

**SAN JOSE STATE UNIVERSITY  
ONE WASHINGTON SQUARE  
SAN JOSE, CA 95192**

**S14-6, University Policy, Policy and Assurance for Humane Care and Use of Animals at San José State University**

**Legislative History:**

**Rescinds University Policy F06-4**

At its meeting of April 28, 2014, the Academic Senate approved the following policy recommendation presented by Senator Gleixner for the Curriculum and Research Committee. SJSU needs a current, comprehensive policy assuring the humane care and use of laboratory animals and animals in the field that is in accordance with federal guidelines.

**Action by University President:**                      **Approved and signed by  
President Mohammad Qayoumi  
on April 30, 2014**

**University Policy:  
Policy and Assurance for Humane Care and Use of Animals at  
San José State University**

- Whereas:                      San José State University recognizes the need to address ethical issues concerning the care and use of animals for University activities; and
- Whereas:                      San José State University must have a current, comprehensive policy assuring the humane care and use of laboratory animals and animals in the field; and
- Whereas:                      That policy must be in accord with current Federal guidelines; and
- Whereas:                      That policy should indicate clearly how animal activities are to be organized and conducted, what procedures are to be followed, what individual responsibilities are with regard to the care and use of animals, and what University committee oversees the humane care and use of animals; now therefore be it
- Resolved:                      That F06-4 be rescinded, and be it further

Resolved: That the attached policy and assurance for humane care and use of animals at San José State University be implemented.

Approved (C&R): 11-0-0

Vote: April 7, 2014

Present: Buzanski, Cheruzel, Desalvo, Gleixner (Chair), Hart, Jaehne, Kohn, Schultz-Krohn, Sibley, Stacks, Trulio

Absent: Swanson, Sujitparapitaya

Workload Impact: There are no anticipated additional workload impacts from the revisions in this policy, relative to the existing University policy.

Financial Impact: There are no anticipated additional financial impacts from the revisions in this policy, relative to the existing University policy.

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POLICY AND ASSURANCE FOR HUMANE CARE AND USE OF ANIMALS AT  
SAN JOSE STATE UNIVERSITY

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1.0 Preamble.

Ethics and the Care and Use of Animals at San José State University

San José State University (SJSU) recognizes this policy as its reference for the humane care and use of animals and for addressing ethical concerns in discussions, evaluations and policy matters regarding the care and use of animals by all individuals at SJSU and its affiliates.

SJSU acknowledges the public debate about the legitimacy, importance and relevance of the ethics of animal care and use. We recognize that within this debate there are a number of legitimate and responsible perspectives, concerns and unresolved issues that are expressed in various ways. We, therefore, commit ourselves to be a respectful and responsible party within this on-going public debate.

SJSU recognizes the relevance, value and significance of the ideals of the humane treatment of animals as part of conducting sound scientific research and quality teaching. Therefore, we commit ourselves to actively seek satisfactory means that do not entail the use of animals; employ ways that minimize the number of animals used; minimize physical and psychological discomfort to the animal; and minimize the extent of euthanasia entailed in our work.

SJSU holds that among the sources of our ethical responsibilities in the care and use of animals are the relationships we have with the other members of the animal kingdom, and the life that we hold in common with them. Therefore, we view our role in the care of animals to be one of stewardship, which includes the responsibility to actively assess and meet the needs of animals in our charge and to provide for their comfort. We view

our role in all instances of animal use to be one that must reflect a deep sense of humility. Our corresponding responsibilities must include efforts to seek and employ methods that embody respect for the life of individual animals and reverence for life itself.

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## 2.0 Purpose.

When animals are used for academic activities at SJSU, every effort will be made to ensure that our faculty, staff, and students understand the ethical and scientific obligations with respect to their care and use. This policy sets forth procedures, guidelines, and standards by which the University and its affiliates shall ensure compliance with all respective government statutes and University expectations with regard to the care and use of laboratory animals.

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## 3.0 Definitions.

3.1 Animal refers to any live or dead non-human vertebrate species that is acquired, utilized or held for intended use in an academic activity, which includes the utilization of animal blood or tissues. Non-living animal tissues covered by this policy include, but are not limited to hair, bone, feathers, scales, teeth, excrement, boluses or secretions.

3.1.1 Operationally, this policy pertains to the care and use of vertebrate animals. In addition, SJSU affirms that the purview of this policy may extend to the use of select invertebrate species as described in *Section 6.5* of this policy.

3.2 Activity refers to any University supported project, whether it is publicly or privately funded, involving the use of animals for purposes of research, field study, experimentation, teaching, demonstration, training, testing, exhibition, artistic display, or related academic purpose.

3.3 Handling refers to the physical care, feeding, holding, petting, capture, dosing, sampling, disturbance, dispatch, breeding, baiting, release, transport, immobilization, dissection, treatment, training, or related interaction with an animal.

3.4 Facility refers to any and all buildings, laboratories, rooms, spaces, enclosures, land, vessels or vehicles under the administrative control of SJSU or designated sites at off-campus locations used to support animal-related activities.

3.5 Personnel refers to any SJSU faculty member, research affiliate, employee, volunteer, staff, administrator, permit holder, contractor, or student who is involved with the handling of an animal.

3.6 Protocol refers to the complete written description of an activity, including all permits, attachments and amendments as approved by the Institutional Animal Care and Use Committee.

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#### 4.0 Policy Oversight and Individual Responsibilities.

4.1 Humane care and treatment of animals used in higher education; whether for research or instruction, the arts or sciences, is a university-wide responsibility. It is the policy of SJSU to comply with federal, state, and other regulatory requirements that pertain to the acquisition, care, and treatment of laboratory animals. Therefore, in order to ensure proper implementation of this policy, areas of responsibility are hereby designated to personnel directly engaged in activities involving animals and University officials identified herein.

4.2 As CEO, the University President is responsible to provide the public assurance that all animals associated with legitimate academic activities are being treated in accordance with government standards. The University President is charged with the overall administrative responsibility for ensuring that the institution's animal care and use program meets all legal requirements and humane standards.

4.3 Institutional Official. The University President designates the Associate Vice President for Graduate Studies and Research as the Institutional Official with the responsibility to oversee and administer the institution's program of animal care and use. The Institutional Official will have the administrative and operational authority to: 1) allocate University resources to ensure that the animal care and use program complies with all applicable laws and policies; and 2) define and assign responsibilities and reporting channels essential to the animal care and use program.

4.3.1 The Institutional Official will rely on the Institutional Animal Care and Use Committee (IACUC), Campus Veterinarian, and the Dean of the College of Science (or other individual as designated by the University President) to: 1) oversee the institution's animal care program and facilities; 2) to develop plans and timeline to correct program deficiencies; and 3) respond to reported concerns that may arise concerning the institution's care and use of laboratory animals.

4.3.2 The Institutional Official will have the responsibility and authority to sign correspondence with outside agencies making a commitment on behalf of the University as it pertains to the animal care and use program, and will promptly notify the appropriate agencies, as required, if the IACUC suspends an ongoing activity or there is a serious violation of the Public Health Service Policy on the Humane Care and Use of Laboratory Animals or the Laboratory Animal Welfare Act.

4.3.3 The University President shall act as the Institutional Official if his/her designee is unavailable. In such instances, the Office of the President shall generate a memo to the IACUC Chair indicating that the University President shall assume the role as Institutional Official with the authority to sign all related documents under this role until any further change in designation is indicated in writing. The University President shall promptly notify all Federal agencies of any change in designation of the Institutional

Official as required.

4.4 Campus Veterinarian. The University President shall appoint one Doctor of Veterinary Medicine with the appropriate training, certification and experience in laboratory animal science and medicine who will have direct responsibility for the health and welfare of animals associated with any University supported activity. Responsibilities include monitoring animal health and welfare, routine clinical assessments of the animal colonies, treating illness or injury requiring veterinary medical care, laboratory diagnosis and necropsy when required, and maintaining the institution's Program of Veterinary Care (PVC). The institution's PVC shall describe standard veterinary practices for the acquisition, housing, stabilization, and quarantine of newly introduced species; colony surveillance and preventative medicine schedules; veterinary enrichment program; selection and utilization of suitable analgesic, anesthetic and tranquilizing agents in laboratory animals; proper performance of surgical procedures and perioperative care of laboratory animals; and methods of euthanasia.

4.4.1 To ensure the health and welfare of laboratory animals and personnel at the University and at satellite locations, the Campus Veterinarian will have unlimited access to all facilities with due respect for the demands of work in progress. Additionally, the Campus Veterinarian will be authorized to coordinate consults and/or contracts with veterinary specialists on an as needed basis to ensure adequate veterinary care is provided for all species associated with the program.

4.4.2 The Campus Veterinarian will report directly to the Institutional Official and have the authority to halt any activity involving animals when the health or welfare of the animals or personnel involved is deemed to be inappropriately in jeopardy, including those activities approved by the Institutional Animal Care and Use Committee, until the appropriate review or action has been taken by the IACUC.

4.5 Institutional Animal Care and Use Committee [IACUC]. The IACUC is an administrative committee appointed by the University President (or his/her designee) responsible to ensure adequate review and oversight of all activities, facilities, and programs related to the care and use of laboratory animals within the jurisdiction of San José State University. The IACUC derives its authority from Federal law and is required to: 1) review and approve all animal activities, including modifications to an approved animal care and use protocol, prior to commencement of the project or modification thereto; 2) review at least once every six months the institution's animal care and use program; 3) inspect at least once every six months all the institution's animal facilities (including satellite locations); 4) prepare and submit reports of the IACUC semiannual evaluations to the Institutional Official describing the nature and extent of the institution's adherence to all applicable regulations and policies governing animal care and use; 5) review and investigate reported concerns of non-compliance involving the care and use of animals at the institution or its affiliates; and 6) have the authority to suspend activities that involve the use animals.

4.5.1 The IACUC is required to notify the US Department of Agriculture (USDA) and/or the Office of Laboratory Animal Welfare (OLAW), through the Institutional Official, within fifteen business days of the institution's failure to adhere to time tables presented for corrective action on significant deficiencies noted in the institution's Animal Care Program or its facilities.

4.6 The Dean of the College of Science (or other individual as designated by the Institutional Official) will report directly to the Institutional Official and is charged with overseeing the institution's Animal Care Facilities (ACF), ACF support staff, and repository of records in the Animal Care department office. Record keeping responsibilities shall include maintaining: 1) minutes of IACUC meetings, including records of attendance; 2) complete records of application submissions, active animal use protocols, and proposed significant changes to animal use protocols, indicating whether IACUC approval was granted or withheld, for a minimum of three years upon completion of the activity; and 3) internal and external inspection reports or oral/written communications with governmental representatives concerning the institution's animal care program. All records shall be accessible for audit and copying by authorized government officials at reasonable times and in a reasonable manner.

4.7 Animal Care Facility Operations Manager [ACFOM] will have the appropriate veterinary training, certification and/or experience in laboratory animal science and is charged with overseeing the day-to-day activities of the ACF and all animals resident therein. The ACFOM will: 1) provide adequate veterinary care to all animals as directed by a veterinarian; 2) coordinate requests with investigators for the procurement, receipt, housing, care, utilization and transfer of live animals; 3) be responsible for implementing professionally acceptable standards for the proper care and use of animals within the animal care facility, and ensuring that those standards are being met; 4) organize and maintain documents related to animal care and use including: animal use protocol descriptions, all IACUC-related business, and correspondence with government agencies; 5) serve as the IACUC coordinator, whereas investigators will coordinate protocol activity requirements through the ACFOM who will keep the IACUC informed; 6) be available to escort inspectors for internal and external audits of the institution's animal care facilities and program as required; and 7) provide veterinary support, resources and training to the campus community as approved by the IACUC.

4.8 The Principal Investigator [PI] of an activity is charged with ensuring and maintaining compliance with this policy as a lead for each activity. PIs are: 1) responsible for overseeing laboratory operations and experiment conditions; 2) considered the protocol director to ensure that all IACUC requirements and safety recommendations are being met; 3) directly responsible for animal welfare associated with their approved protocol; and 4) to verify adequate procedural knowledge and practical skill of all personnel under their direction related to the care and use of laboratory animals.

4.9 Reporting Animal Welfare Concerns. Any person may report, anonymously or otherwise, concerns related to animal care and use at San José State University or

Moss Landing Marine Laboratories by contacting the IACUC Coordinator, the Campus Veterinarian, or the IACUC Chair. Contact numbers for reporting concerns shall be prominently posted on the IACUC website and in common areas where animals are housed or used. No individual shall be discriminated against or be subject to any reprisal for reporting violations of federal law or any requirement set forth by way of this policy or as indicated under individual protections under institutional whistleblower policies.

4.9.1 The IACUC will promptly investigate all reported animal welfare concerns or complaints of non-compliance with institutional policies that involve the care and treatment of animals at SJSU or its affiliates. Any reported animal welfare concern will be promptly investigated and reviewed by the Institutional Official, the Campus Veterinarian, and the IACUC Chair (or IACUC subcommittee, as deemed appropriate by the Institutional Official). Results of complaint investigations shall be immediately reported to the IACUC in writing. The IACUC may consider a wide variety of actions following such an investigation, including suspension of the activity and termination of an approved protocol. When requested, the IACUC shall follow up with the individual/s that relay concerns related to animal care and use with relevant details of investigation findings.

4.10 The IACUC shall be authorized to take any action deemed necessary at a convened meeting by a majority vote of a quorum of its membership to ensure that an activity involving animals is being conducted in the manner it was approved. Personnel who, in their use of animals, fail to adhere to IACUC requirements are subject to suspension of animal activities by IACUC and referral to the Institutional Official for appropriate action.

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## 5.0 Principles for the Use of Animals.

5.1 Procedures involving the use of animals shall be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society. For all activities, the project purpose, study objective and experimental design shall be clearly defined and justified by the PI to yield useful results, not practically obtainable without the use of animals.

5.2 Animals selected for an activity shall be of an appropriate species and quality and minimum number required to obtain valid results. Each animal use protocol must adequately address: *replacement* (use of inanimate models and methods such as computer simulation and *in vitro* biological systems); *reduction* (statistical justification and/or scientific support of animal numbers associated with an activity); and avoidance of *unnecessary duplication of experiments* in research and curriculum.

5.3 Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain where consistent with sound scientific practices, is imperative (*refinement*). Unless the contrary is established, investigators shall consider that



procedures known to cause pain or distress in human beings may cause pain or distress in other animals.

5.4 Procedures with animals that may cause more than momentary or slight pain or distress shall be performed with appropriate sedation, analgesia, or anesthesia whenever possible. A qualified veterinarian shall evaluate and provide investigators input on the clinical, surgical, and technical aspects of an activity or procedure known to cause more than momentary or slight pain or distress to an animal. Confirmation of veterinary consult shall be clearly documented in the animal care and use protocol for such activities.

5.4.1 If a procedure or manipulation is likely to cause greater discomfort than the attending anesthetization, the animals must first be rendered incapable of perceiving pain and be maintained in that condition until the experiment or procedure is ended. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly dispatched at the earliest, most appropriate time. The PI or personnel in charge of the activity must be prepared to terminate the study whenever s/he believes that its continuation may result in undue or unnecessary injury or suffering to the animal as a humane endpoint.

5.5 The living conditions of animals shall be appropriate for their species and contribute to their health and comfort. The housing, feeding and care of all animals will be directed by the Campus Veterinarian or designee qualified and experienced in the species of interest. When appropriate every effort shall be made to provide physical and psychological enrichment unless to do so would negatively impact the study objective. Standards for the construction, sanitation and use of housing, service, and surgical facilities shall meet those described by all applicable federal regulations and guidelines for the care and use of laboratory animals.

5.6 All animals shall have access to adequate veterinary care, including off-hours, weekends, holidays and campus closures as dictated by the Campus Veterinarian. Animals shall be monitored at appropriate intervals which are dictated by the species, the nature of the intervention, the degree and duration of post procedural pain, distress or discomfort, and possible complications. During monitoring, animals shall be evaluated for the presence of pain, distress or discomfort whereas the criteria are based upon normal behavior patterns for that species.

5.7 Activities involving the care and use of animals must be led and supervised by a qualified faculty member or the Campus Veterinarian (identified as the Principal Investigator), and performed by personnel who are properly trained and experienced. Training and instruction shall be made available through the University Animal Care department and the qualifications of personnel reviewed by the IACUC with sufficient frequency to fulfill individual responsibilities as described in the animal use protocol.

5.8 The conduct of all animal-related activities shall be done utilizing current veterinary practices consistent with acceptable scientific and institutional standards. Additionally,

any ancillary scientific collection and special use permission or site access requirements related to an animal activity must be revealed to and approved by the IACUC.

5.9 All drugs, medical materials, feed and supplements for laboratory animals must be appropriately stored and be kept in-date. All facilities shall be routinely monitored for expired product, which must be properly segregated or promptly disposed of. Veterinary drugs shall be of pharmaceutical grade whenever possible and those drugs used for experimental procedures, anesthesia, analgesia, euthanasia, and emergency care must never be used beyond their expiration date. The use of non-pharmaceutical grade compounds or expired materials for terminal procedures must first be revealed to and approved by the IACUC to determine that the use of such a product will not adversely affect the animal's well-being or compromise the validity of the study.

5.10 All aspects of animal confinement, restraint, movement and transport must be revealed to and approved by the IACUC. Primary conveyances must provide adequate ventilation, protect from temperature extremes and minimize stress to the animal. Animals shall be appropriately secured and monitored at appropriate intervals while in transit to ensure their well-being. Animals must be promptly delivered, received and uncrated at an IACUC approved facility. The movement of animals between buildings must be in accord with IACUC standards that stipulate that animals shall be transported safely in a secure enclosure and in an inconspicuous manner.

5.11 The IACUC must approve the procurement, acquisition; housing, care; transfer, disposal and/or final disposition of live animals, animal carcasses or their parts upon completion of a project. With regard to the transfer of live animals from one IACUC approved study to another, personnel must receive authorization from the ACFOM prior to the intended transfer to ensure that all institutional requirements have been met.

5.12 Methods of euthanasia will be performed by qualified individuals in a manner that induces a rapid state of unconsciousness to insure an immediate and painless death for the animal. Euthanasia procedures conducted on animals must be considered the most humane given the study objective and be in accordance with the recommendations made by the American Veterinary Medical Association (AVMA Panel's Guide on Euthanasia) wherever possible. Deviations from any of the euthanasia practices specified by AVMA recommendations must be justified in the animal use protocol and approved by the IACUC. No animal shall be discarded until after it has been assessed by a qualified individual to be confirmed dead.

5.13 Personnel must follow the guidelines and requirements set forth by the IACUC in accordance with the standards and procedures outlined herein with due consideration of the statement on ethics and the care and use of animals in the preamble to this policy. All animal use protocols must be signed with a statement by the PI signifying that s/he has read and will abide by this policy. Any deviations from the provisions set forth in *Section 5* of this policy must be presented in writing by the PI and granted IACUC approval before the activity commences.

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## 6.0 Activity Descriptions and Protocol Forms.

6.1 Activities involving the care and use of animals by University personnel, on University property or at University facilities, or using University funds (including subcontracts) must be approved by the SJSU IACUC before the activity commences. Protocol submission descriptions must be complete and accurate when presented to the IACUC for review and approval. The IACUC has implemented individual protocol submission forms to suit four activity types: Use of Non-living Animal Tissue; Observational Animal Studies; Use of Fertile Eggs or Invertebrate Species; and the Care and Use of Vertebrate Animals.

6.1.1 Personnel must pursue IACUC approval for instructional, research, artistic and field activities as required by this policy or as requested by individual academic departments, the Office of Graduate Studies and Research, or the San Jose State University Research Foundation. It is at the discretion of the IACUC to review voluntary submissions from the campus community that do not meet the requirements for oversight of a University activity.

6.1.2 SJSU IACUC approval of an activity shall not relieve the investigator of the responsibility to obtain additional permits with the Institutional Review Board (human subjects), Health Physics Committee (radioactive materials), or Recombinant DNA Committee, or to comply with any applicable Federal, State or local laws. The IACUC reserves the right to request proof of permit from other entities/agencies before granting approval of animal-related activities.

6.1.3 The IACUC will not consider, accept or conduct retroactive review of animal protocol submissions involving the care and use of animals led or initiated by SJSU personnel if the activity is considered ongoing or completed. Such activities that are not approved by the SJSU IACUC must immediately be halted and reported to the IACUC for proper investigation and action. Activities that involve the use of animals that have not been previously approved by the IACUC and become evident to the Committee will be investigated and reported to the Institutional Official for recommended action.

6.1.4 The IACUC may consider approving personnel involvement in activities that are led or initiated by outside institutions under an IACUC approved protocol and are considered on-going. It is important that faculty and students communicate their interests to use live animals or their tissues at the earliest possible time to the University Animal Care department office so that the IACUC can be informed and review the appropriate protocol form. Completion of activities involving animals without prior SJSU IACUC approval is considered a violation of this policy.

6.1.5 The SJSU IACUC will consider permitting individual use of data previously collected from activities led or initiated by outside institutions under an IACUC approved protocol. In such situations where outside IACUC oversight was not required by law,

SJSU personnel must be able to show legal association with the activity and that all applicable federal laws and agency guidelines were adhered to with respect to the care and use of live animals.

6.1.6 6.1.6 The SJSU IACUC will consider accepting Alternate IACUC Approval and oversight of an activity initiated by and fully executed at an outside performance site. The SJSU IACUC will only accept Alternate IACUC Approval for the designated time period indicated from the outside performance site. A primary purpose for alternate IACUC approval is to provide appropriate procedural documentation for graduate students to file the paperwork with Graduate Studies and Research. An abbreviated form is available for IACUC review of such requests.

6.2 Protocol submission forms shall be sponsored and signed by a SJSU faculty member or the Campus Veterinarian identified as the Principal Investigator. Protocol forms are to be filled in completely and must be considered by the IACUC as the most current version which cannot be modified or otherwise altered by the submitter. The IACUC may require full resubmission of any protocol application on the appropriate form. Protocol submission forms, submission guidelines, submission deadlines and related information shall be made available on the IACUC resources webpage.

6.2.1 Activities conducted by faculty on sabbatical and visiting scholars or other third party individuals at or through SJSU must be approved by the SJSU IACUC. Therefore, visitors to the University must be supported and represented by an SJSU faculty member or the Campus Veterinarian to pursue IACUC approval for animal-related activities. SJSU affiliates involved with activities at other institutions are subject to all applicable provisions set forth at those institutions.

6.3 *Activities involving the use of non-living tissues.* Non-living tissue samples obtained from an animal's natural habitat, museum collections, commercial sources, road kill, or from a collaborator's scientific archive are subject to IACUC oversight to verify the source and manner in which the samples were obtained. The receipt of voucher specimens into campus museum collections is also subject to IACUC oversight and approval. The IACUC will require a copy of the valid import permit for specimens derived from species of special concern, threatened, endangered or as required by law. The IACUC may require documentation of the date, time, and circumstances of collection, including proof of prior IACUC approval, for tissues shared by outside collaborators. An abbreviated protocol submission form is available for IACUC review of such activities.

6.3.1 Opportunistic sources of obtaining animal tissue include (but not limited to) contracts with tissue banks or utilization of clinical diagnostic samples. In order to use the abbreviated submission form, investigators cannot influence in any way the handling of a live animal to obtain the sample. Tissue acquisition by contracting or subcontracting the collection of samples from live animals (e.g., serum antibody production) will require completion of the protocol for care and use of vertebrate

animals. Additional review requirements may be imposed by outside institutions for the handling or transfer of animals or their parts.

6.4 *Activities Involving Fertile Eggs.* The IACUC requires review and approval for the handling of fertile vertebrate eggs. An abbreviated protocol submission form is available for IACUC review of such activities. Depending on the species being studied and the time manipulations will occur during embryonic development, submission of the protocol for care and use of vertebrate animals may be required. Determination as to which protocol submission form is appropriate should occur upon consultation with the SJSU veterinary staff prior to IACUC consideration.

6.5 *Activities Involving Invertebrate Species.* The IACUC requires review and approval of activities that involve the holding and care of **Cephalopods** at an IACUC approved facility for greater than 12 hours and other multi-cellular invertebrate species if: 1) the species is listed as endangered, threatened or of special concern at federal or local levels; 2) the species is considered poisonous, venomous, or a threat to public health; or 3) the project involves a non-native species that requires permission from a State or local authority to possess or handle, even if specimens are obtained commercially. An abbreviated protocol submission form is available for IACUC review and approval of activities involving invertebrate species.

6.6 *Observational Studies Involving Animals.* For purely observational studies that do not involve handling or disturbing of a live animal in its natural habitat, the IACUC requires review and approval of projects that entail the deployment of recording equipment as part of the study or requires permission from a government authority to approach the species being studied or to gain regional access to sensitive habitats, public lands, sanctuaries or refuges. An abbreviated protocol submission form is available for IACUC review and approval of such activities.

6.7 Any activity that entails the handling or disturbance of a live vertebrate animal is subject to IACUC review and oversight. Such activities must be submitted and approved using the Protocol for Animal Care and Use. Each protocol submission shall meet the requirements outlined in *Section 7* of this policy and accurately describe the project's categorization of pain and distress in laboratory animals.

6.8 *Project Categorization of Potential Pain and Distress in Laboratory Animals* descriptions shall be appropriately assigned for all IACUC approved live vertebrate animal activities. Pain and distress category descriptions shall conform to federal guidelines and be made available on the IACUC resources webpage. Personnel are required to follow the IACUC's interpretation and any recommendations made with regards to project categorization of pain and distress in laboratory animals resulting from protocol review. General information on project categorization of pain and distress in laboratory animals is as follows:

6.8.1 *Category One:* Use of non-living tissues, invertebrates, fertile eggs or observational studies via an abbreviated protocol submission form as described in

Section 6.3 through 6.6 of this policy. Activities identified by a higher pain category level (II, III, IV or V) are to be submitted and approved using SJSU's Protocol for Animal Care and Use.

6.8.2 *Category Two:* Activities that involve the handling of vertebrate species that may produce little or no physical pain or distress, and would not warrant relief of temporary discomfort.

6.8.3 *Category Three:* Activities that may produce more than momentary or slight pain or distress in vertebrate animals in which every effort is made to avoid, minimize and relieve discomfort using the appropriate anesthetic, analgesic or tranquilizing drugs, and improving the animal's well being by providing supportive care as needed. If the IACUC determines that the procedures could potentially cause more than slight or momentary pain or distress to an animal, the PI is required to outline a search for alternatives to all such procedures.

6.8.4 *Category Four:* Activities that may produce significant pain or distress in vertebrate animals in which every effort is made to avoid, minimize and alleviate suffering using the appropriate anesthetic, analgesic or tranquilizing drugs, and improving animal's well being by providing adequate supportive and veterinary care throughout the activity. Activities of this nature require that the Principal Investigator maintain detailed veterinary health records documenting monitoring plans, assessments, pain management, and supportive veterinary care schedules. Category IV studies present an explicit responsibility on the part of the PI to justify the experimental design and implementation of research, and to seek alternative methods to ensure that animal pain and distress is minimized or avoided.

6.8.5 *Category Five:* Activities that involve producing substantial pain or distress in live animals or unavoidable pain, discomfort, or distress whereas use of the appropriate anesthetic, analgesic or tranquilizing drugs to minimize or alleviate suffering are withheld due to adverse impacts on the procedures, results or interpretation of study. Such activities must be deemed irrefutably necessary by design to receive IACUC approval.

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## 7.0 Protocol Review Standards and Procedures.

7.1 The IACUC is charged with institutional review and approval of animal care and use protocols, including proposed significant or minor changes to a protocol, and oversight of ongoing activities that involve the care and use of laboratory animals. The IACUC shall evaluate each animal use protocol description and modification request for (but not limited to):

7.1.1 Adherence to the provisions and standards cited in *Section 5* of this policy.

7.1.2 Protocols that entail the use of live vertebrate animals include identification of the species and approximate numbers to be used; rationale for involving animals and the appropriateness of the animals selected and numbers of animals to be used; a complete description for the proposed use of animals; a description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research or teaching; and a description of a euthanasia method to be used.

7.1.3 The housing and care of animals meets both Federal guidelines and institutional standards, and that animals receive adequate veterinary care and appropriate physical and psychological enrichment wherever appropriate.

7.1.4 Assurance that activities that involve surgery include appropriate provision for pre-operative and post-operative care of animals in accordance with established veterinary medical and nursing practices, and that all survival surgery will be performed using aseptic procedures.

7.1.5 Assurance that the pain and distress category for each proposal is appropriately assigned and that all procedures that may cause more than momentary or slight pain or distress to animals are performed with appropriate sedation, analgesia or anesthesia when possible, with accompanying documentation and scientific justification that less painful or distressful procedures are not available or appropriate.

7.1.6 Assurance that the number of animals to be used is the minimum necessary to achieve valid results and alternatives to the use of live animals have been adequately considered.

7.1.7 Assurance that animal activity locations and facilities are described in the animal care and use protocol. For proposed off-campus facilities the IACUC must approve incorporating them into the institution's animal use program whereas the care and use of animals will be subject to the principles outlined herein.

7.1.8 Assurance from the PI that the proposed animal activity has been examined and is not unnecessarily duplicating work that is ongoing or has already completed, whether in publication or curriculum.

7.1.9 Assurance that the level of personnel involvement, animal handling experience and training or required training, guidance and supervision is described and that all individuals are properly trained and deemed proficient by the PI or designee in the humane care and use of animals before engaging in an animal-related activity.

7.1.10 Assurance that the risks associated with the care and use of animals are reduced to acceptable levels and that personnel are adequately trained. The IACUC shall evaluate and inform the PI of the potential hazards related to chemical usage, bites and exposures, allergens, and risk of zoonotic transmission identified in the approved protocol.

7.1.11 Assurance that the PI or designee has obtained and maintains all applicable Federal, state or local scientific collection, marking and access permits associated with the care and use of animals.

7.1.12 Assurance that any deviation from provisions outlined in this policy, applicable Federal guidelines, or institutional standards in the care and use of animals is revealed to and approved by the IACUC before the activity commences.

7.1.13 Falsification of information on an animal care and use protocol submission or deviation from approved protocol by the PI or personnel may be considered by the IACUC as immediate grounds for suspension of an activity, revocation of IACUC approval for the use of animals and referral to the Institutional Official for appropriate action.

## 7.2 Protocol Review Procedures.

7.2.1 The PI is responsible for submitting a complete protocol application in a timely fashion. The PI shall submit the appropriate animal care and use protocol submission form with attachments for IACUC review in ample time before the proposed project initiation date (60 days prior is recommended). Instructional protocols shall be submitted to and approved by the IACUC in ample time before the commencement of a given semester. In an effort to expedite the protocol review process, investigators are encouraged to allow time for preview of the protocol submission by the IACUC staff or Campus Veterinarian before formally submitting materials for IACUC consideration.

7.2.2 For activities identified at a pain and distress level III or greater, the PI must consult a qualified veterinarian prior to IACUC consideration of the protocol to ensure that methods of analgesia, anesthesia, tranquilization, euthanasia and pre/post operative care are appropriately employed where necessary and are in accordance with current veterinary and nursing practices.

7.2.3 Procedures for preparing and submitting a protocol submission for IACUC review are:

- a. Protocol submissions are to be routed to the IACUC coordinator for processing. The IACUC coordinator reviews all submissions for completeness and provides input/assistance to the PI with developing the submission.
- b. The PI must provide a complete lay description of the proposed use of animals. Submissions that are considered too technical by the IACUC will be returned for full revision.
- c. Complete protocol submissions (including attachments) must be provided electronically accompanied by a single signed hard copy of the entire submission for the protocol file.
- d. The IACUC Coordinator will distribute all protocol submissions in a timely fashion for pre-review by the IACUC.



- e. IACUC members return any pre-review questions, comments or requests regarding the protocol submission to the IACUC coordinator by a designated date.
- f. The IACUC coordinator informs the PI in writing of any IACUC requests for clarification or modification in a letter of pending approval to be provided by a designated date.
- g. At the next convened IACUC meeting the Coordinator presents the meeting agenda to include a list of protocol submissions for review and approval.
- h. The IACUC will discuss the protocol submission and any questions, comments, or requests for modification submitted during the pre-review period, and will consider clarification provided or protocol changes made by the PI, if any.
- i. If the IACUC is not satisfied with the clarification provided by the PI during protocol review, a second letter of pending approval shall be issued for the PI to address. This process shall be repeated until the IACUC is satisfied.
- j. Final IACUC review of a protocol will result in: 1) approval as presented; 2) approved with required modifications (to secure approval); or 3) approval withheld.
- k. The coordinator sends written correspondence to the PI informing him/her of the IACUC's decision.

7.3 Once approved, no changes to the approved animal use protocol can be made without prior written approval by the IACUC, including (but not limited to) extension of the approval period, changes in personnel, number or type of animals used, material alterations, and the inclusion, removal or alteration of procedures performed on animals.

7.3.1 Personnel must make necessary protocol adjustments during an activity in incidents where the immediate well-being of the animal is at stake and contact the veterinary care staff at the earliest possible time. Personnel must bring to the IACUC's immediate attention, for action, any emergent problems or procedural changes, which may affect the health and well-being of personnel or study animals.

7.3.2 An individual animal care and use protocol shall not be granted IACUC approval for a period that extends beyond three years. Animal activities to continue beyond the three-year approval period must be fully rewritten and resubmitted for IACUC review and approval before the approved protocol expires. All animal care and use protocols valid for greater than one year shall be continually reviewed by the IACUC annually on the protocol anniversary date per *Section 7.9* of this policy. At the discretion of the IACUC, a shorter project approval period from that which the PI has requested or additional requirements may be imposed.

7.4 If IACUC approval of a protocol is withheld, the PI may appeal to the IACUC and request to appear at a convened session of the IACUC. The IACUC may reconsider the animal protocol approval status and re-review the protocol in accordance with *Section 7* of this policy. If a re-review of protocol is conducted, the end result of any post-appeal vote by the IACUC will be final.

7.5 Department heads, College Deans and the Institutional Official shall have the authority to deny approval for commencement of an animal-related activity regardless if IACUC approval is previously obtained. However, no institutional entity, individual or body may authorize the commencement of an animal-related activity that has been denied approval by the IACUC.

7.6 The IACUC reserves the right to refuse or suspend review of a protocol submission at any time. Reasons for the IACUC's decision to deny review of a protocol submission shall be provided to the PI in writing.

7.6.1 PIs that have any business with the IACUC known to be delinquent, non-compliant or otherwise unresolved to the satisfaction of the Committee may have approval of any or all ongoing activities under their direction suspended by the IACUC until such matters are considered resolved and in good standing.

7.7 If protocol approval should expire or approval of the activity be suspended by the IACUC while animals are actively held for study, the entire colony shall be considered relinquished and reassigned to the care and oversight of the Campus Veterinarian. Investigators will not be permitted to continue or direct the care or use of relinquished animals until an IACUC approved protocol is established.

7.7.1 The Institutional Official shall assume fiscal responsibility for the housing and care of any and all relinquished or abandoned animals. With support from the Institutional Official, the Animal Care Facilities Operations Manager will have the authority to request funds from the University (by law, not the originating Federal grant or award) to ensure all animals are provided for until the matter of IACUC approval is considered resolved.

## 7.8 IACUC Approval Exemptions

7.8.1 In cases where there is question as to whether or not IACUC approval is required for a proposed animal activity, personnel are to contact the University Animal Care office for advice. Upon consultation with the IACUC Coordinator, the PI of a proposed study involving animals or animal tissues may submit a request for IACUC approval exemption available on the IACUC resources webpage.

7.8.2 The IACUC Chair may grant IACUC approval exemption based on the information provided by the PI with respect to the provisions set forth in this policy. Denial of a request for exemption implies that IACUC approval for the proposed activity is required.

7.8.3 If accepted, an official letter of IACUC approval exemption will be provided to the PI, SJSU Research Foundation, Office of Graduate Studies and Research or outside agencies to satisfy any legal or institutional requirement for oversight of activities involving animal subjects.

## 7.9 Annual review of protocols

7.9.1 All active protocols for animal care and use must be reviewed and approved by the IACUC annually. The IACUC coordinator will route the PI of a protocol the appropriate annual review request information one month before the protocol anniversary date.

7.9.2 The PI is required to respond to all IACUC requests listed on the annual review cover letter and return the completed annual review form provided by the IACUC Coordinator by the designated date. Questions concerning annual review documents should be directed to the IACUC coordinator.

7.9.3 Failure by the PI to respond to the IACUC's request for information related to the annual review of a protocol by the date specified may result in immediate revocation of approval and continuance of the use of animals in an ongoing activity.

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## 8.0 Project Risk Assessment, Personnel Safety and Training.

8.1 All activities will be examined by the IACUC for a safe and healthy work environment to ensure that risks associated with experimental use of animals are maintained within acceptable levels. In addition to complying with departmental Injury and Illness Prevention Program procedures, personnel will be required to adhere to standards set forth by the IACUC with regards to personal protection and safety. The IACUC requires the PI and all personnel associated with an activity to be familiar with the risks, precautions and emergency response procedures with respect to an approved protocol.

8.2 A University-wide Laboratory Animal Occupational Health Program (LAOHP) shall be in-place to ensure medical consult, treatment, health surveillance and related services for all personnel working with laboratory animals in the classroom, at the bench and in the field. The LAOHP shall focus on maintaining a safe and healthy workplace for all personnel and shall be consistent with to all Federal, State and local regulations for Occupational Health and Safety procedures. The LAOHP shall provide the appropriate medical services for all personnel with respect, but not limited to animal bites, scratches and related health exposures, pre-employment screening, immunizations, medical consult and surveillance, and monitoring personnel exposure to hazardous chemicals, allergens or zoonotic diseases.

8.2.1 The extent and level of personnel participation in the LAOHP will be determined by the IACUC at the time of protocol review. The IACUC's decision to provide safety related information and/or require personnel participation in the LAOHP will be based upon the potential hazards identified in the protocol posed by the animals and materials used; on the exposure intensity, duration, and frequency; on the susceptibility of personnel and on the history of occupational illness and injury in the particular workplace. Individual participation in a high-risk activity shall be sanctioned by the

IACUC only with clearance by a LAOHP appointed physician. A complete outline of the institution's LAOHP shall be made available on the IACUC resources webpage.

8.3 The University shall maintain a Crisis Readiness and Response Program (CRRP) to protect the well-being of laboratory animals, personnel and property during times of natural disaster and intentional actions against the University. The CRRP is intended to direct the flow of information, interdepartmental response and resources in an organized fashion. The CRRP shall identify an Institutional Crisis Management Team (ICMT) charged with making triennial assessments of the institution's risk of disaster, recommending and implementing risk-reduction strategies and managing crisis situations in real time. The ACFOM shall review the CRRP annually and report findings (and any changes thereto) to the IACUC where it shall be reflected in the meeting minutes. All personnel directly associated with the CRRP must be adequately trained within 30 days of hire and this documentation supplied to the Animal Care department office.

8.3.1 The University Animal Care department shall maintain a Media Security Policy (MSP) that adequately promotes and enforces the safety of personnel, animals, activities and facilities of SJSU and its affiliates. The MSP is intended to provide guidance on the permitted use and dissemination of photographic and video images related to animals, animal activities and animal facilities. A complete outline of the Animal Care department's Media Security Policy shall be made available on the IACUC resources webpage.

8.4 All personnel shall be appropriately qualified and experienced in conducting procedures on live animals. Personnel who are expected to perform veterinary anesthesia, surgery or other experimental manipulations must be qualified through experience and training to accomplish these tasks in a humane and scientifically acceptable manner.

8.4.1 The IACUC shall make arrangements, when necessary, for all persons who require practical training in the humane care and use of animals with the veterinary care staff before being permitted to handle animals.

8.4.2 Verification of individual training, qualifications, proficiency and understanding in animal welfare law and policies is required by the IACUC before personnel participate on an approved protocol. Personnel training in proper animal care and use, as well as all biological, chemical and physical hazards associated with the approved protocol shall be reviewed by the IACUC with sufficient frequency to fulfill the institution's responsibilities per this policy.

8.4.3 Such training shall include (but not be limited to): principles of the intent and requirements of animal welfare law; alternatives to the use of live animals in research; resources that could prevent unintended or unnecessary duplication of research involving animals; the concept, availability and use of research testing methods that limit the use of animals or minimize animal distress; basic needs, proper handling and care

of each species of animal to be used; proper pre- and post-procedural care of animals; aseptic surgical methods and procedures; proper use of anesthetics, analgesics and euthanating agents; and methods whereby animal morbidity and deficiencies in animal care and treatment are reported.

## 9.0 IACUC Membership and Meeting Bylaws

9.1 IACUC members shall be appointed by the University President and will advise the Institutional Official about matters pertaining to animal care and use in research and instruction at all facilities where animals are held or used. IACUC members are obligated to treat all information and materials presented to them as privileged and confidential so as not to reveal Committee deliberations or action, proprietary information or trade secrets; or to jeopardize individual employment relations or external funding.

9.2 The membership of the IACUC shall be comprised of individuals who are qualified through training or expertise in order to conduct its business. The IACUC shall include no less than five (5) voting members, and shall include at least:

9.2.1 A Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine;

9.2.2 One member without any affiliation with the University except service on the IACUC who is a non-animal user to represent general community interests;

9.2.3 One member whose primary concerns and expertise shall be in a nonscientific area (i.e., ethicist, lawyer, peace officer, member of the clergy);

9.2.4 One member who shall be trained and experienced in research involving animals; and

9.2.5 One Chair and one vice-Chair. The Chair and vice-Chair seats may only be filled by a primary voting member of the Committee who is a full time faculty member within one of the Colleges of the University.

9.3 An individual who meets the requirements of more than one of the categories outlined in *section 9.2* of this document may fulfill more than one required seat of the IACUC.

9.4 No more than 3 IACUC members can be from the same administrative unit of the University.

9.5 Alternate members may be appointed by the University President to serve and participate on the IACUC. Based on their expertise, alternates may serve to fill a variety of primary member seats to be formally identified in their appointment letter. Alternate members may voluntarily attend and participate in any IACUC business. However,

when the primary member and alternate are both present only one vote can be cast amongst them.

9.6 Failure to maintain an adequately constituted committee per *Section 9.2* of this policy would keep the IACUC from meeting to discuss official business until all seats are properly filled.

9.7 The University Animal Care department shall provide staff support to the IACUC by providing announcements and agendas for its meetings, recording the minutes of its meetings, serving as a repository of all IACUC correspondence and records, and the like.

9.8 The IACUC Coordinator shall serve as the first and primary contact point for requests, inquiries and submissions to the IACUC and shall serve as a non-voting member of the IACUC. The IACUC Chair, vice-Chair and Coordinator shall have the authority to verify IACUC approval of animal related activities, modifications thereto, and official business on behalf of the Committee.

9.9 The IACUC is charged with overseeing animal-related activities, monitoring all University facilities and the institution's animal care program, and to recommend changes to this policy for consideration by the Institutional Official. The IACUC shall meet no less frequently than every three (3) months to ensure this provision.

9.10 The IACUC shall make every effort to meet on a monthly basis to review protocols submitted by the campus community and to tend to routine business except during the month of July. Meeting dates and protocol submission deadlines shall be made available on the IACUC resources webpage at the beginning of each semester. Regular meetings may be cancelled by the IACUC Chair if there is no business to transact.

9.11 Outside attendance of an IACUC meeting may be permitted by consent of the IACUC Chair following receipt of a written request submitted to the IACUC Coordinator by the interested party. If permission is denied, the minutes of the IACUC will reflect the reason for denial.

9.12 Emergency meetings of the IACUC may be assembled to address issues surrounding violations of approved protocols; what is viewed by the Campus Veterinarian to be an urgent, significant modification request to an approved study; or issues related to animal welfare or personnel safety.

9.13 When meeting announcements are circulated by the IACUC Coordinator, primary members are responsible to communicate to their respective alternate/s if they cannot attend themselves and produce a group response to ensure representation at a given assembly.

9.14 A simple majority of the voting members shall constitute a quorum, which is required for the IACUC to conduct all official business.

9.15 No member may participate in official IACUC business if there presents a conflict of interest, except to provide information requested by the IACUC, nor may the person who has a conflicting interest contribute to the constitution of a quorum.

9.16 The IACUC may solicit ad hoc reviewers with specific expertise for their input on a case-by-case basis. Ad hoc reviewers may participate in, but not vote on official IACUC business.

9.17 The IACUC shall assemble a subcommittee (at least two members) to conduct a review of the institution's Animal Care Program, as well as inspecting all of the institution's animal care and use facilities at least once every six months. Reports of IACUC semiannual evaluations shall be prepared and submitted to the Institutional Official per federal requirements at least once every six months.

9.18 IACUC procedures for protocol review; protocol approval; response to reported concerns related to the care and use animals; suspension of an activity involving animals; and internal and external reporting shall conform to the procedures outlined in this policy.

#### 9.19 Member Elections and Appointments

9.19.1 To fill vacancies on the committee, the Chair of the IACUC will identify and recommend individuals in writing to the Institutional Official for appointment by the University President.

9.19.2 In April of each year a Chair and vice-Chair shall each be selected by a majority of the IACUC's voting members for a one-year term (August – July). The IACUC Coordinator shall notify the Institutional Official in writing as to the results of the Chair election for confirmation. A member of the IACUC shall serve no more than four (4) consecutive terms as Chair.

9.19.3 Newly appointed members may only participate in official IACUC business upon successful completion of all orientation and training requirements administered by the IACUC Coordinator.

9.19.4 Other than non-affiliated member/s whose appointments are considered on an annual basis, IACUC members are appointed for a term of three years with reappointment possible.

#### 9.20 Member Resignation and Dismissal

9.20.1 Any IACUC member may voluntarily resign their post on the committee at any time by submitting written notification to the IACUC Chair or Coordinator. A minimum

30-day advance notice is requested to ensure functionality of the IACUC through the next scheduled meeting date. Any IACUC member with 'special consultant' status must abide by and possibly terminate their contractual agreement with the University as a matter of resigning their post.

9.20.2 In the event the IACUC Chair resigns or is voted off the Committee per *Section 9.20.3* of this policy, the vice-Chair will immediately assume the Chair position and will complete the departing Chair's term of office. A new vice-Chair shall then be elected from among the voting members at the earliest possible time.

9.20.3 The IACUC may formally dismiss a primary member from the committee with a majority vote by a quorum present. Written notification of dismissal will be provided to the primary member, the department head, Institutional Official and University President. Justifiable reasons for removal of a voting member shall be (but not limited to): 1) violation of ethical conduct; 2) attending less than half of scheduled meetings in a twelve month period; 3) failure to participate in required semiannual site inspections or Program review as a subcommittee at least once every two years; 4) failure to participate and adequately engage in protocol review; or 5) failure to complete required training as an IACUC member.

9.20.4 Removal of an alternate member may be initiated by their respective primary member with approval from the IACUC Chair.

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10.0 The following references have been used collectively in developing this policy and assurance:

- ❖ American Veterinary Medical Association Panel's Guide on Euthanasia (2012)
- ❖ Animal Welfare Act (Public Law 89-544 as amended)
- ❖ California State University System Executive Order 715
- ❖ California State University System Executive Order 890
- ❖ Endangered Species Act (Public Law 93-205)
- ❖ Guide for the Care and Use of Laboratory Animals (NRC, 2010)
- ❖ Health Research Extension Act (Public Law 99-158)
- ❖ Public Health Service Policy on the Humane Care and Use of Laboratory Animals (2002)
- ❖ U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (1985)