

California State University San Marcos
Assurance #A4196-01
ANIMAL WELFARE ASSURANCE

I, Paul Wesley Schultz, as named Institutional Official for animal care and use at California State University San Marcos (CSUSM) provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

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 live 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: All components of the California State University San Marcos that are located on the Main Campus. There are no off-campus satellite facilities and/or other covered components.

B. The following are other institution(s), or branches and components of another institution: None.

II. Institutional Commitment

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

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

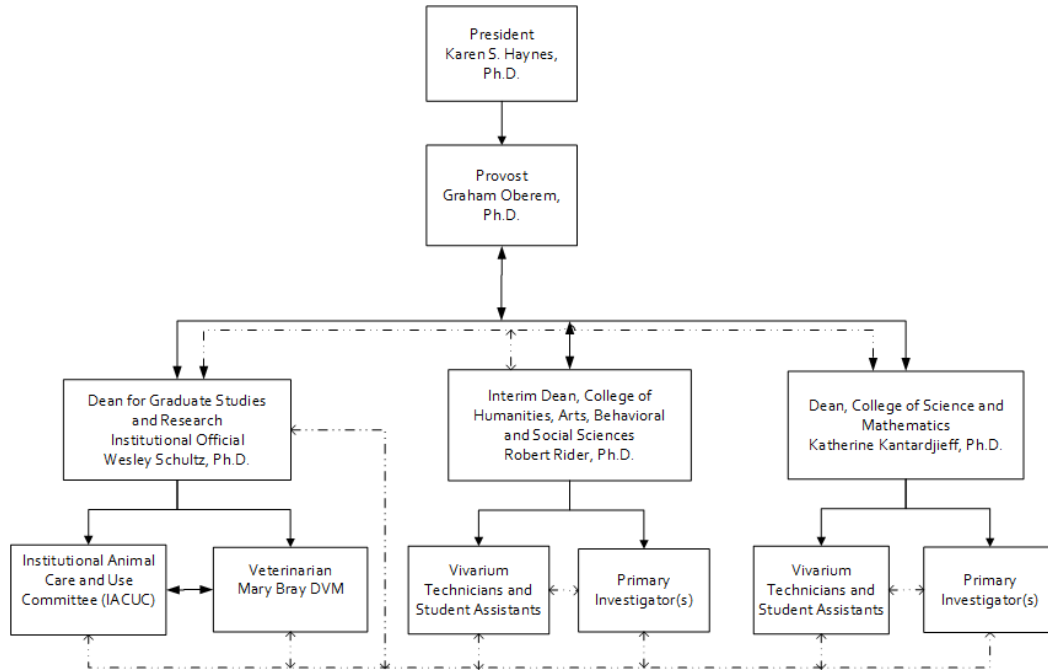
C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and 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 according to the Guide for the Care and Use of Laboratory Animals (Guide).

E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (sub-award) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows:



As indicated above, there are direct and open lines of communication between the IACUC and the Institutional Official (IO) and between the Veterinarian and the IO.

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

1. Name: Mari Bray

Qualifications:

- Degrees: DVM, DACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Bray completed a three year post-doctoral residency in laboratory animal medicine at Yale University from 1989 through 1992 and has been practicing in this field since that time.

Authority: Dr. Bray has delegated program authority and responsibility for the Institution’s animal care and use program including access to all animals. As such she has the authority and responsibility to implement the PHS Policy and the recommendations of the Guide. Dr. Bray has unfettered access to all CSUSM animals.

Responsibilities: Dr. Bray has the responsibility of monitoring the operation of the animal facility. As consulting veterinarian, she provides professional services and expertise in

maintaining research animals in optimal health, in treating animals in emergency medical situations, in periodic inspection of animals, animal quarters, and facility to assure continual compliance with the Animal Welfare Act and other established guidelines and programs for sanitation and maintenance, in general oversight of operations, practices and procedures of the animal facility, and in consultation with the scientists in the selection and utilization of animal models. Dr. Bray is responsible for providing guidance and recommendations in order to assure that the institutional animal care and use program meets or exceeds the requirements of the Animal Welfare Act, USDA Regulations, the PHS Policy, the NRC Guide for the Care and Use of Laboratory Animals, and other applicable federal, state and local statutes and regulations relating to laboratory animals. She is on call 24 hours per day every day of the year, including weekends and holidays.

Time contributed to program: Dr. Bray is present at the Institution an average of approximately 2-3 hours, every three months. One-hundred percent of this time is contributed to the animal care and use program. In addition Dr. Bray contributes on average approximately two hours per month to the program while off-site, reviewing protocols and providing consultation on various program related topics.

2. Name: Alice Smith

Qualifications:

Degrees: DVM

Training or experience in laboratory animal medicine or in the use of the species at the institution: She has been working in this field for more than 15 years with all the species present at the Institution.

Responsibilities: Dr. Smith has delegated program authority and responsibility to implement the PHS Policy and the recommendations of the Guide.

Time contributed to program: As needed. Back-up Veterinarian.

C. The IACUC at this Institution is properly appointed according to 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.

1. The President, as Chief Executive Officer (CEO), has delegated to the Institutional Official the authority to appoint the members of the IACUC. In accordance with the Health Research Extension Act of 1985, this delegation of authority is specific and is in writing.
2. The IACUC consists of at least five members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Section VIII is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations. Not more than three members shall be from any one administrative Unit.

D. The IACUC will:

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

- a. At least once every six months, the Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare), as a basis for the review.
- b. To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. The evaluation will include, but not necessarily be limited to, a review of the following:
 - 1) IACUC Membership and Functions;
 - 2) IACUC Records and Reporting Requirements;
 - 3) Husbandry and Veterinary Care (all aspects);
 - 4) Personnel Qualifications (Experience and Training);
 - 5) Occupational Health and Safety; and
 - 6) Emergency and Disaster Plans
- c. In addition, the evaluation will include a review of the elements in the Institution's PHS Assurance.
- d. If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.
- e. Subcommittees may be used to conduct all or part of the reviews. However, no member will be involuntarily excluded from participating in any portion of the reviews.

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

- a. At least once every six months at least two members of the IACUC will visit all of the institution's facilities and any surgical areas where vertebrate animals are maintained for more than 12 hours. Areas also inspected may include holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are conducted. Equipment used for transporting of the animals will also be inspected.

- b. The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, as a basis for the review. To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.
 - c. If deficiencies are noted during the inspection, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.
 - d. Subcommittees may be used to conduct all or part of the inspections. However, no member will be involuntarily excluded from participating in any portion of the inspections.
 - e. For individual facilities that house or involve only non-USDA covered species, the Institutional Animal Care and Use Committee (IACUC) may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.
- 3. Prepare reports of the IACUC evaluations according to 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. Individual IACUC members will convey their evaluations to the IACUC Chairperson who, in turn, will draft the reports, based on the OLAW Semiannual Report.
 - b. The reports will contain a description of the nature and extent of the Institution's adherence to the Guide and the PHS Policy.
 - c. The reports will identify specifically any departures from the provisions of the Guide and the PHS Policy, and state the reasons for each departure. If there are no departures, the reports will so state. Departures must be approved as part of a protocol, protocol amendment, or other written document, using either FCR or DMR as delineated below in Section III.D.6.
 - d. Departures from the provisions of the Guide that are not IACUC approved are considered deficiencies and addressed as such, i.e., the IACUC will develop a reasonable plan and schedule for discontinuing the departure or for having the departure properly reviewed and approved.
 - e. The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and a schedule for correcting each deficiency.

- f. If some or all of the institution's facilities are accredited by AAALAC International, the report will identify those facilities as such.
 - g. Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee. The final reports will be approved by a majority of the IACUC members and will include any minority opinions. The reports will be signed by at least a majority of the IACUC members. If there are no minority opinions, the reports will so state.
 - h. Following completion of each evaluation, the Chair, or his or her delegate, will submit the completed report to the Institutional Official in a timely manner—generally within thirty days.
 - i. The IO and/or Committee will track all noted deficiencies to ensure that they are appropriately resolved. The IACUC Chair will notify the Institutional Official when all deficiencies have been corrected.
- 4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:**
- a. Any individual may report concerns to the IO or any member of the IACUC.
 - b. Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals according to the University Whistleblower policy.
 - c. All reported concerns will be brought to the attention of the full Committee. If necessary the IACUC Chair will convene a meeting to discuss, investigate, and address any reported concern. Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes.
 - d. The Committee will report such actions to the IO and, as warranted, to OLAW. Reports to the IO may be made via meeting minutes, semiannual report of IACUC evaluations, or by separate letter. Reports to OLAW will be in writing and through the IO. Initial reports to both the IO and OLAW may be made verbally.
- 5. Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:**
- a. Recommendations to the IO are discussed and developed by the Committee.
 - b. The Committee's recommendations are either included in the IACUC Meeting minutes, a report of the IACUC's evaluations, or by separate letter.

- c. Such documents are reviewed and approved by the Committee and then submitted to the IO.

6. Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

- a. Protocols are submitted to the IACUC Chair and the IACUC support staff by email. Either a Full Committee Review (FCR) or Designated Member Review (DMR) may be used.
- b. Pre-review Screening Process - None
- c. If FCR is used:
 - 1) Prior to the review, each IACUC member will be provided with a written description of activities (protocols) that involve the care and use of animals. This will be done electronically unless a hard copy is requested.
 - 2) A quorum (majority of voting members) must be present at a convened meeting. Meetings shall be held in-person or by teleconference when required, to achieve a quorum.
 - 3) Voting shall be by show of hands or by oral vote.
 - 4) A majority must vote to approve the protocol, require modifications to secure approval or withhold approval. Record of dissensions, abstentions, and minority opinions will be included in the minutes of the meeting.
 - 5) Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, titled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.
 - 6) Special attendance requirements: Other than a requiring a quorum, there are no special attendance requirements. However, all members are encouraged to attend.
 - 7) The possible outcomes of FCR are as follows:
 - a) Approval;
 - b) Require modifications (to secure approval); and
 - c) Withhold Approval

- 8) Required modifications subsequent to FCR. When the IACUC requires modifications (to secure approval) of a protocol, such modifications are reviewed as follows:
- a) FCR or DMR following the all applicable procedures as delineated in III.D.6 of this Assurance.
 - b) DMR if approved unanimously by all members at the meeting at which the required modifications are developed, delineated AND if the entire current Committee has previously approved, in advance and in writing, that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.
 - c) Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by IACUC administrative/support personnel.
- d. **If a DMR is to be used:**
- 1) Prior to the review, each IACUC member will be provided with a written description of activities (protocols) that involve the care and use of animals. This will be done electronically unless a hard copy is requested.
 - 2) Any member of the IACUC may obtain, upon request, full committee review of those protocols.
 - 3) If full-committee review (FCR) is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, will be assigned to review those protocols and have the authority to approve, require modifications in (to secure approval) or request full committee review of those protocols.
 - 4) If FCR is requested, the processes outlined above under FCR will be followed (III.d.6.c).
 - 5) Polling records of members to obtain concurrence to use the DMR method, or concurrence by silent assent, and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting. All members will be notified by email with the protocol attached. Members will be given at least 3 business days to respond.

- 6) Other IACUC members may provide the designated reviewer(s) with comments and/or suggestions for the reviewer's consideration only. That is, concurrence to use the designated-member review (DMR) method may not be conditioned.
- 7) After all required modifications are made, a final revised protocol, i.e., an identical document with all required modifications included, is submitted to all designated reviewers for review and approval.
- 8) If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR.
- 9) The possible outcome of DMR are as follows:
 - a) Approval;
 - b) Require modifications (to secure approval); and
 - c) Referral for FCR.

"Withhold approval" is not a possible outcome of DMR.

- e. Expedited/Special Review Process: Other than the procedures above, there are no special or expedited review processes.
- f. No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.
- h. The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.
- j. In order to approve, whether by DMR or FCR, proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements per PHS IV.C.1a-g:
 - 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 the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
 - 3) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, 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, feeding, 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 maintained or studied.
 - 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 euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.
- 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 according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:**
- a. Review and approval of significant changes will be handled in the same manner as new protocols. See Paragraph III.D.6. above.
 - b. Examples of changes considered to be significant include, but are not limited to, changes:
 - 1) in the objectives of a study;
 - 2) from non survival to survival surgery;
 - 3) resulting in greater discomfort or in a greater degree of invasiveness;
 - 4) in the species or in approximate number of animals used¹;
 - 5) in Principal Investigator;
 - 6) in anesthetic agent(s) or the use or withholding of analgesics;
 - 7) in the method of euthanasia; and
 - 8) in the duration, frequency, or number of procedures performed on an animal.

¹Changes of less than 10% in the approximate number of animals used of mice of the genus *Mus* and rats of the genus *Rattus* that are bred for use in research only may, at the IACUC's discretion, be considered minor (not significant).

- c. Significant changes to an IACUC-approved protocol must be reviewed and approved before they are implemented.
- 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 according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:**
- a. Principal Investigators are notified of the committee's decision by e-mail from the IACUC support staff.
 - b. If the IACUC requires modifications of the protocol (to secure approval), it will include in its written notification, a list or description of the modifications required to secure approval.
 - c. If the IACUC's decision is to withhold approval, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
 - d. The Institutional Official is notified by receiving a copy of the PI's notification letter and/or a copy of the IACUC meeting minutes.
- 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 at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:**
- a. Post-Approval Monitoring - All animal health is monitored regularly after the approval of the protocol. Vivarium personnel are charged to monitor protocol compliance and to report any incidence of noncompliance. Vivarium personnel attend IACUC meetings and receive copies of approved protocols. In addition, the Chair of the IACUC and/or the veterinarian performs random audits for compliance with approved protocols. Non-compliance shall be reported to the IACUC chair and support staff. The IACUC chair will then call for a subcommittee to review and investigate the potential non-compliance according to internal SOP's.
 - b. USDA Covered Species – Protocols involving USDA covered species are reviewed by members of the IACUC at least annually by FCR or DMR using the same processes as outlined in III.D.6.

- c. Non-USDA Covered Species – Protocols involving non-USDA covered species are reviewed by a member or members of the IACUC at least annually
- d. Annual protocol reviews are recorded in the IACUC meeting minutes.
- e. The IACUC meeting minutes are reviewed by the Committee.
- f. Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the initial IACUC review. If activities will continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved as described in Paragraph III.D.6 above

10. Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

- a. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.1.a.-g of the PHS Policy (6.b above).
- b. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.
- c. If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Assurance, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation, in writing, to OLAW and to any funding agency. Initial/preliminary reports to OLAW may be made telephonically.
- d. Suspensions, whether temporary or permanent, will be reported to OLAW in accordance with NIH Notice of February 24, 2005, NOT-OD-05-034 Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals.

E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

- 1. The program has been established by the CSUSM Safety, Risk and Sustainability (SR&S) Services. Medical Monitoring will be provided to personnel whose exposure qualifies them to be integrated into the program and per the request of the subject matter expert who is the Faculty Member, Principal Investigator, Supervisor, or SR&S Representative. Services

will also be offered to faculty, staff and student employees per the criteria of the medical monitoring program. Among the greatest health and safety risks for personnel with frequent exposure to animals is the development of allergies to animal urinary proteins. CSUSM has implemented procedures to minimize these types of risks.

2. The occupational health and safety program includes, but is not limited to, the following:
 - a. Administration and Management:

The University President has assigned overall management for the Injury Illness and Prevention Program (IIPP) to the Vice President for Finance and Administrative Services. The Director of Safety, Risk & Sustainability is responsible for implementation of the IIPP. The Occupational Health and Safety program for personnel that work with animals or are exposed to their environment is administered through the IIPP.
 - b. Scope:

The Occupational Health and Safety program is administered by the office of Safety, Risk & Sustainability Services. The program is designed to promote a safe work environment by minimizing the risk of illness or injury associated with working with or around research animals and research-related hazards. The program covers all individuals who work with animals directly as well as those who may be exposed (indirectly) to animals or their by-products in common areas or laboratories. An individual primarily participates in the program by determination of the Faculty Member, Principal Investigator, or Supervisor. Participation may also be advised/required if a Risk Assessment by the SR&S Representative determines the need/requirement.
 - c. Health Histories and Evaluations:

Medical monitoring is required for employees who are assigned to Animal Care Program positions and perform animal husbandry as an essential function of their job. Other employees that would be required to participate in the program are those who work with or enter areas with non-human primates, pregnant non-rodent mammals, wild birds, or wild mammals. Faculty, Staff, Volunteers and Student Interns are included in the medical surveillance program per the risk assessment done by SR&S or the responsible Faculty (PI) or Administrator (MPP or Supervisor). This area will follow the CSUSM medical monitoring program, including physical examination (Pre-employment, Annual and Prior to Termination, if deemed appropriate per the risk assessment and by request of the Faculty Member, Principal Investigator, or Supervisor). Personnel may be asked to complete a Medical History Questionnaire and a Risk Assessment. The risk assessment is based on job tasks, the species exposed to, the hazard that is evident, best practices, and the periods of exposure. All personnel that have significant contact with animals complete this questionnaire. Questionnaires are completed collaboratively with the Faculty Member, Principal Investigator, Supervisor, or SR&S Representative. This information is reviewed by SR&S (following HIPAA rules and regulations) and if necessary the occupational medicine provider will evaluate and prescribe appropriate medical surveillance. The program currently

provides the following services:

- Medical screening and risk assessment for new and current employees
- Urgent care for injuries and exposures
- Immunizations based on assessed risk (including tetanus vaccination for all personnel having significant contact with animals)
- Health surveillance programs
- Employee education (e.g., allergies, asthma, zoonotic disease, hygiene)

Additional monitoring may also include tuberculosis screening and serum banking as appropriate for the species (i.e., non-human primates). Any persons working with non-human primates receive specialized training and monitoring (e.g. TB screening/serum banking) under the program and special precautions are taken to maintain a Cercopithecine Herpesvirus-1 (Herpes B) negative colony. Animal handlers who work with non-human primates are advised that persons who are immunosuppressed due to medication or underlying medical conditions may be at a higher risk for B-virus infection

d. Hazard Identification and Risk Assessments:

This identification and assessment will be based on the evaluation and judgment of the subject matter expert (SME), which is the Faculty Member, Principal Investigator, Supervisor, or SRS Representative. SR&S will work in collaboration with the SME. As mentioned above the risk assessment is based on job tasks, the species exposed to, the hazard that is evident, the periods of exposure, and possibly best practices.

e. Procedures in Place to Alleviate Hazards and Minimize Risks:

Education for employees regarding allergies, zoonoses, personal hygiene and the handling of hazardous agents will be provided by the Faculty Member, Principal Investigator, Supervisor, Veterinarian or SR&S, prior to engaging in work that involves contact with such agents. This training is done by several methods, to include one-on-one training with the supervisor and/or with SR&S, online training for potential WAG exposures, and as part of classroom lectures/training. Depending on the assessed risk additional training may be required before the individual may start work. Refresher education regarding zoonoses and personal hygiene will be offered by the Veterinarian, SR&S, or a trained delegate at least once annually. This training must be documented by the trainer and retained by the Office of Safety, Risk & Sustainability Services. Per the campus chemical hygiene plan various controls (Engineering, Administrative and Personal Protective Equipment) are in place to address the exposure hazards. The training that is required is per CAL OSHA and provided by the Faculty Member, Principal Investigator, Supervisor, Veterinarian or SR&S. CSUSM does not have the facilities to work with primates but those employees who work at other institutions will follow their programs and be provided the medical surveillance from CSUSM. Only technicians trained in primate husbandry, handling and potential zoonotic diseases will be allowed to work in other institutions primate rooms.

- f. Immunizations:
Job-related recommended immunizations are voluntary at the employee's choice, except for mandatory immunizations if indicated due to specific work exposure (for example, non-human primate contact may require measles vaccination). If deemed necessary through a risk assessment completed by SR&S, Tetanus immunization may be available by request of the Faculty Member, Principal Investigator, Supervisor, or SR&S. Refer to section "c" for more information. This prophylactic will be determined by the occupational medicine provider's risk assessment, required or recommended by a pertinent authorized agency (ex. NIOSH, CDC, FDANIH, etc) practices.
- g. Precautions taken during pregnancy, illness or decreased immunocompetence:
CSUSM personnel who work in research, teaching laboratories or handle animals will receive education and training regarding risks specific for their work area and job duties. As part of this training, information will be given regarding causes and risk factors for those who have unusual circumstances, such as pregnancy, animal allergies or immunodeficiency, will be trained about these additional health risks. Where appropriate, it will be provided before starting work. This applies to all immune compromised laboratory personnel who may be at increased risk for development of infectious diseases as a result of research or teaching activities. Research or teaching activities include personnel who work directly with potential pathogens as well as personnel who have exposure because they work in the same laboratory space where infectious agents are studied. Examples from this group include Vivarium staff, research laboratory staff, SR&S staff, Facility Services staff, and custodial workers.
- h. Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas when animals are housed or used:
Personnel who have no direct contact with research animals and do not enter the vivariums but may have incidental or infrequent exposure to research animals are provided an awareness training of this environment by their Faculty Member, Principal Investigator, Supervisor, Veterinarian or SR&S. Personnel that experience indirect contact are offered the same training courses that are required for those who experience direct contact. Indirect contact means you do not touch animals or animal tissue and do not handle animal waste. Examples of persons who may have incidental or infrequent and indirect exposure are Facility Services personnel, police, housekeeping, administrative, and clerical staff who enter lab space where animal work is done.

Availability and procedures for treatment of bites, scratches, illness or injury:

The University is contracted with an occupational medicine provider that manages all injuries and incidents that occur during business hours for work related injuries or illnesses. After business hours the incident is reported to University Police and they provide information on emergency services. 911 can also be called from a campus phone or 760-750-4567 from a cell phone. Refer to section "c" above for more information.

- j. Procedures/program for reporting and tracking injuries and illnesses:
The Occupational Health and Safety program for personnel that work with animals or are exposed to their environment is administered through the IIPP. The IIPP provides for reporting and tracking of injuries. This process is implemented by SR&S in collaboration with University Police. The Workers Compensation program is housed within the office of Safety, Risk & Sustainability Services. Injuries, Illnesses and allergies shall be reported to the individual's supervisor and to the SR&S Office, who will respond to the incident as appropriate.
- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in Section X, Facility and Species Inventory.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

IACUC Members

1. Each IACUC member will be provided with each of the following the following documents:
 - a. PHS Policy for the Humane Care and Use of Laboratory Animals,
 - b. The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals, Eighth Edition,
 - c. A copy of the ARENA/OLAW IACUC Guidebook,
 - d. A copy of this Assurance.
2. All members of the IACUC will complete the Essentials for IACUC Members Curriculum located at the Collaborative Institutional Training Initiative website, www.citiprogram.org. Continuing education will be available; IACUC members will complete CE/refresher training at least once every three years. New members also receive orientation to the program by the Chair at the time they are assigned to the committee. This includes orientation to the program, ensuring all personnel receive the documents above, discussion and questions from the new member and ensuring that the new member understands and completes the CITI program training.
3. Continuing education is also provided by the IACUC veterinarian at meetings or as separate training sessions, when requested.
4. Documentation of training will be maintained for at least three (3) years.

Animal Care and Use Personnel, Scientists, Animal Technicians and other animal users

1. Personnel performing procedures using animals must be appropriately trained. A description of each individual's qualifications, experience and/or training must be provided in the IACUC application. Any person needing additional protocol-specific training will be

identified during the review process and such required training will be a condition of approval of the protocol. Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities under CFR 2.32c and 2.31 and the PHS Policy for the Humane Care and Use of Laboratory Animals.

2. The training shall be tailored to the particular needs of the researchers; however, all researchers, including students in classroom activities, shall receive training in animal care and use legislation, IACUC functions, ethics of animal use and the concepts of the Three Rs, methods for reporting concerns about animal use, occupational health and safety issues pertaining to animal use, animal handling, aseptic surgical technique, anesthesia and analgesia, euthanasia, and other subjects, as required by statute (as delineated in 9 CFR, Part 2, Subpart C, Sections 2.32(c)). Specifically, training and instruction of personnel includes guidance in at least the following areas (by use of online CITI training courses and one-on-one training with the PI or AV):
 - a. Humane methods of animal maintenance and experimentation, including:
 - 1) The basic needs of each species of animal;
 - 2) Proper handling and care for the various species of animals used by the facility;
 - 3) Proper pre-procedural and post-procedural care of animals; and
 - 4) Aseptic surgical methods and procedures
 - b. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;
 - c. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;
 - d. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;
 - e. Utilization of services available to provide information:
 - 1) On appropriate methods of animal care and use;
 - 2) On alternatives to the use of live animals in research;
 - 3) That could prevent unintended and unnecessary duplication of research involving animals; and
 - 4) Regarding the intent and requirements of the Act.
3. Training may be courses, seminars, one-on-one training, conferences, computer-based or online training, and video recordings. However, a principal investigator must ensure that all collaborating researchers are properly trained in the specific research methods for a study.

4. Training in experimental methods, i.e., specific animal manipulations and techniques, will be conducted based on the types of research being conducted at the institution.
5. Continuing education shall be offered to reinforce training and provide updates that reflect changes in technology, legislation, and other relevant areas as determined by the Principal Investigator and/or IACUC on a case-by-case basis. However, all personnel involved in animal care and use will complete CE/refresher training at least once every three years.
6. For investigators transferring from other facilities at which they have received similar training, verification of previous training may be accepted in lieu of some Cal State San Marcos training. Acceptance of previous training in lieu of the Institution's training is solely at the IACUC's discretion.
7. Documentation of all training will be maintained for at least three years and available to OLAW upon request.
8. Effectiveness of training is evaluated by:
 - Ongoing health checks by animal facility caretakers, who report any evidence of pain or distress as well as any mistreatment or evidence of poor training to the IACUC chair and AV
 - Inspections of the animal facilities and records
 - Discussions with lab managers and review of records
 - Review of course synopses

IV. Institutional Program Evaluation and Accreditation

- A. All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to 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 PHS Policy and 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 program or facility deficiencies are noted, reports will contain a 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 the OLAW upon request.
- B. This Institution is Category 2 — not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached.

V. Recordkeeping Requirements


- A. This Institution will maintain for at least three (3) years:
 - 1. A copy of this Assurance and any modifications made to it, as approved by the 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 granted or withheld.
 - 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Dean of Graduate Studies and Research.
 - 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 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
 - 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
 - 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
 - 3. Any change in the IACUC membership
 - 4. 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 Dean of Graduate Studies and Research.

5. Any minority views filed by members of the IACUC
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
1. Any serious or continuing noncompliance with the PHS Policy
 2. Any serious deviations from the provisions of the Guide
 3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Paul Wesley Schultz	
Title: Dean of Graduate Studies and Research	
Address: (street, city, state, country, postal code) 333 South Twin Oaks Valley Road San Marcos, CA 92078	
Phone: 760.750.4029	Fax: 760.750.3150
E-mail: wschultz@csusm.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: 	Date: 2/26/16

B. PHS Approving Official (to be completed by OLAW)	
Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 915-9465	
Signature:	Date:
Assurance Number: A4196-01	
Effective Date: July 1, 2012	Expiration Date: June 30, 2015

VIII. Membership of the IACUC

Date: February 20, 2016			
Name of Institution: California State University San Marcos			
Assurance Number: A4196-01			
IACUC Chairperson			
Name*: James Jancovich			
Title*: Assistant Professor, Biological Sciences		Degree/Credentials*: Ph.D.	
Address*: 333 S. Twin Oaks Valley Rd., San Marcos, CA 92078			
E-mail*: jjancovich@csusm.edu			
Phone*: 760.750.8525		Fax*: 760.750.3150	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Mari Bray	DVM,DACLAM	Veterinarian	Veterinarian
JJ	Ph.D.	Assistant Professor, Biology	Scientist
SN	Ph.D.	Associate Professor, Kinesiology	Scientist
TW	MBA	Academic Support Coordinator	Non-Scientist
DV		Policy Analyst	Non-affiliated

* This information is mandatory.

** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

*** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

**** PHS Policy Membership Requirements:

Veterinarian veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or

	delegated program authority and responsibility for activities involving animals at the institution.
Scientist	practicing scientist experienced in research involving animals.
Nonscientist	member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
Nonaffiliated	individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Contact #1	
Name: Teri Woods	
Title: Administrative Support Coordinator	
Phone: 760-750-4029	E-mail: twoods@csusm.edu

X. Facility and Species Inventory

Date: February, 2016			
Name of Institution: CSU San Marcos			
Assurance Number: A4196-01			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]	Approximate Average Daily Inventory
SCIENCE 1			
SCI I – 216 (utilities)	95	None	None
SCI I - 216A (vivarium) Kristan	125	Mice	140
SCI I - 216B (vivarium) Brown	60	Bearded dragons	15
SCI I – 216C (vivarium) Jameson	50	Mice	180
SCI I – 217 (cage washer)	360	None	None
SCI I – 219 (storage)	63	None	None
Vivarium Foyer	150	None	None
SCI I – 204	145	Salamanders	20
SCI I – 208 or 209	800	Frogs (2 weeks per semester)	9/day/4 wks/yr
SCI I – 311 (Metabolism lab)	112	Mice and dragons	temporary**
SCI I - 313 (Kristan/Spady lab)	113	Mice	temporary**
SBSB			
Storage Room	91	None	None
Procedure Room	117	None	None
Cage Wash Room	248	None	None
Animal Room E	127	Mice	125
Animal Room F	105		65
Animal Room G	120	Rats	113

Note: Unless otherwise indicated, mice and rats means mice of the genus *mus* and rats of the genus *rattus* that are purposely bred for research.

**Temporary locations are locations where animals may be housed, held, or used for research or teaching for periods under 12 hours.