

Animal Welfare Assurance for Domestic Institutions

I, Stephen C. Welter, Ph.D. as named Institutional Official for animal care and use at San Diego State University, 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. 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:
 - College of Engineering
 - College of Health and Human Services
 - College of Sciences
 - Imperial Valley Campus
 - San Diego State University Research Foundation
 - College Area Community Garden
- 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 (subaward) 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:

The lines of authority and responsibility for administering the program and ensuring compliance with this Policy, Graduate and Research Affairs, Division of Research Affairs oversees all research activity conducted through the University. The Vice President for Research has been designated as the IO with signatory authority for the SDSU Assurance of Compliance with the PHS Policy on Humane Use of Laboratory Animals. The Vice President for Research reports to the Provost and to the President who are the Chief Executive Officers. The Assistant Vice President for Research Support Services, Division of Research Affairs is an *ex-officio* member of the Institutional Animal Care and Use Committee and reports to the Vice President for Research. The Research Facilities and Operations Director oversees the vivarium facilities and other duties associated with the SDSU Office of Laboratory Animal Care (OLAC) and reports to the Associate Dean of the College of Sciences. A faculty member appointed by the Vice President for Research serves as the IACUC Chair. The Veterinarian and the IACUC members have an open line of communication with the IO. The Veterinarian has open communication with both the Research Facilities and Operations Director and the IACUC Chair. Both the Veterinarian and Research Facilities and Operations Director are voting members of the IACUC.

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

1) Name: Dr. Mari Bray

Qualifications

- Degrees: DVM, The Ohio State University, D.A.C.L.A.M
- Training or experience in laboratory animal medicine or in the use of the species at the institution:

Dr. Bray has been practicing laboratory animal medicine since she completed a post-doctorate program in 1992, and has been a licensed veterinarian since 1986. She has extensive experience in clinical medicine, diagnostics, protocol processing and review, program oversight, etc. Dr. Bray continues her training in Laboratory Animal Science by reading journals, attending national AALAS annually and keeping in contact with others in her field. In addition she is a Diplomate of the American College of Laboratory Animal Medicine.

Responsibilities: Dr. Bray has the responsibility of monitoring the operation of the animal program as Attending Veterinarian and member of the IACUC. Dr. Clingerman is the primary clinical veterinarian; however Dr. Bray, as consulting veterinarian, provides professional services and expertise in maintaining research animals in optimal health, in treating animals in emergency situations, periodical inspection of animals, animal quarters, and facilities to assure continual compliance with the Animal Welfare Act and other established guidelines (SOPs and policies, as well as laws and regulations) and programs for sanitation and maintenance. Dr. Bray provides guidance to investigators and all personnel involved in the care and use of animals to ensure appropriate handling, immobilization, sedation, analgesia, anesthesia, euthanasia, and oversees the surgery programs, including postsurgical care.

Provisions for Back-up Veterinary Care: Dr. Bray is on call 24/7, or if she is unavailable due to illness or vacation, she provides a backup veterinarian for animal medical emergencies. The emergency phone numbers are posted throughout the facilities. The primary clinical veterinarian and the backup for IACUC needs is Dr. Karen Clingerman of The Scripps Research

Institute.

Authority: Dr. Mari Bray has direct program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program:

As the institutional attending veterinarian and member of the IACUC, she is contracted to be on-site on a regular schedule to attend IACUC meetings and to assist in compliance issues when necessary. She also comes on site on an as needed basis for animal health issues, when the primary clinical veterinarian cannot be there. During her site visits 100% of her time is contributed to the Institution's program. In addition to this time, she reviews all documents off-site. Approximately 11 hours a month are contributed to the program.

2) **Name:** Dr. Karen Clingerman

Qualifications

Degrees: DVM, Virginia-Maryland Regional College of Veterinary Medicine at Virginia Tech

- Certification: Diplomate American College of Laboratory Animal Medicine (DACLAM)
- Training or experience in laboratory animal medicine or in the use of the species at the institution:

Dr. Clingerman is a Diplomate of the American College of Laboratory Animal Medicine and has worked in the field of laboratory animal medicine for 15 years. With over 20 years of clinical veterinary and research experience, she has also worked in private practice and for the USDA Animal Welfare Information Center, as well as conducted animal research. In addition to her role as the Clinical Veterinarian at SDSU, Dr. Clingerman has been employed by The Scripps Research Institute since 2001, initially as a resident in laboratory animal medicine then as the clinical veterinarian for the institution.

Responsibilities:

Dr. Clingerman serves as the primary clinical Veterinarian, working with the Attending campus Veterinarian and the Research Facilities and Operations Director and OLAC to assure appropriate animal husbandry procedures, an appropriate emergency response plan for the animal care and use program and to oversee the Office for Laboratory Animal Care clinical medicine program. She serves on the IACUC as the alternate member for the Attending campus Veterinarian; assists faculty and investigative staff with development of animal models and animal research protocols; and provides, as needed, animal care and use related training; advises, as needed, on appropriate animal users occupational health program; and provides guidance on regulatory issues pertaining to animal care and use.

Time Contributed to Program:

At least 10 hours per month and 100% of those hours are contributed to the animal care and use program.

- 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. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attachment B is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

D. The IACUC will:

- 1) Review at least once every 6 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:

The IACUC uses the 8th Edition of the Guide for Care and Use of Laboratory Animals along with the revised OLAW Sample Semiannual Program Review Checklist to guide the program review. At least two IACUC members participate in the pre-review, and all members are notified to allow for their participation if they so desire. A member of Environmental Health and Safety (Controlled Substance Program Officer and/or Biosafety Officer), the Attending Veterinarian, the Research Facilities and Operations Director, and the IACUC Staff also participate. The program pre-review report is submitted to the full IACUC membership for review, comment and approval. The formal Program Review is reviewed, discussed and approved at a convened meeting.

- 2) Inspect at least once every 6 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:

The IACUC uses the 8th Edition of the Guide for Care and Use of Laboratory Animals along with the revised OLAW Sample Semiannual Facility Review Checklist to guide the facilities inspection. At least two IACUC members participate in these inspections. All members are notified of the facility inspection schedule to allow for their participation if they so desire. A member of Environmental Health and Safety including the Controlled Substance Program Officer, the Attending Veterinarian and/or the Associate Campus Veterinarian, the Research Facilities and Operations Director, and the IACUC Staff also participate. The facilities review report is submitted to the full IACUC membership for review, comment and approval.

- 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:

The Institution adheres to the recommendations of the Guide, the PHS Policy, and AWA which are used as a foundation for the development, implementation, and continuous quality improvement of a comprehensive animal care and use program. This statement is included in the semi-annual report.

After an inspection, reviewer comments are forwarded to the IACUC Staff who prepares draft reports of the evaluations. The level of deficiency (M=Minor, S=Significant, C=Change in Program, or N/A=Not Applicable) is noted, and time schedule for corrections to be made is included. The report is reviewed by all IACUC members for approval, any minority opinions are then included in the report, and the report is signed by a majority of the IACUC members. The IACUC approved report is then forwarded to the Vice President for Research (IO). IACUC approved departures from the Guide and reasons for the departures are included in the report to the IO. IACUC approval of departures is based on scientific, veterinary medical, or animal welfare issues.

If a significant deficiency (defined as one which is or may be a threat to the health and welfare of animals or personnel) is identified, the responsible party is immediately instructed to correct it. We will notify OLAW promptly by submitting a preliminary report until a full investigation and correction plan has been completed. Once the investigation and corrective plan has been completed the significant deficiency is then reported to OLAW through the IO. If the plan for correction is unable to be met within a reasonable, specified timeframe, the Principal Investigator (PI) is notified that all work with animals must stop until the deficiency has been corrected. If necessary, the relevant regulatory and funding agency(s) will also be informed if the significant deficiency is not corrected within the reasonable, specified timeframe.

The IACUC communicates minor deficiencies to the responsible party through standard mail and/or electronic correspondence. The responsible party is given 30

days from the date of correspondence to correct or provide explanation of why more time is needed and provide a realistic timeline for correction. The IACUC Staff tracks and records deficiency correction dates and provides follow-up reports to the IACUC, as needed.

4) **Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:**

The IACUC reviews and, if warranted, investigates concerns involving the care and use of animals resulting from reports of noncompliance reported by research and facility personnel or by public complaints.

The IACUC encourages prompt (24 hours) reporting of concerns related to animal welfare. Allegations should be detailed and specific, and be accompanied by supporting documentation when possible, to allow for a thorough investigation. All reported concerns are reviewed regardless of how they are received.

Reports may be communicated anonymously via the IACUC website. Additionally, individuals may submit a report in-person or by email to the IACUC chairperson, the Assistant Vice President for Research Support Services, the Institutional Official, the Attending or Clinical Veterinarian, the Research Facilities and Operations Director or an IACUC member. The identity of persons submitting reports will be kept strictly confidential.

The IACUC has developed and follows a set policy and procedures for the review, investigation, and follow-up to reported concerns involving the care and use of animals. Upon knowledge of a concern, the IACUC Chair will form a subcommittee to investigate the concern within 3 business days. The subcommittee will review, investigate if warranted and present its findings to the IACUC at either the next convened meeting or a special convened meeting, as necessary. If the IACUC has made a determination of noncompliance the IACUC Chair will communicate the concerns and action plan to the Principal Investigator via a written report summarizing the findings of the investigation, IACUC concerns and corrective action required. A summary of the findings will be communicated to the person initiating the review, if identified. The IO will also be notified. If the noncompliance is determined to be reportable or recurring and if warranted reports are also provided to OLAW, APHIS, and/or funding agency(s).

Notices for reporting concerns are posted throughout animal facilities and in laboratories approved for animal procedures. The IACUC adheres to the San Diego State University Code of Conduct with regard to protection against retaliation.

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:**

The Institutional representative, Assistant Vice President for Research Support Services, Division of Research Affairs, routinely attends the meetings and informs the IO of important animal care and use issues. The substance of the IACUC discussions concerning important campus wide animal care and use issues requiring advice or approval from the IO may also be passed along directly by letter from the IACUC chair. In addition, the minutes of each meeting are posted to a secure member-only website for viewing by the IO at any time.

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:**

All persons affiliated with SDSU conducting research or instructional activities

involving vertebrate animals (living or dead) or specimens, who perform the work on or off campus, regardless of funding, are required to submit their research plan to the Division of Research Affairs for review determination. The IACUC Staff provides guidance to the PIs in determining the appropriate review type for the performance of those activities.

One week prior to an IACUC meeting an agenda is sent to the members listing protocol activity to be discussed at the meeting. The agenda also includes a report of the status of all protocols reviewed by Designated Member Review (DMR) and other administrative actions that have taken place since the last meeting. The minutes of the last meeting are also sent at this time.

Generally, all new protocol submissions, third year renewals, or amendments to existing protocols are reviewed by Full Committee Review (FCR) however can also be reviewed by Administrative Review (AR) or Designated Member Review (DMR), as deemed necessary.

Full Committee Review (FCR):

Upon electronic receipt of a new animal protocol form (APF) the IACUC staff communicates with the PI as necessary to ensure the submission is complete and all necessary attachments have been included. A protocol number is assigned and a file created. The protocol is logged into various secure databases for tracking purposes. The completion of necessary training for the PI and all other personnel listed on the protocol is verified, or the individuals are enrolled in training and scheduled for vivarium orientation, as needed. A primary reviewer is assigned to evaluate the protocol, routing sheets and reviewer checklists are prepared, submission is routed to the reviewer, the Veterinarian, and to the OLAC Manager, as well as EH&S and Controlled Substance Program Officer, as needed. The PI is notified of the status of the submission at the various stages of review.

If review comments are submitted to the IACUC Staff in a timely manner the preliminary review comments received from the primary reviewer, the veterinarian, etc. are compiled and forwarded to the PI for return comment in advance of the meeting. The primary reviewer provides a brief overview of the proposed research activity to the IACUC at a convened meeting. Discussion takes place and a vote is taken and passed by a majority of the members present to either approve the protocol, require modifications to secure approval, or deny approval.

If approved, a letter is sent to the PI for notification of the approval, the next annual renewal due date and protocol expiration date.

If modification to the protocol is necessary for approval a majority of members present is required to review the revised protocol by DMR subsequent to FCR or by FCR at a subsequent convened meeting.

If the committee votes for DMR subsequent to FCR the IACUC Staff will work with the PI and the reviewers outside a convened meeting until approval can be granted. Once approved the approval date will be recorded in the report for the next convened meeting. If at any time during the DMR the reviewers feel the protocol should be sent back to committee for FCR discussion it will be included on each subsequent convened meeting agenda until approved.

Once determined the protocol is approved, an IACUC approval letter is sent to the PI. The letter will also include whether any additional compliance reviews (i.e., Institutional Biosafety Committee, Diving Safety, Environmental Health and Safety oversight, or Institutional Review Board, etc.) will be required.

If approval is denied by the convened committee, a letter is sent to the PI with an explanation for the action. The PI may resubmit a protocol for review provided the issues are correctable. Approval can be granted if revisions made are acceptable to the IACUC.

Designated Member Review (DMR):

A written description of the DMR subsequent to FCR process is reviewed and approved unanimously by the IACUC.

Generally FCR is used to evaluate proposals. However DMR can be used for all submissions. In addition, the DMR is used subsequent to FCR when additional modifications are required to secure approval. The DMR can either be the original protocol reviewer or as assigned by the IACUC Chair. This is implemented in accordance with guidance entitled "Guidance to IACUCs Regarding the Use of Designated Member Review (DMR) for Animal Study Proposal Review Subsequent to Full Committee Review (FCR)."

All IACUC members receive a list of submissions to be reviewed by DMR and are given a brief overview of the submission with access to the specific protocol information. If any member feels that a submission should go before a full committee, then its review must be deferred to the next convened IACUC meeting. Any member can make the decision to send the submission to full-committee review at any time during the 2 to 5 day review period for FCR. If FCR is not requested, at least one member of the IACUC, qualified to conduct the review, is assigned by the IACUC Chair from a sequential list of IACUC members. The Veterinarian receives all submissions, along with a representative of Environmental Health and Safety and/or the Research Facilities and Operations Director may also receive a copy of the protocol to review on an as-needed basis. The designated reviewer does not have the authority to withhold or deny approval, however, and must refer the protocol to the IACUC for full-committee review. If more than one designated reviewer is assigned, they are given identical copies of the protocol to review, and share their questions, comments and requests with one another and the IACUC Staff, the IACUC Staff compiles the review comments and sends to the PI.

The method and outcome of review is documented on the report of activity since the last meeting which is attached to the next IACUC meeting agenda.

Types of Administrative Review (AR):

1. Changes in Personnel other than the PI:

Additions and deletions of personnel, other than the PI, are administratively reviewed by the IACUC Staff. A change of PI on an existing protocol requires FCR. The IACUC Staff will ensure that all such personnel are appropriately identified, adequately trained, and enrolled in applicable occupational health and safety programs. All criteria regarding personnel training and qualifications are maintained and documented by the IACUC Staff.

2. Other Changes:

Changes that are handled administratively without IACUC approved policies, consultations, or notifications include:

- correction of typographical errors and grammar,
- addition of funding source (if animal numbers and all animal activities have been previously reviewed and approved),
- change in protocol title (if all animal activities have been previously reviewed and approved, and contact information updates.

3. Veterinary Verification and Consultation (VVC):

Some significant changes to previously approved animal activities may be handled administratively by the IACUC office in consultation with the Veterinarian as authorized by the IACUC, if the changes meet the VVC criteria in accordance with OLAW NOT-OD-14-126 "[Guidance on Significant Changes to Animal Activities](#)" and as itemized below.

The Veterinarian will not be conducting Designated Member Review (DMR), but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policies is appropriate for the animals in this circumstance.

The IACUC Office will document the basis of the changes, and through his/her review, the Veterinarian provides documentation that the modifications proposed meet the criteria set forth below. The Veterinarian can request IACUC review (via DMR or Full Committee Review (FCR)) of the proposed changes for any reason. If the VVC review is conducted and will not require committee review it will be reported to the IACUC at the next convened meeting.

Significant changes include changes that have, or have the potential to have, a negative impact on animal welfare however some activities may be considered significant even if they may not have a direct impact on animal welfare.

Overall categories eligible for administrative review with VVC include changes to:

- a. Drugs and Drug Doses:
 - 1) Change in doses of previously approved drugs to levels known to be safe;
 - 2) Addition of clinical medications as prescribed by the veterinarian;
 - 3) Change in method of drug administration to another method of equal or lesser invasiveness (limited to SC, IP, IV, PO);
 - 4) Change in frequency of administration;
 - 5) Change in diet as long as new diet does not create a new change in animal health status.
- b. Anesthesia, Analgesia and Euthanasia:
 - 1) Change of anesthesia or analgesia agent;
 - 2) Addition of an anesthetic or analgesic as recommended by the veterinarian;
 - 3) Method of euthanasia as long as AVMA-stipulated conditions are met.
- c. Blood and Tissue Collection for Genotyping:
 - 1) Change between approved methods of blood collection (route, frequency, volume).
 - 2) Change between tissue types for genotyping;
 - 3) Collection of additional tissue after euthanasia;
 - 4) Non-invasive collection of urine or saliva.
- d. Procedures:
 - 1) Addition of special husbandry or nursing care as prescribed by veterinarian;
 - 2) Addition of pre-defined Category C behavioral tests to protocols that already include behavior testing;
 - 3) Variations to previously approved surgeries that do not increase the invasiveness or expected outcomes.
- e. Animal Numbers Changes:
 - 1). An increase in previously approved animal numbers by 10 % or less.

Significant changes NOT eligible for VVC include:

- a. From non-survival to survival surgery;

- b. Resulting in greater pain, distress, or degree of invasiveness;
- c. In housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
- d. In species;
- e. In study objectives;
- f. In Principal Investigator (PI); and
- g. That impact personnel safety.

Other Information:

No member may participate in the review or approval of a research project in which the member has a conflicting interest (i.e., financial, personal or professional) except to provide information requested by the IACUC. If a member of the committee has a conflict of interest and will be recused during the vote, steps are taken prior to the convened meeting to insure a quorum will still be present at the meeting without the recused member.

If necessary, meetings can be convened on an emergency basis provided a quorum of voting members are present. Alternatively, emergency meetings could be conducted by teleconferencing consistent with guidance provided in NOT-OD-06-052 "Guidance on Use of Telecommunications for IACUC meetings under the PHS Policy on Humane Care and Use of Laboratory Animals." All members would be given sufficient notice to participate and a quorum of the voting members must convene on the same conferencing line.

References:

Current AVMA guidelines for the euthanasia of Animals
PHS Policy
The Guide for the Care and Use of Laboratory Animals
Animal Welfare Act
SDSU Blood Collection Policy 2019
SDSU Analgesia and Anesthetic Dosage Reference Document 2020

- 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:

Review of proposed significant changes follow the procedures described in Part III. D. 6 above.

- 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:

The Division of Research Affairs provides support to the IACUC through the IACUC Staff, who attend the meetings and record actions taken by the IACUC for each protocol reviewed via meeting minutes.

Once the submission has been reviewed either by FCR, DMR, or AR:

If approved, a letter signed by the Chair is sent to the PI to notify of the approval, the next annual renewal date, and protocol expiration date.

If modification to the protocol is needed to secure approval, correspondence is sent to the PI summarizing the points in question. Also see section III. D. 6 above.

If approval is denied by the convened committee, a letter is sent to the PI with an explanation for the action. The PI may resubmit a protocol for review provided the issues are correctable. Approval can be granted if revisions made are acceptable to the IACUC.

The Institutional representative, Assistant Vice President for Research Support Services, Division of Research Affairs, routinely attends the meetings and informs the IO of important animal care and use issues. The substance of the IACUC discussions concerning important campus wide animal care and use issues requiring advice or approval from the IO may also be passed along directly by letter from the IACUC chair. In addition, the minutes of each meeting are posted to a secure member-only website for viewing by the IO at any time.

- 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:

Protocols are approved for three years. However, PIs are required to submit annual reports of continuation for all continuing protocols for review and approval by the IACUC. After two such annual reviews, the PI must complete an entirely new protocol. The third year renewal of the protocol (new protocol) must be reviewed and approved by the IACUC prior to the expiration date of the current protocol if the work is to continue.

- 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:

Should the IACUC become aware of a potentially serious problem, the issue would be investigated and discussed at a convened meeting with a quorum of members present. A summary report of the investigation and IACUC determination is then prepared and submitted to the IO for review. If a majority of members present votes to approve a suspension, the PI is notified in writing by the IACUC Chair that no further work with animals may be performed under the specific protocol until the PI has adequately addressed the concerns. If an activity is suspended, the IO immediately reports the suspension with an explanation to OLAW.

- 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:

The campus Occupational Health and Safety program is managed by SDSU's Environmental Health and Safety Department (EH&S). A representative of Environmental Health and Safety is a member of the IACUC and provides on-the-job health and safety training. A comprehensive Injury and Illness Prevention Program (IIPP) developed by EH&S functions as an "umbrella" program to all occupational health and safety programs of the campus including Hazard Awareness and Communication, Hazardous Materials and Wastes Management, Biohazard Control, Chemical Hygiene, Personal Protective Equipment, and Medical Surveillance. The IIPP was developed to facilitate the identification, evaluation and control of workplace hazards including hazards inherent in the care and use of animal in instruction and research, to provide measures to prevent and monitor potential exposure to hazards, to implement procedures for injury and illness investigation, and to train SDSU employees including animal care personnel, principal investigators, or laboratory staff with direct contact with animals, animal

wastes, or animal tissues.

EH&S performs hazard identification and risk assessment of animal facilities and experimentation on a scheduled basis. EH&S provides occupational health and safety training to SDSU animal care personnel, principal investigators, and laboratory staff with direct contact with animals, animal wastes, or animal tissues. This training includes zoonosis for the species in-house, notification and special precautions for pregnancy, decreased immunocompetence, allergy prevention, or any other illness, hazard communication, use of personal protective equipment, proper handling of biological, chemical, and hazards, handling and disposal of hazardous wastes, general laboratory safety procedures and personal hygiene. Respiratory protection is recommended for personnel handling laboratory animals to prevent allergies and is required when emptying dirty cages. However, respiratory protection is required when handling field rodents. In addition, respiratory protection and other approved personal protective equipment are required when performing animal experimentation involving airborne transmissible disease or other known zoonotic diseases. Disposable gloves are mandatory when handling all animals. EH&S maintains the medical surveillance program for SDSU animal handler and care personnel. Pre-assignment and annual medical examinations are required. Animal handler and care personnel receive appropriate health monitoring and physical examinations. Employees who are immunocompromised are restricted from working with laboratory animals. All laboratory animal handler and care personnel are reminded that all animal bites or injuries must be reported to their immediate supervisor and medical treatment must be provided. Medical care for bites, scratches, illness or injury involving SDSU animal care personnel, principal investigators, and laboratory staff, are referred either to Alvarado Hospital or the Occupational Medicine Department of Sharp Rees Stealy Medical Centers, students of the university are routed to Student Health Services on campus. We are required to provide tetanus vaccinations to animal careworkers.

- 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 the attached Facility and Species Inventory table. See Attachment C.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

Only full time faculty or professional staff with an advanced degree can be responsible for the project and serve as the PI on an APF. Student researchers, residents, and postdoctoral fellows cannot be listed as the PI. The APF is designed to help the PI meet institutional requirements, IACUC requirements, and OLAC animal facility policies.

The requested information on the APF allows the IACUC to ensure that the principal investigator is qualified and holds sufficient knowledge to perform the research or use animals in their teaching and to train their personnel working with animals in the humane practice of animal care and use, to minimize the number of animals required to obtain valid results and limit animal pain and distress, etc. Each member of the IACUC is given a copy of this approved Animal Welfare Assurance. In addition, all personnel including the principal investigator are required to complete Collaborative Institutional Training Initiative (CITI) training every three years.

Web Based Training

The CITI Program's Animal Care and Use materials cover general principles of ethical care and use of animals in research, training, and testing, as well as focusing

on the care and use of particular animals. Content is designed to meet U.S. Department of Agriculture (USDA) and Office of Laboratory Animal Welfare (OLAW) requirements for basic training in the humane care and use of animals.

Training is separated into learner groups based on the research activities and species used. The learner groups are as follows, including the listed submodules:

Laboratory - Not Handling (Mouse/Rat)

- Laboratory Animal Work - No Animal Handling mice and rat models

Laboratory -Handling (Mouse/Rat)

- Laboratory Animal Work - With Animal Handling mice and rat models
- Reducing Pain and Distress in Laboratory Mice and Rats
- Working with Mice in Research
- Working with Rats in Research Settings

Wildlife - Not Handling

- Wildlife Animal Work - No Animal Handling

Wildlife - Handling (Amphibians)

- Wildlife Animal Work - With Animal Handling - Amphibians
- Working with Amphibians in Research Settings

Wildlife - Handling (Fish)

- Wildlife Animal Work - With Animal Handling - Fish
- Working With Fish in Research Settings

Wildlife - Handling (Reptiles)

- Wildlife Animal Work - With Animal Handling - Reptiles
- Working with Reptiles in a Research Setting

IACUC Member

- IACUC Member

IACUC Community Member

- IACUC Community Member

Most modules contain a quiz. A minimum aggregate score of 80% is required to pass the courses. There are several additional, optional modules also available for completion if the personnel so choose to complete.

Hands-on and Vivaria Entrance Training:

In addition to the CITI Animal Care and Use Training, OLAC Orientation is required for all personnel who will be in direct contact with animals. The specific content and degree of detail will vary depending on the knowledge, previous experience and expertise of the target audience. This orientation can include but is not limited to:

- Vivaria Entrance Procedures
- Protective Clothing/Hygiene
- Procedure & Survival Surgery Rooms
- Procedure Room
- Animal Receiving & Quarantine/Isolation
- Animal Movements
- Euthanasia procedures
- Cage cards/Animal Identification
- OLAC Responsibilities
- Emergency Contact Information
- Training/Educational Resources
- Handling/Restraint
- Euthanasia Procedures


- Breeding Management
- Clinical Techniques - Blood Draw, Injections, etc.

In addition, all OLAC personnel attend relevant conferences, seminars and topic specific training exercises when deemed necessary and appropriate.

IACUC members receive materials at the beginning of their service that include the institutional policy on animal care and use, a copy of the Animal Welfare Assurance, a copy of the current AWRs, The Guide for the Care and Use of Laboratory Animals, PHS Policy on Humane Care and Use of Laboratory Animals, the OLAW Institutional Animal Care and Use Guidebook and any other relevant information as necessary. In addition, training is supplemented with relevant topic specific discussion at convened meetings as time permits.

IV. Institutional Program Evaluation and Accreditation

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.

- (1) 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 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 Institutional Official, Stephen C. Welter, Ph.D.
 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 Institutional Official, Stephen C. Welter, Ph.D..
 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: Stephen C. Welter, PhD	
Title: Vice President for Research	
Name of Institution: San Diego State University	
Address: <i>(street, city, state, country, postal code)</i> 5500 Campanile Drive, San Diego, CA 92182-8220	
Phone: 619-594-2978	Fax: 619-594-4109
E-mail: swelter@sdsu.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:

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:

Effective Date:

Expiration Date:

VIII. Membership of the IACUC

Date: January 2020			
Name of Institution: San Diego State University			
Assurance Number: D16-00340 (Legacy #A3728-01)			
IACUC Chairperson			
Name*: Todd W. Anderson			
Title*: Professor, Department of Biology		Degree/Credentials*: Ph.D.	
Address*: (street, city, state, zip code) 5250 Campanile Drive, San Diego, CA 92182-1933			
E-mail*: tanderson@sdsu.edu			
Phone*: 619-594-0995		Fax*: 691-594-4109	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
See Attachment B			

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:	Rick Gulizia

San Diego State University
D16-00340 (Legacy #A3728-01)

Title: Assistant Vice President for Research Support Services/Institutional Official Representative	
Phone: 619-594-5938	E-mail: rgulizia@sdsu.edu

X. Facility and Species Inventory

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
SEE ATTACHMENT C			

Attachment B - SDSU IACUC Membership Roster 2019-2020

IACUC Member #		Degree/ Credential	Position Title/Occupational Background	PHS Policy Membership Requirement
Chair 1	Todd Anderson	PHD	Biology Professor	Scientist
Vet	Mari Bray	DVM	Veterinarian	Attending Veterinarian
2		PhD	Psychology Professor	Scientist
3		PhD	Biology Professor	Scientist
8		BS in Communications, Contract Management Cert. and Certified Research Administrator	Sponsored Research Contracting and Compliance	Member - Non-Voting
13		BS	Environmental Health & Safety Alternate	Member
14	Karen Clingerman	DVM	Veterinarian	Clinical Veterinarian
16		BS	Research Facilities and Operations Manager	Animal Care Oversight Member
17		PhD	Biology Professor	Scientist
18		PhD	Anthropology Professor	Scientist
19		PhD	Biology Research Associate	Scientist
20		BS	Director of Research Affairs	Graduate and Research Affairs Ex-officio Member
21		PhD	Exercise and Nutritional Sciences Professor	Scientist
23		BS	Environmental Health & Safety Biosafety Officer	Member
25		BA, RLAT	Office of Laboratory Animal Care	Member - Non-Voting
26		BS	Retired Pharmacist	Non-Affiliated / Non-Scientist

FACILITY AND SPECIES INVENTORY**Attachment C 2020**

DATE: January 2020

NAME OF INSTITUTION: San Diego State University

ASSURANCE NUMBER: D16-00340

Laboratory, Unit, or Building*	Gross Square Feet (including service areas)	Species Housed in Unit (use complete common names)	Approx. Average Daily Inventory
Building	5345 sq. ft.	Rats	150
Building	1801 sq. ft.	Mice	3000
Building	580 sq. ft.	Mice	50
Building	130 sq. ft.	Rats	20
Building	345	Mice	200
Building	3000 sq. ft	Mice	1000
Building	110 sq. ft.	Snakes, lizards	100
Building	5,500 sq. ft.	Fish	100
Building	380 sq. ft.		
Building	Two 32 ft ³ chicken coop with wire fencing and nesting area	Chickens	12
Building	114" x 130" or approx. 100 sq ft	Zebrafish	<7,500

*Institutions may identify animal areas in any manner, e.g., initials, ID number, etc. However, the name and location must be provided to OLAW upon request.