



Animal Welfare Assurance
in accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals for
San José State University
#D16-00389

I, Pamela C. Stacks as named Institutional Official for animal care and use at San José State University, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (Policy).

Section I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving vertebrate animals supported by the PHS, HHS and/or NSF. This Assurance covers only those facilities and components listed below.

A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:

1. San José State University
2. College of Business
3. College of Education
4. College of Engineering
5. College of Health and Human Sciences
6. College of Humanities and the Arts
7. College of International and Extended Studies
8. College of Science
9. College of Social Sciences
10. Moss Landing Marine Laboratories
11. San José State University Research Foundation

B. The following are other institution(s), or branches and components of another institution:

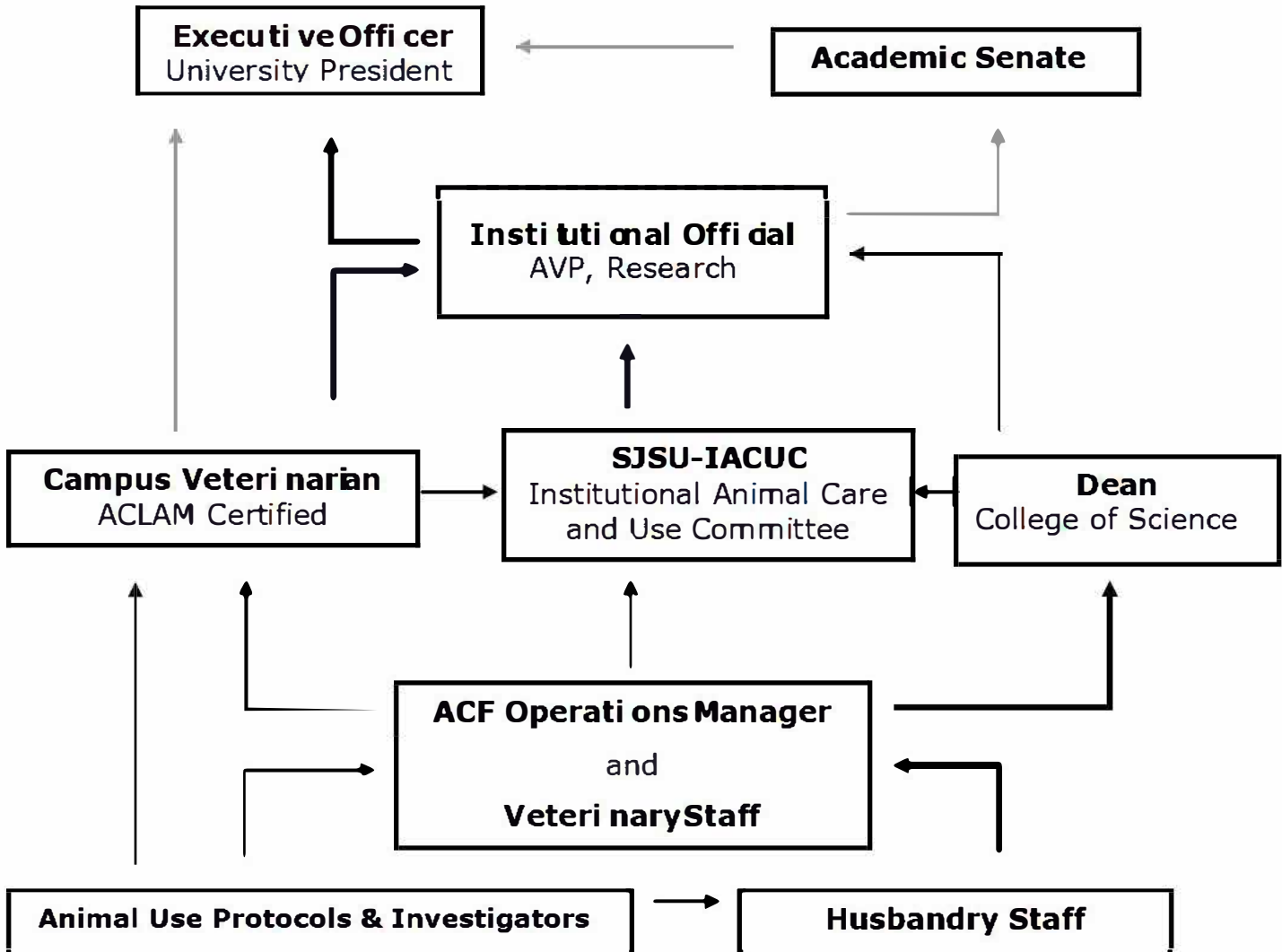
11. None

Section II. Institutional Commitment

- A. This institution will comply with all applicable provisions of the Animal Welfare Act (AWA) and other Federal statutes and regulations pertaining to the care and use of laboratory animals.
- B. This institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training."
- C. This institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.
- D. This institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals, hereinafter referred to as *the Guide*.
- E. This institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

Section III. Institutional Program for Animal Care and Use

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



The lines of authority and responsibility for administering the program and ensuring compliance with this Policy emanate from the level of Animal Use Protocols, Investigators and Husbandry staff. The Animal Care Facility Operations Manager (ACFOM) reports to the Dean of the College of Science and supervises the husbandry staff and veterinary staff. The ACFOM is a member of the veterinary staff and is a lead in the personnel training program. Veterinary health reports are monitored by the veterinary staff and Campus Veterinarian, conveyed to the Institutional Animal Care and Use Committee (IACUC) as appropriate. The IACUC and Campus Veterinarian shall attend convened

meetings no less than every three months to discuss the institutional animal care and use program, activities and facilities. Routine matters are then shared by the IACUC, Campus Veterinarian and the Dean via formal reporting to the Institutional Official, currently the Associate Vice President, Research. The Campus Veterinarian has the authority to address the Executive Officer at anytime during their appointment. It is the responsibility of the Institutional Official to implement policy as supported by the Dean, IACUC and Campus Veterinarian in order to remain compliant with PHS Policy. Policy matters will be routed through the Academic Senate (if routine) or presented directly to the Executive Officer (University President) for acceptance.

B. The qualifications, authority, and percent of time contributed by the veterinarians who will participate in the program are as follows:

B-1 Dr Rosemary Broome (Attending Veterinarian). Degrees: BS; D.V.M., University of California at Davis, 1984; Completed residency in laboratory animal medicine, University of California at Davis, 1987; and Masters of Preventative Veterinary Medicine (MPVM), University of California at Davis, 1987. Board Certification: Diplomate in the American College of Laboratory Animal Medicine (DACLAM), 1997. Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Broome has over 25 years experience working full time directing research animal care and use programs in academia and industry. She currently consults part time with both large and small biotechnology programs, global pharmaceutical companies, and academic institutions. Dr Broome receives ongoing training and continuing education through participating and attending professional meetings and forums sponsored by AALAS, PRIMR and the American College of Laboratory Animal Medicine. Dr Broome has direct program authority and responsibility for the Institution's animal care program including access to all animals. As Campus Veterinarian Dr Broome is present at the institution for three (3) hours and contributes approximately six (6) hours to the animal care and use program every month.

B-2 Dr [REDACTED] (clinical veterinarian); D.V.M., [REDACTED] University, 1990; ACF Faculty Coordinator, College of Science, 1994; Chairperson, SJSU-IACUC, 2001-2005. Dr [REDACTED] has delegated program authority and responsibility for Institution's animal care facilities as a relief veterinarian including access to all animals. Dr [REDACTED] has twenty (20) years experience in laboratory animal medicine for the species being attended. On average Dr [REDACTED] is present at the institution three (3) hours and contributes approximately three (3) hours to the animal care and use program every three (3) months.

B-3 Dr [REDACTED] (consulting veterinarian, marine animal medicine); D.V.M., University [REDACTED] 1973; Director, [REDACTED] Veterinary services, 1994; Dr [REDACTED] is responsible for providing clinical consult and veterinary services for marine animals (pinnipeds, elasmobranchs, fishes and sea birds); coordinating in-house personnel training sessions for care and handling of marine animals; and recommending husbandry practices for captive marine animals. Dr [REDACTED] has

forty three (43) years experience in marine mammal medicine and care. Dr [REDACTED] has delegated program authority and responsibility for the institution's animal care and use program including access to all animals. Dr [REDACTED] is present at the institution four (4) hours and contributes approximately six (6) hours to the animal use program every three (3) months.

B-4 Dr [REDACTED] (consulting veterinarian, exotic animal medicine), D.V.M., [REDACTED] University, 1996; Veterinarian, [REDACTED] Veterinary Hospital, 1998; Dr [REDACTED] is responsible for providing clinical consult and veterinary services for exotic animals (e.g., reptiles, birds and amphibians); coordinating in-house personnel training sessions for care and handling of exotic animals; and recommending husbandry practices for captive exotic animals. Dr [REDACTED] has delegated program authority and responsibility for the institution's animal care and use program including access to all animals. Dr [REDACTED] has twenty five (25) years experience in clinical medicine of reptiles, fish, birds and amphibians. Dr [REDACTED] is present at the institution one (1) hour and contributes approximately four (4) hours to the animal use program every three (3) months.

C. The Institutional Animal Care and Use Committee (IACUC) at this institution is properly appointed in accordance with the PHS Policy IV.A.3.a and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy, Section IV.A.3.b. Attached is a list of the chairperson and members of the IACUC listed by position, degrees, title profession or specialties, and institutional affiliation (**Exhibit A**).

D. The IACUC will:

D-1 Review at least once every six months the Institution's program for humane care and use of animals, using *the Guide* as a basis for its evaluation. The IACUC procedures for conducting semiannual program evaluations are as follows:

- a. All members of the IACUC are invited to participate in the semiannual review of the Institution's animal care and use program. The program review is completed primarily by a subcommittee of the IACUC consisting of at least two (2) voting members.
- b. The IACUC subcommittee uses the OLAW Sample Semiannual Program Review Checklist, *the Guide*, and 9 CFR Chapter I, subchapter A as a basis for its evaluation.
- c. Aspects of the program review include, but are not limited to: regulations, policies and principles; authority, composition, and function of the IACUC; institutional oversight of the animal care and use program; reporting responsibilities and procedures; protocol review procedures; veterinary care and preventative medicine; surgery and euthanasia guidelines, husbandry practices; common research practices and special considerations, standard operating procedures; record keeping

requirements; animal transport; institutional response to reported animal use concerns; personnel training and security; institutional occupational health program; crisis preparedness and response; and the most recent post approval monitoring and protocol annual activity reports; .

- d. The subcommittee will promptly report to the IACUC coordinator who shall record all findings and recommendations about the institution's animal care program. Any deficiencies noted in the animal care program will be identified as minor or significant, to include a recommended plan and timeline for appropriate corrective action where appropriate.
- e. The subcommittee's semiannual program review report is reviewed at a convened meeting of the IACUC in a timely manner.

D-2 Inspect at least once every six months all of the institution's animal facilities, including satellite facilities, using *the Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

- a. All members of the IACUC are invited to participate in the semiannual inspection of the Institution's animal facilities, including satellite locations. The facilities inspection is completed primarily by a subcommittee of the IACUC consisting of at least two (2) voting members.
- b. The IACUC subcommittee uses the OLAW Sample Semiannual Facility Inspection Checklist, *the Guide*, and 9 CFR Chapter I, subchapter A as a basis for its evaluation. Key aspects of the facility inspection include, but are not limited to:
 - Facility construction, design and functionality
 - Room condition, monitoring and maintenance
 - Primary enclosure identification and record keeping
 - Animal environment, space, housing arrangement and enrichment
 - Quality, handling and use of animal food, water and bedding materials
 - Room sanitation, material storage, waste disposal, and pest control
 - Appropriateness, use and maintenance of research areas
 - Cage wash operations and material sanitation
 - Veterinary care and provisions for weekend care and emergencies
 - Personnel training, staffing and work place safety.
- c. The subcommittee will promptly report to the IACUC coordinator who shall record all findings and recommendations about the institution's animal care facilities. Any deficiencies noted in the animal care facilities will be identified as minor or significant, to include a recommended plan and timeline for appropriate corrective action where appropriate.
- d. The subcommittee's semiannual facilities inspection report is reviewed at a convened meeting of the IACUC in a timely manner.

D-3 Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

- a. A quorum of the IACUC will convene to discuss the nature and extent of the institution's adherence to *the Guide*, PHS Policy, and 9 CFR Chapter I,

subchapter A. The IACUC will specifically identify any departures to *the Guide* and the reasons for each departure shall be stated and reported in the semiannual report to the Institutional Official.

- b. The IACUC will review all findings noted in the semiannual program review and facility inspection reports and categorize each deficiency as minor or significant, or as a recommendation to improve the institution's animal care program or facilities.
- c. The IACUC will discuss and develop an individual response plan and timeline for appropriate corrective action for each recommendation made and deficiency noted in the semiannual report to the Institutional Official.
- d. The IACUC will use the OLAW Sample Format for the Semiannual Report to the Institutional Official to outline all findings and recommendations related to semiannual business reporting.
- e. The IACUC will indicate in its report dates when the program evaluation and facility inspections were conducted and when they are next due by.
- f. The IACUC will identify and include any member's minority view/s or, where appropriate, provide a statement indicating that there were no minority views expressed within its membership to include in the report.
- g. A quorum of the IACUC will review and endorse the semiannual report to the Institutional Official with their approving signature.
- h. Semiannual reports of the IACUC shall be hand delivered to the Institutional Official in a timely manner by the IACUC Chair and/or IACUC Coordinator for a face-to-face meeting and discussion.
- i. The status of corrections for semiannual business shall be regularly placed on IACUC meeting agendas for continual monitoring and discussion at the appropriate interval until each deficiency or recommendation as detailed in the semiannual report to the Institutional Official is considered remedied to the satisfaction of the IACUC.

D-4 Review concerns involving reports or complaints of noncompliance with regulations or institutional policies involving the care and use of animals at the institution. The IACUC procedures for reviewing animal welfare concerns are:

- a. Contact numbers for the IACUC coordinator and the Attending Veterinarian shall be posted in all animal use and holding areas throughout the animal care facilities and on the IACUC resources webpage outlining how individuals can report concerns anonymously.
- b. The IACUC Chairperson, Institutional Official and the Attending Veterinarian shall promptly review all concerns initially, and if warranted, appoint a subcommittee to perform an investigation. If it is revealed, every effort will be made by the institution to conceal the reporting individual's identity to the fullest extent of applicable laws. The institution shall comply with applicable whistleblower policies, nondiscrimination against the reporting party, and protection of the complainant from reprisals.
- c. Review any subcommittee findings at a convened meeting of the IACUC and take appropriate action, if warranted, up to and including suspension of a protocol as described in section III.D-10 of this Assurance and

notification of the Institutional Official, OLAW and USDA where appropriate.

- d. The IACUC will notify the Institutional Official in writing within 10 days of having fully investigated reports or complaints of noncompliance with regulations or institutional policies involving the care and use of animals, including recommended action where appropriate.

D-5 Make written recommendations to the Institutional Official regarding any aspect of the institution's Animal Care Program, facilities, or personnel training. IACUC procedures for making recommendations to the Institutional Official are to:

- a. Evaluate, usually by subcommittee of at least two (2) voting members, any aspect of the Animal Care Program, facilities or personnel training program as described in section D-1 of this Assurance.
- b. Review subcommittee reports in a timely manner at a convened meeting as described in section D-3 of this Assurance.
- c. Submit all findings and recommendations in a formal report directly to the Institutional Official, including minority views, as described in section D-3 of this Assurance.

D-6 In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals as set forth in the PHS Policy at IV.C. IACUC procedures for protocol review are as follows:

- a. Protocol submissions are received by the IACUC coordinator. The coordinator reviews all submissions for completeness and provides input/assistance to the protocol director with developing the submission.
- b. Protocol submissions are distributed to all IACUC members and are managed only by Full Committee Review (FCR) at a convened meeting.
- c. IACUC members return any pre-review questions, comments or requests regarding the submission to the IACUC coordinator by a designated date.
- d. The IACUC coordinator informs the protocol director in writing of reviewer requests for clarification or modification in ample time before the next convened meeting.
- e. The IACUC has established the following policies and practices for meeting assembly, attendance, and member voting:
 - i. A quorum is required to conduct official IACUC business and any actions or decisions require a majority vote.
 - ii. No IACUC member may contribute to the constitution of a quorum or participate in review or approval of a protocol if the member has a conflicting interest (e.g., is personally involved in the project), except to provide information requested by the IACUC.
 - iii. Protocols undergoing FCR may only be approved after being discussed at a convened meeting with a quorum present.
 - iv. The IACUC may invite consultants to assist in review of complex protocols when necessary. Consultants may not vote unless

- they are officially appointed by the University President as a voting member of the IACUC.
- v. The IACUC shall appoint a Vice-Chair who is subordinate to the Chair and be able to assume the Chair's duties when the Chair is not present or due to a conflict of interest.
 - vi. If circumstances surrounding a protocol activity are deemed urgent by the Campus Veterinarian, the Chairperson will notify the IACUC and call for an emergency convened session.
 - vii. The IACUC may assemble by teleconference only if a face-to-face meeting cannot be assembled in sufficient time under exceptional circumstances as determined by the Chairperson. If teleconferencing is used, the IACUC will follow the provisions for conducting convened meetings via tele- or videoconferencing as outlined in the NIH Guide for Grants & Contracts NOT-OD-06-052.
- f. At a convened meeting of the IACUC, the Chairman uses the meeting agenda to address a complete list of protocol submissions pending review by the Committee.
 - g. The coordinator will inform the IACUC if any reviewer remarks were made during pre-review of a submission, and will provide members copy of response materials submitted by the protocol director, if any.
 - h. The IACUC may take final action at a convened meeting as a result of FCR and vote to:
 - i. Approve (as presented);
 - ii. Require modifications in (to secure approval); or
 - iii. Withhold approval.
 - i. The coordinator sends written correspondence to the protocol director informing him/her of the IACUC's decision.
 - j. Alternatively, the IACUC may vote to table further discussion of a protocol or employ Designated Member Review (DMR) to manage final approval of a protocol subsequent to FCR per section D-6.k of this Assurance.
 - i. The IACUC has approved this provision in policy that is subsequently reviewed and agreed to by all members annually. The policy clarifies that the IACUC may by unanimous vote at a convened meeting use DMR per section D-6.k of this Assurance to manage approval of a protocol or significant change thereto. Any member of the IACUC may, at any time, request to see the final protocol or amendment with revisions, and/or request FCR of the submission.
 - k. Designated Member Review (DMR) process:
 - i. Prior to implementing DMR, all committee members are afforded the opportunity to call for FCR of a protocol submission. If only one member requests FCR then that method of review must be used.
 - ii. If FCR is not called for, then the Chairperson (or vice-Chair) designates one or more members to manage review the protocol. The IACUC coordinator notifies the full committee of DMR designation of any protocol.

- iii. The designated reviewer(s) may require the protocol director to provide clarification or modification in (to secure approval) of a protocol submission.
- iv. DMR may only result in unanimous approval or require protocol modifications in (to secure approval). DMR must all view and approve the final version of a protocol. DMR decisions may not result in withholding approval of a protocol; and in such cases the protocol will be reassigned by the coordinator to be managed by FCR.
- v. DMR is a valid method of review and as such the decisions rendered by the designated reviewer(s) is/are considered final. If there is more than one designated reviewer, the final approval must be unanimous. If the final DMR decision is not unanimous, the protocol will be reassigned by the coordinator to be managed by FCR.
- vi. At the next convened IACUC meeting the coordinator announces the status or final action of those protocol submissions managed by DMR as they appear in the minutes.
- I. Applications and proposals approved by the IACUC may be subject to further appropriate review and approval by officials of the Institution. However, those officials may not approve the commencement of an activity involving the care and use of animals if it has not been approved by the IACUC.

D-7 Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

- a. Significant changes to an approved protocol are considered changes that have, or the potential to have, a negative impact on animal welfare. The IACUC has approved policy that differentiates a significant change (i.e., change in PI designation, new animal housing location or procedural changes that have a potential to increase the degree of pain or distress to an animal) from a minor change (e.g., 15% threshold on increase of animal numbers) or administrative change (e.g., addition of personnel). The protocol director is required to submit a protocol modification request describing any significant changes for IACUC review and approval before the change is instituted.
- b. Procedures for IACUC review of a proposed significant change to an approved protocol will conform to procedures as described in section III.D-6 of this Assurance.

D-8 Notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy

IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

- a. The IACUC coordinator will notify the protocol director in writing of the IACUC's decision regarding each protocol submission as defined in section III.D-6.h of this Assurance. The Institutional Official shall receive copy of the meeting minutes to reflect IACUC deliberations and its decision for all protocol submissions.
- b. The protocol director will be notified in writing that the approval duration for the protocol is no longer than that of three years for each application.
- c. If approval of an activity is withheld by the IACUC, written notification to the protocol director will include the reasons for the IACUC's decision. In such cases, the protocol director will be encouraged to respond to the IACUC with any questions or concerns in person or in writing.

D-9 Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy at IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows:

- a. Approved protocols shall be monitored and reviewed annually on or before the protocol anniversary date. An annual protocol review questionnaire is completed and submitted by the protocol director requiring a written narrative relaying details associated with the protocol to include (if applicable), but not limited to:
 - i. An annual report of animal activity [by number of animals, procedures conducted and respective pain category description] since the last review period;
 - ii. unanticipated results or aspects of animal activities;
 - iii. any unexpected (e.g., not described in the approved protocol) morbidity and/or mortality associated with the animals;
 - iv. assurance that IACUC requirements related to animal care and use, personnel training and/or modification requests will be adhered to; and
 - v. call for any written modifications to the protocol description, personnel involvement or personnel training for IACUC approval.
- b. Review the annual review questionnaire, protocol narrative and activity reports in accordance to *the Guide*, PHS Policy, and 9 CFR Chapter 1, subchapter A by FCR at a convened meeting as described in section III.D-6 of this Assurance.
- c. Require the protocol director to complete and submit a new application once every three years for ongoing activities. Triennial reviews by the IACUC are a complete *de novo* review of the protocol submission using the criteria and procedures for review specified in IV.C of the PHS Policy as described in section III.D-6 of this Assurance.

- d. The IACUC will not permit investigators to continue work involving the use of animals beyond the expiration date of a protocol, even if the protocol renewal is pending IACUC review.
- e. In addition to annual review, the IACUC will routinely discuss and employ Post Approval Monitoring (PAM) measures at appropriate intervals to ensure procedural consistency and adherence to the approved protocol. The authority and responsibility of the IACUC are not contravened by the established PAM program. IACUC procedures for employing PAM are to:
 - i. discuss no less than annually at a convened meeting respective IACUC approved protocols to select and schedule for a PAM site visit;
 - ii. conduct PAM visits with at least two voting IACUC members examining areas where animals are housed and used, observing activities in progress whenever possible, and inspecting research, clinical and training records associated with such activities; and
 - iii. review in a timely manner at a convened meeting with a quorum present the PAM inspection report and send a final report to the investigator to share commendation for full compliance, make recommendations on operations that would improve animal welfare or compliance; and/or identify areas of non-compliance and the appropriate remedy or action. Final reports generated by the IACUC PAM visits that identify serious or ongoing non-compliance with the approved protocol, PHS Policy, or the Guide will be forwarded to the Institutional Official for proper action and reporting as described in section VI.B of this Assurance.

D-10 Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.7. IACUC procedures for suspending an ongoing activity are as follows:

- a. Any individual may relay a concern of animal care and use anonymously to the clinical or husbandry staff, IACUC office, IACUC Chair, IACUC member, Campus Veterinarian, or Institutional Official.
- b. The Campus Veterinarian has the authority to temporarily halt an activity if the health, safety or welfare of the animal(s) or personnel associated with an activity is inappropriately in jeopardy until the IACUC can convene to review the situation and respond appropriately.
- c. Suspension of an activity involving animals may occur only after review of the matter at a convened meeting of a quorum of the IACUC and the suspension must be approved by a vote of a majority of a quorum present.
- d. If the IACUC suspends an activity involving animals, the Institutional Official (in consultation with the IACUC) reviews the reasons for suspension, takes appropriate corrective action, and reports that action with a full explanation to OLAW, USDA and other Federal agencies as required per section VI.B of this Assurance.

E. The occupational health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals is summarized below:

E-1 The Laboratory Animal Occupational Health Program (LAOHP) is designed to reduce occupational health risks to personnel to acceptable levels and to facilitate a safer work environment through education, health assessment, protection and surveillance. A trained occupational health physician at the campus Wellness Center is involved with the planning and implementation of the LAOHP. The LAOHP is administered through the campus Wellness Center in cooperation with campus Environmental Health and Safety, Office of Risk Assessment, Animal Care Department and the IACUC. The LAOHP is tailored appropriately to an individual's degree of risk and includes preventative health and surveillance services, zoonosis and allergy training and monitoring, project risk assessment and safeguards, and practical training for personnel working with laboratory animals and hazardous materials in the classroom, in the laboratory and in the field.

E-2 Covered Personnel are faculty, staff, students, visitors, IACUC members, and volunteers who directly work with vertebrate animals, animal tissues or body fluids, or work in the animal care facilities. IACUC members review incoming animal use protocols along occupational health and safety dimensions in order to identify potential animal-related risks to personnel associated with animal activities. Veterinary support personnel are actively enrolled in the LAOHP by their supervisor and receive a pre-employment health evaluation at the time of hire. Service personnel, including security and maintenance technicians, are considered for safety training and health services under the LAOHP appropriate to the level of risk prior to coming into contact with laboratory animals. Animal room locations have clearly displayed postings on the exterior door indicating potential for risk and exposure to personnel, available supply of appropriate PPE in the immediate area and how to proceed to receive safety training or to relay health concerns while working in these areas.

E-3 Procedures for Risk Identification and Hazard Management: Written policies, procedures and routine monitoring of hazardous biologic, chemical and physical hazards usage and disposal is managed by College of Science (CoS) Safety Committee in cooperation with the IACUC and campus Environmental Health and Safety. The CoS Safety Committee is charged with establishing and routinely monitoring safety programs (in accord with the Biosafety in Microbiological and Biomedical Laboratories manual) to assess hazards and determine the safeguards needed for their control. The CoS Health and Safety Committee will verify that facilities and hazard management and disposal practices comply with institutional and government standards during routine site inspections and audits of animal care and use areas. The IACUC is charged with identifying, monitoring and education with regard to animal-related hazards as identified in the investigator's protocol. Hazard management includes anesthetic gas scavenging systems, dose preparation, administration and storage of noxious compounds,

controlled substance handling, equipment usage and maintenance, biological sample handling, personal protection and Safety Data Sheet documentation in these areas. Training in proper hazard management is required by the IACUC for all personnel associated with an animal activity to be provided and documented by the Principal Investigator or their designee. The IACUC will identify project-related hazards during protocol review and will assign each protocol a "Health Risk Category" at the time it is approved. This process is meant to facilitate a safer work environment through education (e.g., zoonosis information), assessment and surveillance (e.g., LAOHP Physician), and training. Appropriately, the IACUC's criteria for protocol risk category assignment will be based on the potential hazards 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. The extent of personnel participation in the LAOHP is dependent upon individual risk of exposure and IACUC assignment to Health Risk Category 1 (RC-1), Category 2 (RC-2) or Category 3 (RC-3):

a. RC-3 is considered the highest acceptable risk, which includes duties performed by veterinary clinical staff, animal care staff, and individuals who are at serious risk of exposure (e.g., working with non-human primates, hoofed animals or highly toxic compounds). Specific risk factors may be variable and are dependent on individual contact with live animals or materials as identified in the approved protocol. Personnel involved with projects identified by the IACUC as RC-3 will be informed they must participate in the LAOHP for medical consultation and to receive health clearance by the LAOHP physician prior to working with live animals or hazardous materials. The LAOHP physician will evaluate personnel using the LAOHP questionnaire as a basis to determine individual participation and what preventative health measures are necessary in the event of an animal-related exposure and consult with campus Environmental Health and Safety where appropriate to define response procedures in the event of a possible chemical exposure.

b. RC-2 indicates average to potential high risk of exposure (such as bites, scratches, hazardous substances, allergies or zoonotic diseases) for personnel having routine contact with purpose-bred animals or participating in certain field studies. Upon reviewing the IACUC's recommendation with the Principal Investigator, personnel associated with the study may then determine whether or not they should proceed by participating in the LAOHP for prior medical consultation and evaluation (including pregnant or immune compromised individuals).

c. RC-1 covers all approved animal activities posing minimal risk of exposure to personnel having minimal contact with purpose-bred animals or inherent risks associated with participating in field trips. Investigators, students and maintenance staff will be informed of the

LAOHP services available to them and are encouraged to complete and submit an LAOHP questionnaire at any time during the activity.

E-4 Pre-employment Medical Evaluation: Personnel participation in the LAOHP for a medical evaluation is confidential and considered voluntary for personnel engaged in low risk health category level I & II activities as explained in section E-3. Individuals that wish to work with laboratory animals and decline medical evaluation or collection of health history under the LAOHP must declare their intention by signing and registering a medical waiver with the campus Wellness Center physician. Registering a medical declination waiver will not preclude any individual from participating in or receiving necessary LAOHP training in safe practices outlined in section E-7 of this Assurance as dictated by the IACUC or Principal Investigator on the project.

E-5 Immunizations are administered to personnel at the direction of the LAOHP physician and is dependent upon the specific circumstances, identified risk factors and determined medical need. The LAOHP physician reviews completed LAOHP questionnaires with personnel upon during medical evaluation appointments and determines what immunizations are necessary. All employees shall be offered immunization against tetanus toxoid. Proof of health clearance by the LAOHP physician is required for all veterinary staff and animal care employees as a condition of hire.

E-6 Preventative Medicine Program is employed and managed confidentially by the director of campus wellness center who reviews LAOHP questionnaires and determines what follow-up is necessary. Veterinary care personnel are required to receive routine medical consults with a LAOHP physician at 18-month intervals. The student health center provides medical consults and pertinent LAOHP information to all personnel.

E-7 Personnel Training is provided to faculty, staff, students, contractors and volunteers associated with the Animal Care Program in all aspects of the LAOHP per section G of the Assurance. Personnel education in project-related risks, including PPE requirements, zoonosis information, chemical safety, managing exposures, acknowledgement of risk exposure (e.g., allergens to rodents), and health monitoring and surveillance, is identified by the IACUC at the time of animal protocol approval. Project-specific training is required by the IACUC for all personnel associated with an animal activity to be provided and documented by the Principal Investigator or their designee in these areas. Such training includes precautions, special considerations and services for personnel who are pregnant, have illness or decreased immunocompetence. Facility orientation and practical training in animal use and its associated hazards is a routine service to investigators provided by the veterinary staff to capture personnel new to the Animal Care Program. The IACUC will verify that personnel are sufficiently trained in all aspects of the LAOHP during routine site inspections and audits of animal care and use areas.

E-8 Personnel Hygiene. Personnel are instructed to wash hands routinely after all procedures; and not to eat, drink, smoke or apply cosmetics in any of the animal care facilities. The IACUC will verify availability and proper use of facilities for maintaining personal hygiene (i.e., laundry facilities, first aid equipment and shower facilities, where appropriate) during routine site inspections and audits of animal care and use areas.

E-9 Personal Protective Equipment is provided to personnel working with animals as part of their employment or at their request. Personal Protective Equipment (PPE) tailored to the area in which animal care personnel are working, or species working with, such as: lab coats, disposable gowns, safety glasses, latex and steel mesh gloves, respirators, surgical face masks, face shielding, chemical resistant aprons, boots and gloves. Appropriate PPE is provided to all personnel in all locations upon commencement of each exercise. Dedicated coverings are to be worn at the workstation or area where such gear is required. The appropriate PPE to be worn is detailed in Standard Operating Procedures (SOP) or relayed by the course instructor or research advisor as outlined in the approved animal care and use proposal.

E-10 Allergies: The LAOHP properly addresses the risk of allergies for individuals who come in contact with laboratory animals. Medical surveillance services are available to promote early diagnosis and monitoring of acute, chronic and pre-existing allergies. The IACUC, University Animal Care department and Principal investigator provide sufficient personnel training about animal allergies (acute versus chronic), early recognition, preventative control measures, and reporting of allergy symptoms, and proper PPE and techniques for working with animals, including proper use of facilities and respirators, as required. Acute allergic reactions are managed promptly by calling 911 and include follow-up health advisement and monitoring by the LAOHP physician where appropriate. Respirator fit testing and training is coordinated through the campus Wellness Center and CoS.

E-11 Procedures for Reporting and Treating Injuries: If personal injury or exposure occurs, personnel are instructed to apply first aid report the incident to their instructor or supervisor as soon as possible. Injuries shall be promptly assessed and treated by the LAOHP physician or the nearest emergency room. If the situation is life threatening, personnel are to dial 911 or contact university police for assistance. A formal incident report must be completed and submitted to the department administrator within 24 hours. Medical treatment and follow-up care are available to all personnel through the campus LAOHP.

E-12 Zoonosis Surveillance: For purpose-bred animals maintained in the animal facilities having clean health reports, health screening is performed at appropriate intervals as outlined in the institution's Program of Veterinary Care. This institution does not have the appropriate facilities to manage Animal Biosafety Level III or IV studies. The IACUC addresses risks associated with animal activities (particularly field activities) during protocol review and

investigators are educated as to the possible health risks and appropriate exposure response and reporting procedures. Zoonoses surveillance for all personnel is coordinated through the campus Wellness Center. The IACUC will verify that personnel are appropriately trained in zoonoses and zoonoses surveillance procedures during routine site inspections and audits of animal care and use areas.

F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached table (**Exhibit B**).

G. Personnel training and continuing education is considered an integral part of the institution's animal care and use program. Training and instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

G-1 IACUC Members will be appropriately trained to evaluate and discharge their collective responsibility. All IACUC members will have direct web link access to or be provided hard copy of:

- a. PHS policy for the Humane Care and Use of Laboratory Animals
- b. Institutional Assurance D16-00389
- c. Guide for the Care and Use of Laboratory Animals (NRC, 2010)
- d. AVMA Guidelines on Euthanasia (2013)
- e. Animal Welfare Act, AW Regulations and Policies
- f. Professional Society Guidelines for Use of Animals in Field Research

IACUC members and coordinators are required to successfully complete online training hosted by Collaborative Institute Training Initiative (CITI) per section G-3.i of this Assurance, including courses: Essentials for IACUC members, Chairs and Administrators; Working with the IACUC, and at least one species-specific course of their choice. Prior to being recognized as a voting member of the IACUC, members shall attend a comprehensive animal care program and facilities orientation administered by the coordinator. Online training verification shall be regularly maintained and renewed at least every three years for all voting members and IACUC staff. IACUC members and administrators shall be encouraged to regularly engage in continuing education (e.g., pre-meeting warm-up topics and attending conferences) with emphasis on animal welfare regulation, institutional policy and procedures, and animal care program oversight.

G-2 Animal Care Personnel: Individuals directly responsible for the monitoring and care of animals shall be appropriately trained in species-specific characteristics and management of animals before performing animal care duties. Research personnel identified in the animal use protocol as providing routine animal care for their project shall have training verification by the campus veterinarian or designee to ensure the individual's level of proficiency and understanding of animal husbandry procedures. Animal Care personnel will

be required to successfully complete CITI's species-specific training courses relevant to their work per section G-3.i of this Assurance. Online training verification shall be regularly maintained and renewed at least every three years.

G-3 Personnel Involved in Research and Student Teaching: All personnel involved in the care and use of animals must be identified in the IACUC protocol. A description of each individual's qualifications, experience and necessary training with the species of interest, experimental model and procedures involved shall be provided for IACUC review. Any individual requiring protocol-specific training be identified and successful completion of such training per sections G-3.ii & iii of this Assurance will be a condition of approval of the protocol. The institutional personnel training program follows a multimodal approach:

i. Module One: All personnel, including IACUC members, involved in the care, treatment and use of animals are required to successfully complete online training relevant to their work. The IACUC shall require verification of online training for personnel associated with animal activities prior to permitting individual participation on the animal use protocol. Online training verification shall be regularly maintained and renewed every three years for all personnel active in the Animal Care Program. Online core training shall include, but is not limited to:

- IACUC policy and animal welfare oversight expectations
- Minimization of animal numbers (reduction)
- Justification for using live animals (replacement)
- Concept, availability, and use of research or teaching methods that limit the use of animals or minimize pain, distress and discomfort (refinement)
- Species-specific characteristics and proper handling of each species.
- Utilization of services available to provide information on appropriate methods of animal care and use; alternatives to the use of live animals in research, teaching and testing; verification that could prevent unintended or unnecessary duplication of research or teaching efforts involving animals; and expectation of the Animal Welfare Act/Regulations and PHS Policy on Care and Treatment of Laboratory Animals.
- Methods whereby deficiencies and adverse events in animal care and use are reported and can be done anonymously without reprisal

ii. Module Two: All personnel shall have access to the appropriate training resources and technical assistance in the care and use of laboratory animals for all activities. Investigator-led training and veterinary oversight is essential to proper oversight where animals are used. Animal Care Program orientation and introductory technical training is available through the veterinary staff to all personnel in the care and use of animals. Such training shall be required prior to granting individual access to Animal Care Facilities and may be required when IACUC-approved pilot procedures are conducted. Proficiency monitoring and hands-on training shall be continually offered to all personnel to promote individual confidence and competence in animal care and use

where applicable. Specifically, as applicable, training and instruction of personnel includes guidance in at least the following areas:

- Pre- and post-procedural care of animals
- Proper aseptic and surgical technique
- Proper use of anesthetics, analgesics and tranquilizers in the protocol
- Students shall be evaluated by IACUC during protocol review to be adequately trained and prepared before participating in animal-related activities as part of their course work.

Personalized training records shall be initiated by the Principal Investigator or his/her designee and maintained in the research or teaching laboratory for a period of 3 years for regular audits by the IACUC and veterinary staff.

- iii. Module Three: Advanced personnel training in surgery and specialized techniques involving animals shall be conducted as directed by the campus veterinarian or by the IACUC during protocol review. Practical training shall be introduced using online resources (e.g. JoVE journal) and/or attending a hands-on technical workshop, and overseen by a qualified lab official or vet staff member as identified in the IACUC protocol. Individual proficiency in surgical and specialized techniques that have potential for causing significant impact on animal welfare shall be verified by the campus veterinarian or their designee to ensure individual competency. The trainer will certify no individual unless the individual is adequately guided and assisted, and found to be proficient at the task required of him/her before being allowed to participate in animal-related activities unsupervised.

G-4 Documentation Requirements and Verification of Personnel Training – the protocol director shall maintain training documents for all personnel associated with their approved protocol/s. A standardized personnel training form template is available to all animal users via the IACUC online resources page. Personnel transferring from other institutions at which they have received similar training, verification of previous training may be accepted by the IACUC to replace some aspects of the institutional training requirements. Documentation that all personnel have read the approved IACUC protocol and individual training certification using modules 1, 2 and/or 3 must be kept up-to-date and be made available to the IACUC upon request for the duration that any person is active in the Animal Care Program. Personnel training records shall be maintained by the institution for three (3) years and shall be made available to OLAW upon request.

IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION

All of the Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be reevaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to *the Guide*. Any departures from *the Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant

deficiencies from minor deficiencies. Where appropriate, reports will contain reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to OLAW upon request.

This Institution is Category Two (2) – not accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). As noted above, past reports of the IACUC's semiannual evaluations (program review and facility inspections) will be made available upon request. The semiannual report to the Institutional Official of the most recent evaluations (program review and facilities inspections) is attached (**Exhibit C**).

V. RECORD KEEPING REQUIREMENTS

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

1. A copy of this Assurance and any modifications thereto, as approved by OLAW/PHS.
2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
4. Records of semiannual IACUC reports and recommendations (including minority views) to the Institutional Official, Dr. Pamela C. Stacks.
5. Records of accrediting body determinations.

B. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity. Applications and proposals involving the care and use of animals shall be evaluated by the IACUC to insure the project conforms with the Institution's Assurance and meets the following requirements:

1. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
2. Procedures that may cause more than momentary or slight pain or distress to animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the protocol director.
3. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be euthanized at the earliest, most appropriate time and, if appropriate, during the procedure.

4. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feed, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling and use of the species being used.
5. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
6. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
7. Methods of animal euthanasia will be consistent with the recommendations of the AVMA Panel on Euthanasia. Deviations to the AVMA Panel's recommendations on euthanasia shall be outlined in the IACUC-approved protocol with proper justification for scientific reasons.

C. All records shall be made accessible to OLAW or other PHS representatives at a reasonable time and in a reasonable manner.

VI. REPORTING REQUIREMENTS

A. This Institution's reporting period is January 1 – December 31 of each year. The IACUC, through the Institutional Official, will report in writing to OLAW on January 31 of each year. The report will include:

1. Any change in the accreditation status of the Institution (e.g., if the institution becomes accredited by AAALAC or AAALAC accreditation is revoked), any change in the description of the Institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, this institution will provide OLAW with written notification that there are no changes.
2. Notification of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Dr. Pamela C. Stacks.

B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full written explanation of the circumstances and actions taken with respect to: any serious or continuing noncompliance with the PHS Policy; any serious deviations from the provisions of *the Guide*; and any suspension of an animal activity by the IACUC. Timely initial/preliminary reporting will be made to OLAW by telephone where appropriate.

C. Reports filed under VI.A and VI.B of this Assurance shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Dr. Pamela C. Stacks
Title: Associate Vice President, Research
San José State University

Address: One Washington Square
San Jose, CA 95192-0025

Phone: 408-924-2488

Email: Pamela.Stacks@sjsu.edu

Signature: 

Date: January 28, 2019

B. PHS Approving Official

Doreen H. Bartlett
Senior Assurance Officer, Division of Assurances
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive Suite 2500 MSC 6910
Bethesda, MD 20892
bartletd@od.nih.gov
301-496-7163

Signature: Doreen H.
Bartlett -S

Digitally signed by Doreen H.
Bartlett -S
Date: 2019.01.31 08:24:42
-05'00'

Date: January 31, 2019

C. Effective Date of Assurance: January 28, 2019

D. Expiration Date of Assurance: January 31, 2023

Exhibit A

- **IACUC Membership List (Section VIII)**
- **Chairperson Contact Information (Section VIII)**
- **Other Key Contacts Regarding Assurance (Section IX)**

SECTION VIII

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE ROSTER

SAN JOSE STATE UNIVERSITY

ASSURANCE #D16-00389

September 4, 2018

SCIENTIST & CHAIR:

SHELLEY CARGILL, PhD

ASSOCIATE PROFESSOR, DEPARTMENT OF BIOLOGICAL SCIENCES

ONE WASHINGTON SQUARE, SAN JOSE, CA 95192-0100

PHONE: 408924-4891 FAX: 408-924-4840

EMAIL: SHELLEY.CARGILL@SJSU.EDU

<i>MEMBER NAME/CODE</i>	<i>DEGREE/CREDENTIALS</i>	<i>POSITION TITLE</i>	<i>PHS REQUIREMENTS</i>
ROSEMARY BROOME	D.V.M., DACLAM	ATTENDING VETERINARIAN	VETERINARIAN
	PhD	FACULTY, PHILOSOPHY	NON-SCIENTIST & VICE-CHAIR
HAL	B.Sc.	STAFF, COMMUNITY COLLEGE	NONAFFILIATED
NDJ	M.Sc.	SAFETY OFFICER	MEMBER
HAS	PhD	SJSU FACULTY	SCIENTIST
TRS	M.Sc.	SJSU LECTURER	SCIENTIST
MCG	PhD	FACULTY/ALTERNATE	SCIENTIST
SHS	PhD	FACULTY/ALTERNATE	SCIENTIST
WAY	RVT, CPIA	IACUC ADMINISTRATOR	NON-VOTING MEMBER

SECTION IX: OTHER KEY CONTACTS REGARDING ASSURANCE


ANIMAL CARE PROGRAM MANAGER


Exhibit B

- **Facility Space and Species Inventory (Section X)**

SECTION X
FACILITIES AND SPECIES INVENTORY
San Jose State University
Assurance #D16-00389

September 11, 2018

Location	Gross Square Footage	Species Housed	Average Daily Inventory
██████	240	Mice & Rats	60 & 0
██████	790	Snakes, Tortoises & Frogs	8, 8 & 4
██████	432	Mice & Rats	48 & 0
██████	234	Mice or Frogs	0 or 56
██████	234	Mice or Rabbits	220 or 8
██████	1152	Mice & Rats	449 & 18
██████████	6400	Sea lions & pigeons	4 & 2
██████████	1250	Fin fish	150
██████████	1250	Fin fish	60

Exhibit C

Section IV Attachments

- Semiannual Report to the Institutional Official (May 2018)
- Supplement to Semiannual Report (June 2018)

The California State University
Chancellor's Office
Berkeley
Channel Islands
Chico
Dominguez Hills
East Bay
Fresno
Fullerton
Humboldt
Long Beach
Los Angeles
Maritime Academy
Monterey Bay
Northridge
Pomona
Sacramento
San Bernardino
San Diego
San Francisco
San José
San Luis Obispo
San Marcos
Sonoma
Stanislaus

Date: May 28, 2018

To: Pamela C. Stacks, Ph.D.
Institutional Official for Animal Care and Use

From: Institutional Animal Care and Use Committee

RE: Semiannual Evaluation of the Animal Care and Use Program and Inspection of Facilities at SJSU and Designated Research Sites.

This report represents the IACUC's spring 2018 animal care program review and facilities inspection, as required by Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, Section IV.B.1-3, the *Guide for the Care and Use of Laboratory Animals* (the *Guide*), and USDA Animal Welfare Act (AWA) regulations, as applicable.

Changes in the institution's animal care and use program

There have been no changes to the institution's animal care and use program since the last semiannual report. The institutional animal care and use program remains unaccredited by AAALAC.

Description of the nature and extent of the Institution's adherence to the PHS Policy, the *Guide*, and AWA

There are no departures to the PHS Policy, the *Guide*, and AWA approved by the IACUC during this reporting period.

Evaluation of the institution's animal care and use program

The IACUC conducted its semiannual review of the institution's animal care and use program on 4/20/2018 using the *Guide*, and, as applicable, 9 CFR Chapter I, 2.31. The attached semiannual facilities inspection and program review table outlines one significant deficiency (*line item #1*), two minor deficiencies (*line items # 2 and 3*), and one recommendation (*line item #5*) noted by the IACUC with regard to animal care and use policies, practices and programs at SJSU and its satellites.

Inspection of SJSU animal care facilities and designated research sites

The IACUC conducted its semiannual inspection of the institution's animal care facilities including Duncan Hall on 4/06/2018 and site #2 (MLML) on 4/13/2018 using the *Guide*, and, as applicable, 9 CFR Chapter I, 2.31. The attached semiannual facilities inspection and program review table outlines one minor deficiency (*line item #4*) noted by the IACUC with regard to the animal care facilities at SJSU and its satellites.

Minority views of the IACUC

There were no minority views expressed amongst the IACUC's membership to include.


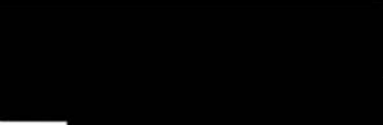
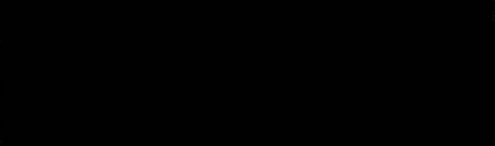

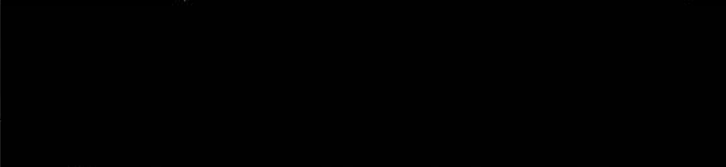

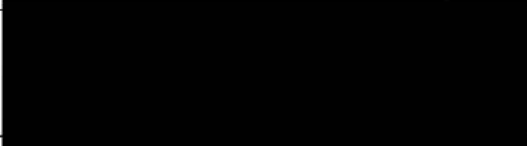

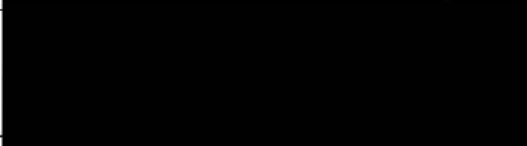
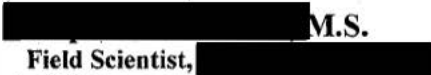
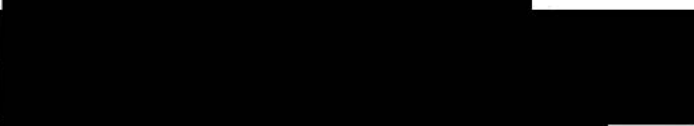
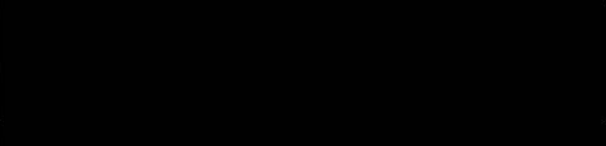

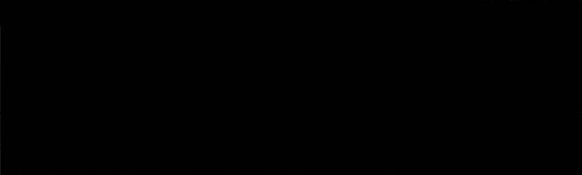
Next scheduled semiannual business of the IACUC

As a condition of this institution's assurance with the Office of Laboratory Animal Welfare and in accordance with the AWA regulations, the next semiannual animal care program review and facilities inspections shall be conducted on or before October 31, 2018.

Attachments: IACUC member approval page
Semiannual Report of Program Review and Facilities Inspection table

SAN JOSE STATE UNIVERSITY INSTITUTIONAL ANIMAL CARE & USE COMMITTEE

IACUC ENDORSEMENT OF THE SPRING 2018 SEMIANNUAL REPORT TO THE INSTITUTIONAL OFFICIAL

 Non-affiliated member	 Not Present <u>5-18-18</u>
Rosemary Broome, DVM, DACLAM Campus Veterinarian	 <u>5-18-18</u>
 , Ph.D. Non-scientist,	 <u>5/18/2018</u>
 , Ph.D. Marine Scientist,	 Not Present
 , M.S. Safety Officer,	 <u>5.18.18</u>
 , M.S. Field Scientist,	 <u>5.18.2018</u>
Shelley Cargill, Ph.D. Scientist and Chair	 <u>5-18-18</u>
 RVT, CPIA IACUC Coordinator (non-voting)	 <u>5/18/18</u>

Refers to:  inspection conducted on 04/13/2018
 inspection conducted on 04/06/2018
Animal Care Program review conducted on 04/20/2018

SJSU IACUC

May 28, 2018

SPRING 2018 SEMI-ANNUAL REPORT OF PROGRAM REVIEW AND FACILITIES INSPECTION TABLE

LINE ITEM	DEFICIENCY CATEGORY	DEFICIENCY DESCRIPTION	PLAN FOR CORRECTION (INCLUDING RESPONSIBLE PARTY AND TIMELINE)
1. Animal Care Program	SIGNIFICANT DEFICIENCY	<p>Animal Housing and Care at [REDACTED]</p> <p>[REDACTED] The IACUC has not received a plan from MLML for corrective action of prior deficiencies or an assurance of animal care program compliance from the Director as requested in the fall 2017 semiannual report.</p> <p>On March 26, 2018 an incident was reported to the SJSU veterinary staff of significant animal mortality at [REDACTED]. The issue was suspected to be a water quality issue and within a matter of three weeks 100% mortality of fishes was noted at both aquarium facility sites. During this time the Campus Veterinarian imposed a moratorium on reoccupying the aquarium facilities until the animal mortality issues could be thoroughly investigated. Veterinary pathology reports on specimens submitted for diagnostics are currently pending. The veterinary staff reports that internal response at MLML to remedy the situation and preserve animal welfare was slow and unorganized. Contributing factors were lack of communication at multiple levels, inadequate diagnostic testing of water quality and character, and insufficient personnel training.</p> <p>The IACUC has determined that there is insufficient reporting of animal morbidity and mortality to initiate the appropriate follow up or veterinary consultation.</p>	<p>On April 30, 2018 all MLML animal care and research teams attended a veterinary-lead training session to review and discuss proper notation and reporting of animal morbidity and mortality in accordance with IACUC standards.</p> <p>Due to the repeated and ongoing minor deficiencies at MLML noted by the IACUC and the patchwork response to mitigate these deficiencies to date, the IACUC does not recognize the [REDACTED] aquarium facilities [REDACTED] as an approved space to hold vertebrate animals. This includes any animal holding spaces at [REDACTED] without prior IACUC approval. To meet institutional expectations with regard to the care and use of laboratory animals, the IACUC requires MLML to formalize an organizational animal care program. The program shall conform to the principles and procedures outlined in the institutional assurance (#A3648-01) with Public Health Service Policy on Humane Care and Use of Laboratory Animals. The program shall cover all fish holding spaces and include, but is not limited to:</p> <ol style="list-style-type: none"> 1) Departmental commitment and program applicability; 2) Departmental lines of authority and responsibility with respect to the Animal Care and Use Program; 3) Policies that conform to the Guide for Care and Use of Laboratory Animals and specifically address: <ol style="list-style-type: none"> a. Routine husbandry and care of animals, including staffing and daily animal monitoring.

Procedures are in-place for animal care staff to note animal morbidity and mortality, however there is little evidence this information is being relayed, reviewed or investigated outside the animal room in effort to preserve animal health.

The current training program for animal care personnel in the aquarium room is marginal. Animal care is assigned to student recruits as outlined in each IACUC protocol. Training records do not provide insight into standards used to train animal care personnel and reflect in multiple instances verification of proficiency for new recruits the same day training was initiated. There is insufficient record of euthanasia training for animal care and research personnel.

Animal care personnel do not have access to water character monitoring instrument values, nor is there equipment available in the animal room to assess minimum water quality parameters of the aquarium enclosures real time.

[REDACTED] facility is on the same water supply circuit as the [REDACTED] aquarium facilities [REDACTED] PI) and [REDACTED] (DVM) report no ill effect and continue to monitor captive marine mammals there.

The IACUC has determined that no USDA species or PHS funded activities were affected by the adverse water quality event. On May 3, 2018 the IACUC Chair submitted a preliminary report to OLAW regarding the adverse water quality event. MLML aquarium facilities currently remain unoccupied of fin fish for teaching or research.

b. Sanitation and maintenance of animal holding tanks, equipment, spaces, and feed storage.

c. Regular monitoring and notation of constituents, condition and quality of aquatic environments.

d. Procedures to monitor and mitigate adverse mechanical events or water quality conditions, including system intake and direct monitoring, personnel alert and internal response and communication procedures. Procedures shall also include animal triage plans based on risk that meet institutional and investigator needs.

e. Animal management documents and record keeping.

f. Veterinary clinical consultation and response procedures, including timely reporting, contingency for euthanization of animals and preservation of samples for diagnostics. Identify a clinical veterinarian with aquatic fish experience.

g. Personnel training. All personnel involved in the care and use of laboratory animals must be adequately educated, trained and/or qualified in basic procedures of laboratory animal science and/or management. All personnel training must be verified and documented.

It is requested that MLML prepare a complete and well-designed aquatic animal care program. IACUC will confer with the IO on a step-wise timeline for completion. When complete, the program document shall be submitted to IACUC for review. The IACUC will conduct a site inspection of MLML facilities as part of the MLML program review. When approved by the IACUC, the program document will be advanced to the IO for review. When accepted by the IO, the IACUC will approve MLML aquarium facilities for holding fishes.








2. Animal Care Program	MINOR DEFICIENCY	<p>Fish husbandry standards and animal care documentation [REDACTED]</p> <p>Standard operating procedures and supporting documents pertaining to routine husbandry and care of fish species are insufficient. Animal room care binders are tattered and falling apart due to high humidity levels in the animal holding room.</p>	<p><i>All husbandry SOPs shall be reviewed by a veterinarian and an aquarist with expertise in the care and use of fin fish, investigators, facility personnel, ACFOM and IACUC to ensure completeness and adherence to the Guide. Maintenance of animal care, IACUC protocols, SOPs and personnel training documents shall be reviewed to ensure documents are appropriately detailed and accessible, and properly protected in the animal rooms. IACUC will confer with the IO on a step-wise timeline for completion to address concerns regarding husbandry standards and animal care documentation as part of requested aquatic animal care program submission.</i></p>
3. Animal Care Program	MINOR DEFICIENCY	<p>Handling and removal of animal carcasses and tissue at MLML. The IACUC and MLML safety officer acknowledge there is no formal process for properly handling and disposing of animal tissues that are potentially hazardous.</p>	<p><i>The IACUC is requesting that the MLML safety officer provide a written plan for proper handling, storage and removal of potentially hazardous and infectious waste and tissues at MLML by the June 15, 2018 IACUC meeting.</i></p>
4. Animal Care Facilities	MINOR DEFICIENCY	<p>Maintaining water temperature in outdoor enclosures [REDACTED]</p> <p>Concerns have been raised about rising tank water temperature in outdoor enclosures during warm sunny days.</p>	<p><i>The MLML Director and Primary Investigator at the [REDACTED] shall address the concern of fluctuating water temperatures in outdoor enclosures, especially during summer months. Policy shall be in-place addressing by what method and how often individual tank water temperature is monitored, how temperatures are kept from rising during summer months and an animal care response plan when temperatures fluctuate beyond the desired range. IACUC will confer with the IO on a step-wise timeline for completion to address concerns regarding outdoor tank management as part of requested aquatic animal care program submission.</i></p>

<p>5. Animal Care Program</p> <p>END OF REPORT</p>	<p>RECOMMENDATION</p>	<p>Tracking prescribed controlled substances [REDACTED] does not hold a DEA license to procure controlled substances, however multiple entries were made in an animal's medical record administering a tranquilizer prescribed by Dr [REDACTED]. The drug container was appropriately stored and secured, but did not have a corresponding tracking log for its use.</p>	<p><i>The IACLIC is recommending that the managers of [REDACTED] initiate a drug tracking system. Product tracking should minimally include initiating a log sheet and vial number when the prescription is received, track each drug use entry on the corresponding log and conduct a semiannual product inventory. The managers at [REDACTED] have been asked to initiate a controlled drug tracking system of the current drug stock by July 1, 2018.</i></p>
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SAN JOSE STATE UNIVERSITY INSTITUTIONAL ANIMAL CARE & USE COMMITTEE

IACUC ENDORSEMENT OF THE SPRING 2018 SUPPLEMENTAL REPORT TO THE INSTITUTIONAL OFFICIAL

 Non-affiliated member	<i>Not Present</i>
Rosemary Broome, DVM, DACLAM Campus Veterinarian	15 June 2018
 Ph.D. Non-scientist,	June 15, 2018
 Ph.D.  Ph.D. Marine Scientist,	15 June 2018
 M.S. Safety Officer,	6.15.18
 Ph.D. Field Scientist,	<i>Not Present</i> 15 Jan 2018
Shelley Cargill, Ph.D. Scientist and Chair	6-15-18
 RVT, CPIA IACUC Coordinator (non-voting)	6/15/18

Refers to:

 inspection conducted on 04/13/2018
 inspection conducted on 04/06/2018
Animal Care Program review conducted on 04/20/2018

SJSU IACUC

June 15, 2018

SPRING 2018 SEMI-ANNUAL REPORT OF PROGRAM REVIEW AND FACILITIES INSPECTION TABLE

LINE ITEM	DEFICIENCY CATEGORY	PLAN FOR CORRECTION (INCLUDING RESPONSIBLE PARTY AND TIMELINE)
1. Animal Care Program	SIGNIFICANT DEFICIENCY	<p>Line items 1.1 & 1.2: Animal Care Program assurance to demonstrate departmental commitment and Program applicability, including departmental lines of authority and responsibility with respect to the Program.</p> <p><i>An Animal Care Program assurance shall be presented to the IACUC in writing with full support of the MLML Director and input from the newly assembled Aquarium Facility Oversight Committee by the August 24, 2018 IACUC meeting date. Correspondence from the MLML Director is also requested affirming if the IACUC's expectations for each plan and timeline of correction outlined herein are reasonable and attainable.</i></p>
2. Animal Care Program	MINOR DEFICIENCY	<p>Line item 2.0: Fish husbandry standards and animal care documentation.</p> <p><i>A fish husbandry SOP shall be assembled with input by an aquarist and a veterinarian with expertise in the care and use of fishes, investigators, and facility maintenance personnel to ensure completeness and adherence to the Guide. The husbandry SOP shall be formulated for fin fish and cephalopods based on program need and risk, and are appropriately detailed as a foundation document to the Program to ensure continuity of animal care, including noting and reporting animal health concerns. Supporting policy documents will be requested at a later time to augment and provide clarity to select aspects of the approved SOP. The IACUC is requesting to review the primary fish husbandry SOP document by the September 21, 2018 IACUC meeting date.</i></p>
3. Animal Care Program	SIGNIFICANT DEFICIENCY	<p>Line item 3.0: Document of animal care procedures that conform to the Guide for Care and Use of Laboratory Animals and specifically address:</p> <p>c. Regular monitoring and notation of constituents, condition and quality of aquatic environments.</p> <p><i>A Program document on routine water quality monitoring shall be assembled with input by an aquarist and a veterinarian with expertise in the care and use of fishes, investigators, and facility maintenance personnel to ensure completeness and adherence to the Guide. The water quality monitoring document shall be evaluated based on program need and risk, and be appropriately detailed to ensure continuity of animal care and provide clarity to the primary husbandry SOP. The IACUC is requesting to review the water quality monitoring document by the September 21, 2018 IACUC meeting date.</i></p>

b. Sanitation and maintenance of animal holding tanks, equipment, spaces, and feed use and storage.

A Program document on sanitation and maintenance of animal rooms shall be assembled with input by investigators, an aquarist and a veterinarian with expertise in the care and use of fishes to ensure completeness and adherence to the Guide. The animal room maintenance document shall be evaluated based on program need and risk, and be appropriately detailed to ensure continuity of animal care and provide clarity to the primary husbandry SOP. The IACUC is requesting to review the animal room maintenance document by the October 19, 2018 IACUC meeting date.

d. Procedures to monitor and mitigate adverse mechanical events or water quality conditions, including animal triage plans, system intake and direct monitoring, personnel alert and internal response and communication procedures.

A Program document on crisis readiness and response shall be assembled with input by an aquarist and a veterinarian with expertise in the care and use of fishes, investigators, and facilities personnel to ensure completeness and adherence to the Guide. The crisis readiness and response plan document shall be evaluated based on Program need and risk, and be appropriately detailed to ensure continuity of animal care. The IACUC is requesting to review the crisis readiness and response plan document by the November 16, 2018 IACUC meeting date.

f. Veterinary clinical consultation and response procedures, including timely reporting, contingency for euthanization of animals and preservation of samples for diagnostics.

A program of veterinary care shall be assembled with input by a veterinarian with expertise in the care and use of fishes and investigators to ensure completeness and adherence to the Guide. The program of veterinary care shall be evaluated based on program need and risk, and be appropriately detailed to ensure continuity of animal care. The program of veterinary care shall also address the assembly and utilization of a decompression chamber where applicable. The IACUC is requesting to review the program of veterinary care by the November 16, 2018 IACUC meeting date.

e. Animal management documents and record keeping.

Program management of enclosure labels, animal room monitoring forms, animal care task sheets and animal morbidity/mortality reporting documents shall be assembled in a policy document with input by an aquarist, investigators and a veterinarian with expertise in the care and use of fishes to ensure completeness and adherence to the Guide. Animal care documents and a devised system to preserve the documents in animal room conditions (i.e. high humidity) shall be evaluated based on program need and risk, and be appropriately detailed to ensure continuity of animal care. The IACUC is requesting to review all animal care documents and record keeping plan by the November 16, 2018 IACUC meeting date.

<p>4. Animal Care Facilities</p> <p>END OF REPORT</p>	<p>MINOR DEFICIENCY</p>	<p>a. Routine husbandry and care of animals, including staffing and daily animal monitoring. <i>A routine animal monitoring and care plan shall be assembled with input by a veterinarian with expertise in the care and use of fishes, MLML Director, Dean [REDACTED] (College of Science) and investigators to ensure completeness and adherence to the Guide. The animal care and monitoring plan shall be evaluated based on program need and risk, and be appropriately detailed to ensure continuity of animal care. The IACUC is requesting to review the animal monitoring and care plan by the November 16, 2018 IACUC meeting date.</i></p> <p>g. Personnel training. All personnel involved in the care and use of laboratory animals must be adequately educated, trained and /or qualified in basic procedures of laboratory animal science and/or management. All personnel training must be verified and documented. <i>A personnel training program shall be assembled with input by a veterinarian, MLML Director, investigators and the Aquarium Room Coordinator to ensure completeness and adherence to IACUC policy and the Guide. The personnel training program be evaluated based on Program need and risk, and be appropriately detailed to ensure continuity of animal care. The IACUC is requesting to review the personnel training program plan by the November 16, 2018 IACUC meeting date.</i></p> <p>Line item #4: Maintaining water temperature in outdoor enclosures (Shorelab facility). <i>The MLML Director shall address the concern of fluctuating water temperatures in outdoor enclosures, especially during summer months. Program policy shall be in-place addressing by what method and how often individual tank water temperature is monitored, how temperatures are kept from rising during summer months and an animal care response plan when temperatures fluctuate beyond the desired range. Policy evaluation shall be made with input by an aquarist, a veterinarian with expertise in the care and use of fishes, facilities personnel and investigators to ensure environment stability of outdoor enclosures and adherence to the Guide. All outdoor enclosures shall be closely evaluated based on program need and risk, and a facilities management document appropriately detailed to ensure continuity of animal care. The IACUC is requesting to review the outdoor tank management plan by the November 16, 2018 IACUC meeting date.</i></p> <p>MLML Animal Care Program Review <i>It is required that MLML have in-place a complete and well-designed aquatic Animal Care Program. When each requested item of the step-wise correction plan is complete (all line items outlined herein), all Program documents shall be assembled by the MLML Director and submitted for IACUC for review. The IACUC will conduct a site inspection of MLML facilities as part of the final Program review. When approved by the IACUC, the Program document will be advanced to the IO for review. When accepted by the IO, the IACUC will approve MLML aquarium facilities for holding fishes.</i></p>
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