



SACRAMENTO
STATE

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE:
PROCEDURES/ASSURANCE

OFFICE OF RESEARCH, INNOVATION, AND ECONOMIC
DEVELOPMENT

RESEARCH INTEGRITY AND COMPLIANCE

LAST REVISED: OCTOBER 18, 2018

CALIFORNIA STATE UNIVERSITY, SACRAMENTO

Assurance No. D16-00695 (A4394-01)

Animal Welfare Assurance for Domestic Institutions

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

Definitions

All definitions are derived from the PHS Policy.

- A. **Animal** – Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.
- B. **Animal Facility** – Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.
- C. **Animal Welfare Act** – Public Law 89-544, 1966, as amended (P.L. 91-579, P.L. 94-279, and P.L. 99-198), 7 U.S.C. 2131 et seq. Implementing regulations are published in the Code of federal Regulations (CFR), Title 9, Chapter 1, Subchapter A, Parts 1,2, and 3, and are administered by the U.S. Department of Agriculture.
- D. **Animal Welfare Assurance or Assurance** – The documentation from an institution assuring institutional compliance with this Policy.
- E. **Guide** – *Guide for the Care and Use of Laboratory Animals*: Eighth Edition, National Academy Press, 2011, Washington, D.C., or succeeding revised editions.
- F. **Institution** – Any public or private organization, business, or agency (including components of Federal, state, and local governments).
- G. **Institutional Official** – An individual who signs, and has the authority to sign, the institution's Assurance, making a commitment on behalf of the institution that the requirements of this Policy will be met.
- H. **Public Health Services** – The Public Health Services, or the PHS, includes the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Food and Drug Administration, and Health Resources and Services Administration, the Indian Health Services, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration.
- I. **Quorum** – A majority of the members of the Institutional Animal Care and Use Committee (IACUC).

I. Applicability of OLAW 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 animal facilities and components operate under Sacramento State, otherwise known as California State University, Sacramento.
 - University Enterprises, Incorporated (UEI)

References:

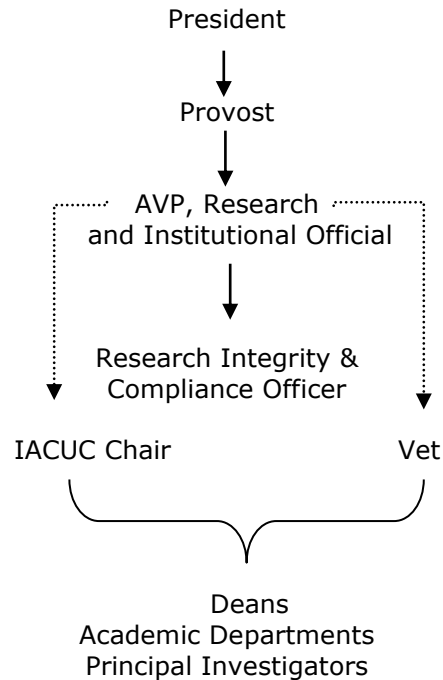
- [Amphibians and fish](#)
- [Privately owned animals](#)
- [Non-PHS funded activities](#)

II. Institutional Commitment

- A. Sacramento State complies with all applicable provisions of the [Animal Welfare Act](#) and other Federal statutes and regulations relating to animals.
- B. Sacramento State is guided by the "[U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.](#)"
- C. Sacramento State 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.
 - Sacramento State notifies the campus of any changes to policies and procedures affecting the care and use of animals, regardless of Assurance status (active or inactive). Current policy and procedures are available on the IACUC website:
<http://www.csus.edu/research/researchintegritycompliance/iacuc.html>.
- D. Sacramento State has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals, 8th Edition (Guide)*.
- E. Sacramento State 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, when the activity is subject to OLAW oversight, and have an Animal Care and Use Committee that adheres to the Animal Welfare Act and other Federal statutes and regulations relating to animals, 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:



i. Both the IACUC and the Veterinarian have direct access to the Associate Vice President for Research, Innovation, and Economic Development, who serves as the Institutional Official and appoints an Administrative Liaison (Research Integrity & Compliance Officer) to the IACUC. The Administrator supports the Committee's activities through the following actions:

- Maintains and holds all IACUC files of record including: protocols, Assurance and Registration, reports, procedure and guidance, protocol forms, committee list, meeting minutes, training completion, and so on;
- Assists in scheduling a meeting location;
- Submits annual reports to federal agencies (OLAW and APHIS), when active;
- Submits Assurance renewal with PHS-OLAW every four years, when applicable;
- Submits Registration renewal with USDA-AWA every three years, when applicable;
- Maintains online training through CITI; and
- Assists with unannounced USDA inspection visits, when active.

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

1) Name: Angela Colagross-Schouten

Qualifications:

- Degrees: Doctor of Veterinary Medicine (University of California, Davis), Master of Preventive Veterinary Medicine (University of California, Davis), Diplomate of the American College of Laboratory Animal Medicine.
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Colagross-Schouten has advanced training in Laboratory Animal Medicine and colony management. She served as a consultant in a contract research environment for more than 17 years providing training, IACUC support, report writing, veterinary care, and technical

project support and vivarium management oversight. She has more than 15 years of IACUC experience, both as member and chair.

Authority: Dr. Colagross-Schouten has delegated program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program: Dr. Colagross-Schouten is present at the Institution an average of approximately three hours bi-annually. One hundred percent of this time is contributed to the animal care and use program. In addition, Dr. Colagross-Schouten contributes on average approximately one hour per month to the program while off-site reviewing protocols and providing consultation on various program related topics.

Contingency Plan: In the event of an emergency when the contracted Vet is not available, the below listed Vet will be called for assistance. If the contracted Vet is not available for a semiannual review and inspection and it cannot be rescheduled within an appropriate timeframe to adhere to the six-month semiannual review requirement, the Vet listed below will be called to temporarily serve in Dr. Colagross-Schouten's place.

2) Name: Kenneth Pawlowski

Qualifications

- Degrees: Doctor of Veterinary Medicine (University of California, Davis)
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Clinical Consultant, Self-owned Pet Hospital, Consultant for surgical centers in clinical trials for investigational veterinary drugs, Member of several veterinary associations, Vet Technician for community colleges.

C. The IACUC 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. Membership selection and appointment are outlined in the University Policy for Animal Care and Use.

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:

- At least once every six months a minimum of the IACUC Chair and Vet review the Institutional Program for Humane Care and Use of Animals. This review normally occurs during scheduled meetings, however if the review occurs outside of a scheduled meeting, all members of the IACUC are invited to participate in this review. The evaluation may include, but not necessarily be limited to, a review of the following: a) IACUC Membership and Functions; b) IACUC Records and Reporting Requirements; c) Husbandry and Veterinary Care (all aspects); d) Personnel Qualifications (Experience and Training); d) Occupational Health and Safety; e) Emergency and Disaster Plans; and f) the OLAW Assurance. To facilitate the evaluation, a checklist based on the sample OLAW Semiannual Program Review and Facility Inspection Checklist is used. The report is presented to the committee for review at a convened meeting.

- 2) **Inspect at least once every 6 months all the Institution's animal facilities, including satellite facilities, using the *Guide* as a basis for evaluation.** The IACUC procedures for conducting semiannual facility inspections are as follows:
 - At least once every six months a minimum of the IACUC Chair and Veterinarian inspect all facilities where animals are housed or used, i.e., holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are conducted. This inspection normally occurs during scheduled meetings, however if the inspection occurs outside of a scheduled meeting, all members of the IACUC are invited to participate in the inspection. Equipment used for transporting of the animals is also inspected. To facilitate the evaluation, a checklist based on the Sample OLAW Semiannual Program and Facility Review Checklist is used. No member will be involuntarily excluded from participating in any portion of the inspections. The semiannual report is presented to the committee at a convened meeting. Facilities inspections occurring outside normal IACUC meeting dates are reported to the IACUC Chair and IO.

- 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 IACUC draft a semiannual report according to the OLAW Semiannual Report to the Institutional Official template. The draft report is reviewed, revised as appropriate at the meeting, and sent to the IO. The final reports are signed by a majority of the IACUC members, normally those who are present at the meeting. The completed reports are submitted to the IO within 30 days following the evaluation.
 - Departures from the PHS Policy and the Guide are identified by the Committee and may be approved or may require correction. If the departure was not previously approved by the IACUC it is considered a deficiency and addressed as such.
 - The reports contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy, identify specifically any departures from the provisions of the Guide and the PHS Policy approved by the IACUC, and state the reasons for each departure. The reports distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports contain a reasonable and specific plan and schedule for correcting each deficiency. Any minority opinions are included. If there are no minority opinions, the reports reflect such.

- 4) **Review concerns involving the care and use of animals at the Institution.** The IACUC procedures for reviewing concerns are as follows:
 - Any individual may report concerns to the IO, IACUC Chair, Institutional Veterinarian, or any member of the IACUC. Reporting information is posted in each animal facility, instructing individuals how and where to report animal welfare concerns and state that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals. Anonymous reports can be made via the Whistleblower Hotline, managed by campus Human Resources. This hotline is required by the IACUC to be posted in each animal lab (poster provided by the IACUC). The campus follows the California Whistleblower Protection Act and does not discriminate against the concerned/reporting party. All reported concerns are brought to the attention of the full Committee. If necessary the IACUC Chair convenes a meeting to discuss, investigate, and address any reported concern. Reported concerns and all associated IACUC actions are recorded in the IACUC meeting minutes. The Committee reports such actions to the IO and, as warranted, to OLAW. Reports to the IO may be provided through meeting minutes, a semiannual report, or a separate written communication.

- 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:
- Recommendations regarding any aspects of the institution's animal program or facilities are discussed and developed by the Committee and reported via the semiannual report to the IO. Any recommendations by the IACUC or Veterinarian outside of the semiannual reports will be written in a report and sent to the Institutional Official by email. Any recommendations made by non-members can be sent directly to the Institutional Official by email.
- 6) **Review and approve, require modifications in (to secure approval), or withhold approval of 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 received by the IACUC Administrator who triages applications to the Chair and Vet to conduct an initial screening to ensure the protocol is complete.
 - b. Prior to Full Committee Review (FCR), each IACUC member receives a list of proposals for review via the meeting agenda. At least one day prior to the meeting, protocols for initial review are available for review. Discussion and review of protocols occur at a convened meeting of a quorum of IACUC members.
 - c. Meetings are conducted semiannually. Official business is not conducted without a quorum. If a quorum is not met, the IACUC Chair may move the meeting as close to the six-month period as possible. Members formally review and approve, require modifications in (to secure approval), or withhold approval for proposed activities according to PHS Policy IV.C.1.a.-g. Approvals are active for a three-year period. Each approved protocol is reviewed annually within the three-year period. Approval of protocols requires the approval vote of a majority of the quorum present. Minority views are noted in meeting minutes.
 - d. The institution or IACUC may decide to use designated-member review (DMR). In such instances the protocol is distributed to all IACUC members to allow all members the opportunity to call for FCR within one week of distribution. If no member is opposed to DMR, the Vet and IACUC Chair, or one or two members designated by the Chair and qualified to conduct the review, conducts the review on behalf of the IACUC. Designated reviewers have two weeks for review and comment. Designated reviewers can approve protocols on behalf of the IACUC. When one or both reviewers require modifications, comments are sent to the Administrator for gathering and dissemination to the Primary Investigator. Once the Investigator returns the edited protocol, the forms are sent back to all original reviewers for a second two-week review timeline. Designated reviewers cannot disapprove a protocol, however either reviewer can decide to send the protocol to FCR. Decisions made during DMR are reported at the following meeting. The approval of a DMR will occur on the date the protocol is approved, however the anniversary for annual review and three-year review will be set to the meeting month that occurred prior to the protocol submission to ensure the approval period does not go beyond three years.
 - e. When modifications (to secure approval) are requested at a FCR, such modifications are reviewed as follows:
 - (1) At the next scheduled meeting by a convened committee. The revised protocol will be available to the committee as an initial review per item b. above and a decision will be made by the present quorum.

(2) By DMR subsequent to FCR. If all members of the IACUC are present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by designated member review, or returned for FCR at a convened meeting. If all members are not present at a meeting, the committee may use DMR subsequent to FCR as all IACUC members agree 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. This is written and agreed upon by all members through review of this document, which also serves as the IACUC's Procedures document. New members will review this document during orientation.

(3) Minor modifications of an administrative nature, i.e. typographical or grammatical errors, required signatures, etc. may be confirmed by IACUC administrative/support personnel.

- 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. 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.

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:

- See paragraph above. Review and approval of significant changes are handled in the same manner as new protocols.
- Examples of changes considered to be significant include, but are not limited to, changes:
 - from non-survival to survival surgery;
 - resulting in greater pain, distress, or degree of invasiveness;
 - in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
 - in species;
 - in study objectives;
 - in Principal Investigator (PI); and
 - that impact personnel safety.

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 Principal Investigator is notified of decisions by email. The written correspondence will include a statement for decisions to withhold approval or require modifications, provide reasons within the returned application, and give the investigator an opportunity to respond in person or in writing.
- The Institution, by means of the Institutional Official, will be notified of all decisions made (approval, withhold approval, or modifications) by receiving a copy of the meeting minutes. Any decisions made (approval, withhold approval, or modifications) by DMR will be communicated to the Institutional Official by copying this position in correspondence with the Principal Investigator.

- 9) **Conduct continuing review of each previously approved, ongoing activity at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.5.** The IACUC procedures for conducting continuing reviews are as follows:
- Protocols previously approved and ongoing receive a continuing review by the IACUC annually. PIs must submit a renewal report as notification for continuing activity. The IACUC conducts a review and votes for continuation at a convened meeting.
 - Prior to the three-year expiration date, the IACUC conducts a complete review and approval of any ongoing activity according to D.6. of this document. If the protocol was approved, for example, at a May meeting, the protocol is reviewed and approved prior to its third year at a November meeting for continuation. This ensures activity can continue without interruption. If the activity was significantly modified in the last three years, a new Initial Submission is required.
 - If no renewal is requested at the annual review stage, or if a closure report is submitted, the protocol will be closed.
 - Post-approval monitoring is accomplished through a variety of IACUC and institutional mechanisms. IACUC mechanisms include continuing reviews that occur annually, semiannual inspections of facilities, ensuring training is completing by all involved students, staff, and faculty prior to review of protocols, reporting noncompliance to the IO or OLAW, and reporting needed resources to the IO for proper care and use of animals. Institutional mechanisms include expertise of technical staff or personnel who oversee the daily operations of animals and labs, reporting from department chairs, related components of Environmental Health and Safety with separate inspection and reporting mechanisms, membership of an EH&S staff on the IACUC for appropriate communication, reporting of outcomes of animal procedures by investigator and/or staff in closure reports, post-operative care by trained personnel, hands-on training in animal procedures offered by PIs, and reporting of incidences involving occupational health and safety.
- 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:
- 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 the PHS Policy. 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.
 - 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 to OLAW when the activity is PHS funded (IV.C.7.). Initial reports to OLAW may occur via telephone.
 - Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC (IV.C.8.).

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 PI is required to assure that they and other protocol personnel have read the occupational health and safety document provided by the IACUC that identifies the most common risks for our campus' animals and facilities. All personnel listed on a protocol are enrolled in the OHSP and require a Risk Assessment and Medical Evaluation. Clinician's communicate with EH&S of a participant's approval to work with animals. This approval is matched with the IACUC's list of enrollees to ensure completion of this requirement. New personnel added in-between approvals must be communicated with the IACUC through a Modification Request.

- *Control and prevention strategies*
 - The Environmental Health and Safety Office oversees several policies and committees that play a role in occupation health and safety on campus. The EH&S has developed and implemented an Injury and Illness Prevention Program (IIPP) in compliance with the requirements of the California Code of Regulations, Title 8, section 3202 (a)(7) that encompasses Respiratory Protection, Hazardous Materials Management, Confined Space Entry, Medical Monitoring, Pollution Prevention, Emergency Preparedness, Radiation & Laser Safety, and Laboratory Safety.
 - The IACUC supplies each Principal Investigator with a document detailing potential occupational hazards when working with or in frequent contact with animals that the PIs are to distribute to all protocol personnel. This document links to EH&S services and reporting mechanisms as well as available health-care through employee insurance or the student health center.
 - This program implements the hierarchy of controls through the appropriate design and operation of facilities and use of appropriate safety equipment, the development of processes and standard operating procedures at the office and department levels, and the provision of appropriate personal protective equipment for employees and students.

- *Hazard identification and risk assessment*
 - All personnel listed on animal use protocols are enrolled in the OHSP and must complete a Risk Assessment with the Principal Investigator. This Assessment will accompany the Medical Evaluation. New personnel added to each protocol in-between approval periods must be communicated to the IACUC through a modification request so that personnel are enrolled and approved prior to working with animals.
 - The OHSP packet, that must be read by all animal personnel, outlines hazard identification, including: allergies, animal bites and scratches, zoonosis, sharps, hazardous materials, radiation, ergonomics, noise, and others. The document outlines steps to take to mitigate such hazards. In addition, the online Collaborative Institutional Training Initiative (CITI) required course covers similar hazards and prevention strategies.
 - Risk assessment forms are included in the OHSP packet. This form helps identify hazards (as outlined above), analyze those risks and determine appropriate ways to eliminate or control the hazard.
 - IACUC inspections are reported to the IO, who is responsible for communicating requests for appropriate resources to correct identified safety hazards. This may involve the EHS.
 - Contact with animals by facilities, security, or police is not frequent enough to justify enrollment in the OHSP. Information describing zoonosis and allergy risk and prevention is posted outside of each animal facility for all personnel who enter the animal facilities infrequently.

- *Facilities, equipment, and monitoring*
 - Exposure control measures shall be established to ensure that no worker is exposed to airborne concentrations of hazardous materials equal to, or greater than, the permissible exposure limits, action limits, or ceiling limits established by Cal/OSHA. Therefore, equipment that is designed to provide employee protection or emergency equipment must be maintained and certified as required by Cal OSHA. Personnel must also be knowledgeable in the proper use of such equipment.
 - Proper use of the following equipment is outlined in the OHSP packet: Chemical Fume Hoods, Autoclaves/Sterilization, Fire Protection Systems and Equipment, Eyewashes and Safety Showers, Personal Protective Equipment, and Personal Hygiene.
 - Appropriate animal housing systems based on the types of animals used, hazards posed, capabilities of the facilities, and design of the experiments are selected. Appropriate facilities, equipment, and procedures are used for bedding disposal. Safety equipment is properly maintained, and its function periodically validated. This is verified by the IACUC during protocol review and facility inspections.
 - The IACUC conducts biannual inspections of all animal facilities using the OLAW Semiannual Program Review and Facility Inspection Checklist. Deficiencies are reported to the IO in a semiannual report and affected colleges and departments are copied.

- *Personnel training*
 - The IACUC require CITI training for all personnel involved in the animal activity. Additional training must occur if personnel or students will be handling animals. This is normally face-to-face instruction provided by the PI. Topics may include proper animal handling, animal restraints, respiratory protection and other personal protective equipment, accident reporting and emergency notification. A training sign-in sheet is provided in the OHSP packet for PI's to track and store. The OHSP packet, which must be distributed to all animal personnel, addresses pregnancy, illness, or decreased immune-competence, and these items are reviewed during the Medical Evaluation. Personnel who become pregnant, ill, or immunocompetent are encouraged to be re-evaluated or to see their personal health physician.

- *Personal hygiene*
 - Information about personal hygiene and PPE is available in the OHSP packet, and includes contact information for requesting PPE or reporting hazards to EHS.
 - Personal hygiene is also a component of IIPP training. Appropriate PPE are available for animal facilities and laboratories. Departmental protocols for soiled attire may vary depending on the hazard, and may result in disposing, laundering, or decontaminating the attire. All personnel using animal facilities and laboratories are not permitted to eat, drink, use tobacco products, apply cosmetics, or handle or apply contact lenses in rooms and laboratories where animals are housed or used.

- *Animal experimentation involving hazards*
 - The Chemical Hygiene Plan outlines the policies and procedures governing experimentation with hazardous biologic, chemical, and physical agents. The Environmental Health & Safety Committee assists in the evaluation and safe use of hazardous materials or procedures and has oversight of departmental safety procedures, including hazardous waste management and spill prevention.
 - One IACUC member must be from Environmental Health & Safety and allows for a collaborative approach to compliance.

- *Personal protection*
 - All employees have access to standard personal protective equipment including: caps, gloves, masks, face shields, protective eyewear, and gowns. Other protection will be made available when necessary, such as hearing protection in high-noise areas or respiratory protection where exposure to contaminated airborne particulate materials or vapors may be present.
 - Information about personal hygiene and PPE is available in the IACUC's Occupational Health and Safety document and includes contact information for requesting PPE or reporting hazards to EHS.

- *Medical evaluation and preventive medicine for personnel (including immunizations, vaccinations, and procedures for reporting and treating bites, scratches, and injuries.)*
 - All enrolled individuals must complete a Medical Evaluation. Employees are evaluated through the Sacramento State's Occupational Health & Safety process at Kaiser Permanente. Non-employee students are evaluated through the Student Health Center on campus.
 - Vaccination, health and safety information is posted in the laboratory. All staff members are instructed to immediately notify the Safety Coordinator and the Health Center/their medical provider with any concerns regarding allergies, bites or scratches.
 - All full-time benefited employees have health insurance available to them through the university or University Enterprises Inc. On-call and per-diem employees are responsible for their own health insurance. All employees are covered by Workman's Compensation. Emergencies can be taken to the Student Health Center, or if necessary, to the emergency room of a near-by facility (Sutter Memorial Hospital).
 - All students are required to have proof of measles and rubella immunization and students who are 18 years of age or younger when they first enter the university are required to have proof of hepatitis B. In addition, the student health center offers tetanus shots at a nominal rate should they need it. Employees have access to immunizations through their medical provider.
 - Allergen hazards from working with rodents include reaction to dander, saliva, urine and bedding material. All staff members are instructed to use personal protective equipment appropriately to minimize the risk of allergic reactions. If a staff member does report a reaction, they are advised to immediately contact the Student Health Center or their own physician for treatment as needed.
 - Information about health risks is available in the OHSP packet, and includes contact information for reporting injury or illness and access to health care.
 - Urgent Care information must be posted in each animal facility in the event of bites, scratches, illness or injury. Posters are available on the IACUC website. This poster contains urgent care for employees and students during business hours and non-business hours.

F. The total gross number of square feet in each animal facility, the species of animals housed there and the average daily inventory of animals, by species, in each facility will be on file in the Office of Research, Innovation, and Economic Development and provided to OLAW for Assurance purposes as an attachment to this document.

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

- Specific animal use and care training must be completed by Principal Investigators, scientists, animal technicians, and other personnel involved in animal care, treatment or use prior to a new protocol submission and must be active for the life of the animal subject activity. This requirement is fulfilled

through the Collaborative Institutional Training Initiative (CITI) online course. Required modules cover basic foundational knowledge and is to be supplemented with one of the species-specific courses. Certification is valid for three years, at which time an abbreviated renewal course will be available in CITI, and again in year six. After nine years, the full training module must be completed.

- Students working with animals are also required to take a CITI course. If students will be working directly with animals, a species-specific course must also be completed. It is the Principal Investigator's responsibility to conduct specific care training and track certification of any students or staff working on their IACUC approved protocols.
- The CITI basic course for animal use in research cover the following topics: Introduction to Working with the IACUC, Federal Mandates, Veterinary Consultation, research or testing methods that minimize the number of animals required to obtain valid results and minimize distress, Alternatives, Avoiding Unnecessary Duplication, Endpoint Criteria, Personnel Training and Experience, Occupational Health and Safety, Euthanasia, Making Changes after Approval, Reporting Misuse, Mistreatment, or Non-Compliance. Supplemental modules are also available for researchers in unique situations. Species-specific modules cover detailed information regarding housing, handling, surgery, distress and more.
- IACUC Members are expected to take the basic CITI training required of investigators. A species-specific course is also required of members if they are also active researchers. New members are provided with the following supplemental information during an orientation with the Administrator:
 - 1) The PHS Policy for the Humane Care and Use of Laboratory Animals;
 - 2) The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals;
 - 3) The ARENA/OLAW IACUC Guidebook; and
 - 4) A copy of this Procedure/Assurance.

Orientation with new members covers the above materials and guides members through CITI registration for completing the required basic CITI training (and species-specific training when applicable). Ongoing education is offered through CITI as it is required every three years. Learning opportunities are sought and distributed to the committee by the IO, Chair, and/or Administrator.

- Note: For investigators transferring from other facilities at which they have received similar training within the last three years, verification of previous training may be accepted in lieu of some Institutional required training. Acceptance of previous training in lieu of the Institution's training is solely at the IACUC's discretion.

IV. Institutional Program Evaluation and Accreditation

All of Sacramento State's programs and 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.

This Institution is Category 2 — not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

V. Recordkeeping Requirements

- A. This Institution will maintain for at least 3 years (IV.E.1.):
 - 1) A copy of this Procedure/Assurance that has been 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 given or withheld;
 - 4) Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Dr. Yvonne Harris, the Associate Vice President of Research, Innovation, and Economic Development; and
 - 5) Records of accrediting body determinations.
- B. This Institution maintains 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 (IV.E.2.).
- 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 (IV.E.2.).

VI. Reporting Requirements

This section is applicable when Sacramento State has an active Assurance with the PHS. The reporting requirements are in accordance with IV.F.1-3 of the PHS Policy.

- A. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, submits 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. Notice of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities and submitted the evaluations to the Institutional Official, the Associate Vice President of Research, Innovation, and Economic Development; and
 - 5. Any minority views filed by members of the IACUC.
 - 6. If there are no changes to report, written notification that there are no changes will be provided.

References:

- [Annual reporting requirements](#)
 - [Sample annual report to OLAW](#)
- 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*, or
 - 3. Any suspension of an activity by the IACUC.