of animal well-being; euthanasia, and other aspects of animal care as specified in the Animal Welfare Act and the Guide for the Care and Use of Laboratory Animals.

Effective: 6/20/2006

Supersedes: 1/17/86

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The Campus Veterinarian must provide guidance to investigators and personnel involved in the care and use of animals to ensure appropriate handling, immobilization, sedation, analgesia, anesthesia, and euthanasia. The CV must provide guidance or oversight to surgery programs and provide oversight of post-surgical care. The CV (or his/her delegate) must review all protocols prior to the initiation of any project or activity involving laboratory animals. The CV (or his/her delegate) must provide a program of preventative health care and an adequate program of emergency health care for all animals including weekends, holidays, and after hours.

E. Animal Care Program (ACP)

The Animal Care Program is the central campus organization, under the direction of the CV, and is responsible for assuring adequate animal housing, environment and management, physical environment, behavioral management, husbandry, population management, physical plant, veterinary medical care, animal procurement and transportation, oversight of surgery, anesthesia, analgesia, and euthanasia, animal records, and personnel training.

Per Title 9 C.F.R., Chapter 1, Subchapter A - Animal Welfare, the program must establish and maintain appropriate methods to control, prevent, diagnose, and treat diseases and injuries; weekend, holiday, and emergency care must be readily available; assure daily observation of all animals to assess their health and well-being; provide guidance to the principal investigator, and other personnel, involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia; assure adequate pre- and post- procedural care in accordance with current established veterinary medical and nursing procedures.

F. Animal Welfare Program (AWP)

The AWP is the office of record for the IACUC at UCSD and provides the means by which the responsibilities of the IACUC are met. The AWP Director serves as the advisor on animal welfare and regulatory matters at UCSD and reports to the Vice Chancellor for Research.

The Animal Welfare Program is responsible for filing all regulatory documents on behalf of the Institutional Official and the IACUC as required by law; coordinating the Animal Use Protocol review process and maintaining records as required by law; reviewing personnel qualification applications and identifying training needs; conducting animal use protocol audits; conducting the mandatory training for personnel working with animals; acting as the UCSD liaison with regulatory and accrediting agencies; and managing campus-wide compliance programs to ensure compliance with federal, state, county and UCSD animal welfare regulations.

G. Department Chairs, ORU Directors and Deans

Department Chairs and ORU Directors are responsible for the following: ensuring that all activities involving the use of animals in research and/or training within his/her department or center have been reviewed and approved by the IACUC prior to the use of any animals; reporting to the Vice Chancellor for Research (VCR) the failure of a faculty member to obtain prior review and approval before commencing research on or use of animals; reporting to the IACUC that a faculty or staff member has failed to carry out animal research responsibilities; requiring that each Principal Investigator has complied with all institutional conflict of interest rules and regulations; and advising the Animal Welfare Program office within five working days of the termination of any appointment of a Principal Investigator.

Effective: 6/20/2006

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In addition, by approving with their signature on research or training grant proposals, Department chairs, ORU directors and Deans ensure that adequate space, resources and supplies are available, or will be made available, for the conduct of the proposed efforts, and that the investigator is eligible and competent to perform or supervise the research.

Department chairs, ORU directors and Deans with administrative jurisdiction over laboratories where animals are being used for IACUC-approved research or training purposes, are ultimately responsible for the proper care and use of the animals in those facilities. To this end, each Department chair, ORU director or Dean should work closely with the Campus Veterinarian and the Animal Care Program staff.

H. Principal Investigators

Principal Investigators agree to the following "Investigator Assurances" at the time of animal protocol submission and whenever animals are used in teaching, research or testing at the University of California San Diego:

Agree to abide by PHS Policy, USDA Regulations, UCSD policies for the care and use of animals, the provisions of the ILAR Guide to the Care and Use of Laboratory Animals, and all other federal, state, and local laws and regulations governing the use of animals in research.

Agree that emergency veterinary care will be administered to animals showing evidence of pain or illness, in addition to routine veterinary care as prescribed for individual species; understand that it is the PI responsibility to provide current and updated emergency contact information for personnel who must be contacted in an animal emergency; understand that any unanticipated pain or distress must be reported to the veterinarian or his/her designee.

Agree to consult a veterinarian in the preparation of any protocol that includes procedures that could cause pain and distress to a vertebrate animal.

Assure that all experiments involving live animals will be performed under PI supervision or that of another qualified biomedical scientist listed on the protocol.

Certify that all personnel having direct animal contact, including PI, have been trained in humane and scientifically acceptable procedures in animal handling, administration of anesthetics, analgesics, and euthanasia to be used in the project.

Certify that all personnel in the project will attend the mandatory Orientation to Research at UCSD class and all other mandatory classes as determined by the Personnel Qualifications Form of each individual.

Agree that the use of hazardous agents in animals may only be initiated after approval from EH&S.

Agree that all personnel working on the protocol will be given the opportunity to participate in the Medical Monitoring Program at the Center for Occupational and Environmental Medicine (COEM) and that all personnel on the protocol will be made aware of the hazards involving the use of live animals and tissues.

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Agree to submit an amendment for any proposed changes to this protocol and wait for IACUC approval before beginning the work.

Agree that should the PI use the project described in the protocol as a basis for a proposal for funding (either extramural or intramural), it is the PI responsibility to ensure that the description of animal use in such funding proposals is identical in principle to that contained in the animal use protocol.

Agree that it is the responsibility of the Principal Investigator to ensure the safe and ethical conduct of all research conducted under this protocol, and to assure that all research is carried out following federal, state, local, and UCSD policies governing animal research.

Agree to maintain complete, up-to-date and accessible records of procedures on animals as required by policy and regulation.

I. Faculty, staff, students, volunteers

All faculty, staff, students and volunteers who handle, observe, or use animals in teaching testing or research at UCSD must be appropriately qualified or supervised for conducting procedures on animals; participate in required training and receive required certification of training; participate in Risk Assessment Questionnaire for Employees with Animal Contact and (as required) the Medical Monitoring Program at the Center for Occupational and Environmental Medicine (COEM); abide by and carry out the decisions of the IACUC; treat all animals with respect, in a humane and responsible manner.

J. UCSD Occupational Health and Safety Program for Animal Research Workers

Federal regulations require that the Institutional Occupational Health and Safety Program must be integrated with the overall animal care and use program (CDC and NIH 1993; CFR 1984a,b,c; PHS Policy). The program must be consistent with federal, state, and local regulations and should focus on maintaining a safe and healthy workplace. The program should follow the most current recommendations of the National Research Council publication Occupational Health and Safety in the Care and Use of Research Animals. The program must have strong central administrative support and strong interactions among several institutional functions, including the research program (as represented by the investigator), the animal care and use program (as represented by the campus veterinarian and the IACUC), the Environment Health and Safety program, occupational health services (COEM), and the administration (e.g., human resources, finance, and facility-maintenance personnel).

K. Center for Occupational and Environmental Medicine (COEM)

The services which must be provided by the Center for Occupational and Environmental Medicine (COEM) for the UCSD campus include the following:

- 1. Risk surveillance.** Review the Risk Assessment Questionnaire for Employees with Animal Contact and assignment of employees to Medical Surveillance as appropriate.
- 2. Medical consultation.** Conduct consultations, including a physical exam and assessment of health risks associated with an employee's animal exposure and medical work history. Consultations will be conducted no less than every three years for employees required to participate in medical surveillance.

Effective: 6/20/2006

Supersedes: 1/17/86

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3. **Serum banking or testing.** Collect, store and test serum as is determined necessary by the clinician.
4. **Tuberculosis Testing.** Perform skin tests or chest radiography as prescribed by the COEM clinician.
5. **Vaccinations.** Offer tetanus, rabies, or other vaccinations as recommended by the COEM clinician.

L. **Environment, Health and Safety (EH&S)**

Professional EH&S staff must assess each animal protocol containing hazardous biologic, chemical, or physical agents (including ionizing and nonionizing radiation). These staff members should be qualified to assess dangers associated with the programs and to select safeguards appropriate to the risks. The occupational health and safety program must ensure that the risks associated with the experimental use of animals are reduced to acceptable levels. Potential hazards - such as animal bites, chemical cleaning agents, allergens, and zoonoses - that are inherent in or intrinsic to animal use should also be identified and evaluated.

EH&S specialists with knowledge in appropriate disciplines should be involved in the assessment of risks associated with hazardous activities and in the development of procedures to manage such risks, including providing appropriate signage, training, and assignment of appropriate personal protective equipment. The extent and level of participation of personnel in the occupational health and safety program should be based on the hazards posed by the animals and materials used; on the exposure intensity, duration, and frequency; on the susceptibility of the personnel; and on the history of occupational illness and injury in the particular workplace. Environment, Health and Safety staff will operate a campus wide hearing protection and respiratory protection program which includes all animal research workers.

The occupational health and safety program for animal research workers requires active participation not only by Environmental Health & Safety, but also the Principal Investigator, the Animal Care Program, the IACUC, and COEM.

M. **Office of Contract and Grant Administration (OCGA)**

The OCGA (or Health Sciences Project Pre-award Office or SIO pre-award offices) shall review all research proposals submitted for extramural support to determine their conformance with University and funding agency policies. OCGA will verify that applications and proposals submitted that involve the care and use of laboratory animals shall contain the requirements as stated in PHS Policy. OCGA shall advise research investigators of the status of their respective proposals and designated agency policy on the humane care and use of animals.

OCGA shall forward a copy of the Request for Extramural Support (RES) and the proposal to the Institutional Animal Care and Use Committee/Animal Welfare Program and to the Animal Care Program prior to awarding funding for those projects. OCGA shall require IACUC/AWP verification of animal protocol approval prior to awarding funds.

