SAN JOSÉ STATE UNIVERSITY
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Amendment B to University Policy S14-6, Policy and Assurance for Humane Care and Use of Animals at San José State University

Legislative History:

On April 15,2024, the Academic Senate approved Amendment B to University Policy S14-6. Policy and Assurance for Humane Care and Use of Animals at San José State University presented by Senator Shaffer for the Curriculum and Research Committee.

Approved and signed by President Cynthia Teniente-Matson on April 29, 2024.

University Policy

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

Amendment B: S14-6, 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

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; and

Whereas: IACUC meeting bylaws are now detailed in a Standards of Practice document in SJSU's Research Compliance Unit to allow for more flexibility with changing federal regulations; be it therefore

Resolved:	That the following amendment to S14-6 be adopted.
Approved:	April 8, 2024
Vote:	7-0-0
Present:	Kourosh Amirkhani, Megan Chang, Stefan Frazier, Marie Haverfield, Ellen Middaugh, Scott Shaffer, Hiu-Yung Wong (Chair)
Absent:	Marc d'Alarcao, Heather Lattimer, Richard Mocarski, Sahithya Swaminathan, Cristina Velarde
Workload Impact:	None
Financial Impact:	None

UNIVERSITY POLICY

Policy and Assurance for Humane Care and Use of Animals at San José 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.

2.0 Purpose.

When animals are used for academic activities at SJSU, every effort will be made to ensure that faculty, staff, and students understand their ethical and scientific obligations

with respect to animal care and use. This policy sets forth standards, procedures, and guidelines by which SJSU and its affiliates shall ensure compliance with federal and University expectations with regard to the care and use of animals for academic purposes.

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 and 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 extends to the use of Cephalopods and 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 Pain refers to a complex experience that typically results from stimuli that damage or has the potential to damage tissue; such stimuli prompt withdrawal and evasive action on behalf of an animal.

3.5 Distress refers to an aversive state in which an animal is unable to adapt to stressors/stress and results in maladaptive behavior and physical pathology. Stress can manifest as an external or internal event, which induces an alteration in biological equilibrium.

3.6 Discomfort refers to a state of uneasiness and hardship for an animal; deprivation of comfort or ease.

3.7 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 an animal-related activity.

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

3.9 Protocol refers to the complete written description of an animal-related activity, including all permits, attachments, and subsequent amendments, approved by the Institutional Animal Care and Use Committee.

3.10 Submission refers to any proposal, policy, or document related to the care and/or use of animals that is pending review or approval by the Institutional Animal Care and Use Committee.

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 and state 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 charged with the overall administrative

responsibility for ensuring that the institution's animal care and use program is in full accord with all applicable federal regulations. The University President is responsible for providing public assurance that animals associated with legitimate academic activities are properly cared for and being treated in accordance with IACUC-approved standards.

4.3 Institutional Official. The University President may designate responsibility to the Institutional Official (e.g. the Associate Vice President for Research) to oversee and administer the institution's Animal Care Program. Designation of the Institutional Official requires formal written appointment by the President indicating, minimally, that the designee shall 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 institutional assurances; and 2) define and assign responsibilities and reporting channels essential to the animal care and use program and this policy.

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 to: 1) oversee the institution's animal care program and facilities; 2) to develop plans and timelines to correct program deficiencies; 3) respond to reported concerns that may arise concerning the institution's care and use of animals; and 4) the animal care and use training program for personnel.

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. The Institutional Official shall promptly notify the appropriate external agency if the IACUC suspends an approved 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, if applicable.

4.3.4 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 the respective 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 the SJSU Animal Care Program. As Veterinary Director, responsibilities of the Campus Veterinarian 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 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 The Campus Veterinarian shall serve as a voting member of the IACUC and report to the Institutional Official. To ensure the health and welfare of animals used in teaching and research, the Campus Veterinarian will have unlimited access to all facilities under control of the University where animals are held or used with due respect for the demands of work in progress. The Campus Veterinarian shall 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 SJSU animal care program.

4.4.2 The Campus Veterinarian shall have the authority to halt any activity involving animals approved by the IACUC if the health or welfare of the animals or personnel involved is deemed to be inappropriately in jeopardy until which time the IACUC can review the circumstances and take appropriate corrective action.

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 care and use animals.

4.5.1 The IACUC shall maintain meeting and membership bylaws approved by the Institutional Official that are in accord with all applicable laws and regulations.

4.5.2 The IACUC Chair shall monitor committee membership and make recommendations to the Institutional Official to ensure that the IACUC is functional and properly constituted. The IACUC Chair shall monitor committee assembly and conduct to ensure that meetings are conducted in accordance with IACUC bylaws.

4.6 The Dean of the College of Science (Dean) is charged with overseeing operations and maintenance of the institution's Animal Care Facilities (ACF) and ACF support staff. The Dean shall be included on ACF inspection reports generated by the IACUC to relay all commendations, deficiencies, or recommendations to improve the animal care facilities. Where appropriate, the Dean shall respond to the IACUC Chair in a timely manner with input on corrective action plans to ACF deficiencies noted in IACUC reports.

4.6.1 The Animal Care Program Manager (ACPM) shall be responsible for maintaining a repository of records in the Animal Care department office, which the Dean will have access to at all times. 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. Animal care program documents shall be accessible for audit as required by law at reasonable times and in a reasonable manner.

4.7 Animal Care Program Manager [ACPM] 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 ACPM shall have access to all animal holding and use areas and 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 ACF and its satellites, 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 direct submissions and protocol activity requirements through the ACPM 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 directed by the IACUC.

4.8 The Principal Investigator [PI] is charged with ensuring compliance with this policy for all animal activities under their lead. PIs are: 1) considered the protocol director to ensure that all IACUC requirements and campus safety protocols are adhered to; 2) directly responsible for animal welfare associated with their work and are charged with ensuring that those involved promptly seek veterinary consultation if the health or welfare of an animal is in jeopardy; 3) responsible for overseeing laboratory and field operations, and experiment conditions; 4) responsible to verify adequate procedural knowledge and practical skill of all personnel under their direction in the care and use of animals; 5) responsible to promptly report to the IACUC any adverse or unanticipated study event that results in animal morbidity or mortality; and 6) responsible to ensure that all records related to animal care and use are complete and current, and reports and submissions are accurate and submitted to the IACUC in a timely manner.

4.9 Reporting Animal Welfare Concerns. Any person should report, anonymously or otherwise, concerns related to animal care and use at San José State University and Moss Landing Marine Laboratories by contacting the Animal Care Program Manager, 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 at campus facilities. No concerned or reporting individual shall be

discriminated against or be subject to intimidation, coercion, or reprisal for reporting animal welfare concerns or violations of federal law, or any requirement set forth in this policy, or as indicated for individual protections under existing 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. Reports of such investigations shall be submitted to the Institutional Official for the appropriate action. The IACUC may consider a wide variety of actions following such an investigation, including suspension of the activity and termination of an approved protocol. If requested, the ACPM or Campus Veterinarian shall follow up with the reporting individual/s to share relevant findings of the final investigation.

4.10 The IACUC is authorized to take any action deemed necessary 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 and/or this policy are subject to suspension of animal activities by IACUC and referral to the Institutional Official for appropriate action.

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 animal *replacement* (use of inanimate models and/or taxonomically lower species, and methods such as computer simulation and *in vitro* biological systems); animal *reduction* (statistical justification and/or scientific support of animal numbers associated with an activity are the minimum number necessary to achieve valid results); 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 consultation 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 applied level of anesthesia, 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.

5.4.2 If an emergent situation occurs where the well-being of the animal is at stake, investigators shall immediately halt the activity and contact the attending veterinarian for animal welfare consultation. The PI must bring to the IACUC's immediate attention any adverse study event that impacts the health or well-being of study animals for review and possible action.

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. Animal welfare policy training shall be made available through the University Animal Care department. Personnel involvement and qualifications in the care and use of animals shall be 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 Details related to animal holding and study locations, including animal confinement, restraint, and transport, must be revealed to and approved by the IACUC. Holding areas and primary conveyances must provide adequate ventilation, protection from temperature extremes and minimize stress to the animal. During transport 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 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 ACPM 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 should be in accordance with the current recommendations made by the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of animals 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 complete and accurate, and signed with a statement by the PI signifying that they have 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.

6 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 descriptions must be complete and accurate when presented to the IACUC in a

timely manner for review and approval. No change to an approved protocol may be instituted without prior written approval from the IACUC.

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 College of Graduate Studies, or the San Jose State University Research and Tower Foundations. It is at the discretion of the IACUC to voluntarily review submissions from the campus community that do not meet policy requirements for oversight of an animal activity.

6.1.2 SJSU IACUC approval of an activity shall not relieve the Principal Investigator of the responsibility to obtain additional permits with the Institutional Review Board (human subjects), Health Physics Committee (radioactive materials), or Institutional Biosafety Committee (recombinant DNA use and Biological Use Authorizations), or to comply with applicable Federal, State or local requirements. The IACUC reserves the right to request proof of permit from institutional committees or other agencies before approving animal-related activities.

6.1.3 Initiating or conducting animal activities without securing SJSU IACUC approval is considered a violation of this policy. The IACUC will not consider, accept or conduct retroactive review of protocol submissions involving the care or use of animals led or initiated by SJSU personnel if the activity is considered completed. Ongoing activities that are not approved by the SJSU IACUC must be immediately halted and reported to the IACUC for proper investigation and action. Activities that are not in compliance with this policy will be promptly investigated by the IACUC 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.

6.1.5 The SJSU IACUC will consider accepting alternate IACUC approval and deferring oversight of an ongoing activity that is initiated, led, and/or conducted by a third-party or organization. Where applicable, the SJSU IACUC will only approve such submissions for the designated approval period indicated by the IACUC from the third-party performance site. An application form is available for IACUC review of such requests.

6.1.6 The SJSU IACUC will consider permitting individual use of data previously collected from activities led or initiated by a third-party or organization 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.

6.2 IACUC protocol submissions shall be sponsored and signed by a SJSU faculty

member or other individual institutionally recognized with PI status per University policy S18-5, or the Campus Veterinarian, identified as the Principal Investigator. Protocol forms used must be the most current version available and filled in completely. The IACUC may require full resubmission of any protocol application on the appropriate form. Protocol submission forms, submission deadlines and contact information for submission guidance 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 outside institutions shall comply with applicable provisions set forth by the IACUC at those institutions.

6.2.2 If the PI is planning a leave or sabbatical rendering them unable to oversee ongoing study conditions, the appropriate arrangements shall be made to ensure the proper use of animals. Where appropriate, PI leave plans should be shared with the Animal Care Program Manager for animals being held for study. The Campus Veterinarian shall make a recommendation to the IACUC and Institutional Official if PI oversight becomes a concern. If the PI is placed on any leave or suspension, then the animals shall be considered relinquished and reassigned to the care and oversight of the Campus Veterinarian. Investigators will not be permitted to handle or direct the care or use of relinquished animals under the control of the Campus Veterinarian. If necessary, the Dean and/or Institutional Official may request funds from the respective University department and/or Research Foundation to ensure all animals are adequately provided for. The Dean, in consultation with IACUC and Campus Veterinarian, will determine the duration of time the colony may be maintained under the care of the Campus Veterinarian.

6.3 *Activities Involving the Use of Non-living Animal Tissues.* Non-living tissue samples obtained post-mortem or 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 verification of a 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 form is available for IACUC review of such activities.

6.3.1 Opportunistic sources of obtaining animal tissue include (but are 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.

6.3.2 Where applicable, investigators are encouraged to collaborate internally and share tissue samples made available from ongoing projects to reduce the number of animals required for other studies. The ACPM shall be a resource to investigators to coordinate tissue sharing that will require IACUC approval for the recipient using an abbreviated protocol form.

6.4 *Activities Involving Fertile Eggs from Vertebrate Animals.* The IACUC requires review and approval for the handling of fertile vertebrate eggs. An abbreviated protocol form is available for IACUC review of projects using fertile eggs in early-stage development. Depending on the species being studied and the time the manipulations will occur during embryonic development, submission of the protocol for animal care and use 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 or use of multicellular 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 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 form is available for IACUC review and approval of such activities.

6.5.1 The IACUC requires review and approval of activities that involve the handling of Cephalopod species using the protocol for animal care and use.

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 or private lands, sanctuaries or refuges. An abbreviated protocol form is available for IACUC review and approval of such activities.

6.7 Activities that entail the holding, 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.

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 protocol for animal care and use. During protocol review the IACUC reserves the right to reassign the projected pain and distress category designation for any activity. 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 covered by this policy, fertile vertebrate eggs in early gestation, or observational animal studies approved

using an abbreviated protocol form as described in *Section 6.3 through 6.6* of this policy. Activities identified as a higher pain category level (II, III, IV or V) are to be submitted and approved using the IACUC's protocol for animal care and use.

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

6.8.3 *Category Three:* Activities that may produce minor pain or distress in vertebrate animals and Cephalopods 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 activities could potentially cause more than slight or momentary pain or distress to an animal (as defined in category III, IV or V), the PI is required to consult with a qualified veterinarian on the protocol design and 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 and Cephalopods 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 where appropriate. Activities of this nature (e.g., invasive surgery) require that investigators maintain detailed animal care records documenting animal 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, to seek alternative methods, and to properly train personnel working on the study to ensure that animal pain and distress is properly recognized and alleviated, or avoided.

6.8.5 *Category Five:* Activities that involve greater than momentary pain or distress, or unavoidable pain, discomfort, or distress in vertebrate animals and Cephalopods 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. The PI must explore and document means by which any animal suffering shall be mitigated to the greatest extent possible, including supportive care and beneficial modifications to the animal's environment. Such activities must be deemed irrefutably necessary by design to receive IACUC approval.

7 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 Assurance that 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 valid research or teaching; and a description of a euthanasia method to be used.

7.1.3 Assurance that the housing and care of animals meets Federal standards, and that animals receive adequate veterinary care and physical and psychological enrichment where appropriate per IACUC standards.

7.1.4 Assurance that activities involving 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 technique.

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 their 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 shall obtain and abide by all applicable Federal, state or local scientific collection, marking and access permits associated with the care and use of animals.

7.1.12Assurance 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 and Approval.

7.2.1 The PI is responsible for screening the protocol application for accuracy and completeness prior to IACUC consideration. 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 must be submitted to and approved by the IACUC in ample time before the commencement of a given semester. The PI is encouraged to allow time for preview of the protocol submission by the IACUC staff or Campus Veterinarian before formally submitting materials for IACUC consideration.

7.2.2For 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 appropriate, employed where necessary, and are in accordance with current veterinary and nursing practices.

7.2.3 Procedures for handling a protocol submission for IACUC review and approval are:

a. The complete protocol submission is routed to the IACUC Coordinator electronically for processing by the submission deadline. The Coordinator reviews all submissions for completeness and may provide input or assistance to the PI with developing the submission before accepting it.

b. The PI must provide a complete lay description of the proposed use of animals. Submissions that are considered too technical for a lay audience by the IACUC will be returned for full revision.

c. When the submission is accepted for IACUC review the Coordinator will issue a reference number for the protocol and instruct the PI when to sign the application documents.

d. The Coordinator will distribute all protocol submissions for pre-review by the IACUC prior to the meeting date.

e. IACUC members return any pre-review questions, comments or requests regarding the protocol submission to the Coordinator by a designated date.

f. The 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. f. At the next convened IACUC meeting the Coordinator presents the meeting agenda to include a

list of protocol submissions for review and approval.
g. 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.
h. If additional clarification is needed, the IACUC may issue a second letter of pending approval for the PI to address. The PI may be invited to attend an IACUC meeting to address any lingering concerns about the submission directly.
i. IACUC review of a protocol will result in the submission being: 1) approved as presented; 2) approved with required modifications (to secure approval); or 3) denied approval.
j. The Coordinator shall send written correspondence to the PI informing them of the IACUC's decision.

7.3 Once approved, no changes to the approved animal use protocol can be instituted 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, or the inclusion, exclusion, or alteration of experimental conditions or procedures performed on an animal.

7.3.1 If an unforeseen incident occurs where the well-being of the animal is adversely impacted, investigators shall immediately halt the activity and contact the attending veterinarian for consultation. Any changes recommended or instituted by a veterinarian in such instances must be promptly presented to the IACUC in the form of an amendment for review and approval before future changes are made under the approved protocol.

7.4 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 for de novo review by the IACUC in ample time before the protocol expires. All animal care and use protocols valid for greater than one year shall be reviewed by the IACUC annually on the protocol anniversary date per *Section 7.10* of this policy. At the discretion of the IACUC, a shorter project approval period from that which the PI has requested, as well as additional requirements, may be imposed.

7.5 If IACUC approval of a protocol submission is denied, the PI may appeal to the IACUC and request to appear at a convened session of the IACUC. Resubmission of a protocol that was denied approval should only occur after a formal appeal at a convened meeting of the IACUC.

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

7.7 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.

7.7.1 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.

7.8 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 may be reassigned to the care and oversight of the Campus Veterinarian. Investigators will not be permitted to handle or direct the care or use of relinquished animals under the control of the Campus Veterinarian until an alternate IACUC-approved protocol is in-place.

7.8.1 The Principal Investigator shall assume fiscal responsibility for the housing and care of any and all relinquished or abandoned animals held under the veterinary holding protocol. If necessary, the Dean and/or Institutional Official may request funds from the respective University department to ensure all animals are adequately provided for until the matter of IACUC approval is considered resolved.

7.9 IACUC Approval Exemptions

7.9.1 In cases where there is a question as to whether or not IACUC approval is required for a proposed animal activity, personnel should consult with the University Animal Care office. 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.

7.9.2 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.

7.9.3 If accepted, an official letter of IACUC approval exemption will be provided to the PI to satisfy requirements for animal subjects oversight.

7.10 Annual review of protocols

7.10.1 All active protocols for animal care and use shall 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.

7.10.2 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.

7.10.3 Failure by the PI to respond in a timely manner to the IACUC’s annual review request may result in protocol approval suspension for an ongoing animal activity.

8 Project Risk Assessment, Personnel Safety and Training.

8.1 All activities will be assessed 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 University Injury and Illness Prevention Program (IIPP) procedures implemented by SJSU Environmental Health & Safety, personnel will be required to adhere to standards set forth by the IACUC with regard to personal protection and safety. The IACUC requires the PI and all personnel associated with an activity to be familiar with the personnel safety risks, precautions to mitigate safety hazards and emergency response procedures with respect to an IACUC-approved protocol.

8.1.1 In the event of an injury related to animal handling or potential exposure to a zoonotic disease, personnel shall immediately seek medical attention and report any such exposure to their PI or appropriate supervisor. The PI or supervisor is required to report personnel accidents and injuries to Risk Management or University Personnel within 24 hours of the incident to ensure appropriate follow-up care is offered.

8.2 A University-wide Laboratory Animal Occupational Health Program (LAOHP) shall be in-place to ensure medical consultation, treatment, health surveillance, workplace ergonomics, and related services for all personnel working with study animals in the classroom, research labs, workshops, studios, and in the field. The LAOHP shall focus on maintaining a safe and healthy workplace for all personnel involved in IACUC-approved activities and shall be consistent with all Federal, State and local Occupational Health and Safety requirements. The LAOHP medical services shall include pre-employment health screening, immunizations, medical consultation and surveillance, and managing personnel injury and exposure to allergens, chemicals, and pathogens.

8.2.1 The IACUC will inform the PI of the minimum level of personnel participation in the LAOHP at the time of protocol approval. 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 an activity deemed high-risk by the IACUC shall be sanctioned by the IACUC only with clearance by a LAOHP appointed physician. Instructions for personnel enrollment into the LAOHP shall be made available on the IACUC resources webpage.

8.3 The University Animal Care department shall maintain a Crisis Readiness and Response Program (CRRP) to protect the well-being of laboratory animals during times of natural disaster, systems failures, and intentional actions against the University. In time of need, the CRRP shall 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 assessments of the institution's risk of disaster, recommending and implementing risk-reduction strategies and managing crisis situations in real time. The ACPM 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.

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 applies to all personnel on the permitted use and dissemination of photographic and video images related to animals, animal activities and animal facilities. The Animal Care department's Media Security Policy shall be made available on the IACUC resources webpage.

8.4 The IACUC shall maintain a personnel training program for all individuals responsible for the care or use of animals. All personnel shall be appropriately qualified and experienced in conducting procedures involving 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. Personnel shall also have access to and, where appropriate, engage in continuing education and training in the care and use of animals as it relates to their work.

8.4.1 IACUC policy 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 euthanizing agents; and the means whereby animal morbidity and animal-related concerns are managed and reported.

8.4.2 Verification of individual qualifications and basic understanding of animal welfare policies is required by the IACUC before personnel can be associated with an approved protocol. For ongoing activities, IACUC policy training for all personnel listed on an approved protocol shall be renewed no less than every three years, or as otherwise requested by the IACUC or IACUC Coordinator.

8.4.3 The PI is responsible to ensure and document individual training and proficiency in animal care and use procedures. The IACUC may require individuals to receive veterinary training and/or certification in practical animal handling or surgery before being permitted to participate in certain activities. The ACPM shall verify and document individual training and proficiency of ACF personnel responsible for animal care.

9 IACUC Membership

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 composed of individuals who are qualified through training or expertise in order to conduct its business. The IACUC membership shall conform to Office of Laboratory Animal Welfare (OLAW), under the US Department of Health and Human Services, requirements; this includes no fewer 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 for their 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 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 Member Resignation and Dismissal

9.7.1 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.

9.7.2 In the event the IACUC Chair resigns or is voted off the Committee per *Section 9.7.3* 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.

9.7.3 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.

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

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

- American Veterinary Medical Association Guidelines for the Euthanasia of Animals (2020)
- Animal Welfare Act (Public Law 89-544 as amended)
- California State University System Executive Order 715
- California State University System Executive Order 890
- SJSU Policy S18-5
- 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)