

SAN FRANCISCO STATE UNIVERSITY
ASSURANCE OF COMPLIANCE
WITH
PUBLIC HEALTH SERVICE
POLICY ON HUMANE CARE AND
USE OF LABORATORY ANIMALS

San Francisco State University, hereinafter referred to as institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or supported activity by this institution.

"Institution" includes San Francisco State University.

II. INSTITUTIONAL POLICY

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 make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all other applicable laws and regulations pertaining to animal care and use.

9/08

D. This institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

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

The Chief Executive Officer of this institution, President Robert Corrigan, has responsibility for appointing members of the Institutional Animal Care and Use Committee (IACUC). The Institutional Official (IO), Dr. Jaylan Turkkan, Associate Vice President for Research and Sponsored Programs and Professor of Psychology, is responsible to the President of the University. Both the IACUC, through its Chair, and the Attending Veterinarian report directly to the IO. Animal care personnel report to the Biology Animal Facility Manager, who serves on the IACUC.

The Attending Veterinarian consults with both the Facility Manager and the Chair, and provides written reports to the Manager, Chair, and the IO as needed, but at least once every six months. The Chair reports all of the Committee's proceedings and any other pertinent information to the IO on an as-needed basis, including summaries of protocols approved and a copy of the minutes of the IACUC meetings held at least once every six months.

Investigators may contact the Facility Manager, IACUC members or Chair, or the Attending Veterinarian for advice, questions, or concerns. Complaints of animal misuse or abuse may be addressed to any member of the Committee or the IO. Investigation will follow by the IACUC and the IO.

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

The Attending Veterinarian is a VMD and has over 38 years of veterinary experience with more than 32 years in laboratory animal medicine. The Attending Veterinarian has been Board-certified in Laboratory Animal Medicine since 1978 and completed a training program in Laboratory Animal Medicine at Stanford University. The Attending Veterinarian achieves continuing education through attendance at forums sponsored by the American College of Laboratory Animal Medicine and at other professional meetings. The Attending Veterinarian is active as a consulting veterinarian to laboratory animal programs at other institutions.

The Attending Veterinarian has direct or delegated responsibility for all activities involving animals. The Attending Veterinarian will:

1. Provide clinical veterinary services described in the AWA, including requiring and monitoring diagnostic testing and quarantine disease prevention, and verifying that principles of the Guide are followed with respect to surgery. 100% of the Attending Veterinarian's time is devoted to implementing this policy.
2. Attend at least one IACUC meeting every six months. These meetings include agenda items, program review, and inspection of animal facilities. The Attending Veterinarian is a voting member of the IACUC and, as such, can recommend approval or disapproval of procedures involving animals.
3. Visit the animal facility at least every six months (although historically 4-6 times/year), and to check on specific animal health problems as needed. During these visits, the Attending Veterinarian monitors all activities involving animals. In the case of deviation from a IACUC approved protocol, the Attending Veterinarian has the authority to immediately halt such procedures.
4. Be on call all year to answer questions on animal care, health, research, and facilities by telephone, e-mail, or, when required, personal visit. The Attending Veterinarian is also available for consultation in the planning stages of research and for training in any aspect of animal care and use and in specialized procedures.

When the Attending Veterinarian is unavailable, a back-up Veterinarian is on call for both routine and emergency issues. The Attending Veterinarian makes these arrangements and informs the facility Manager and the IACUC Chair of the appropriate contact information.

C. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy at IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, position titles, specialties and institutional affiliations.

All members will be appointed by the President of the University. The Chair will be a member of the faculty. Additional non-voting members may be appointed to the Committee as deemed appropriate by the IO. A quorum will consist of a majority of the voting members of the Committee.

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 evaluations are based on the Sample Semiannual Program and Facility Review Checklist. The Committee members ensure, using the form as a

guide, that IACUC membership and performance criteria have been met; that records and reporting requirements have been met; that adequate veterinary care is being provided; that all personnel handling animals have been appropriately trained; that dedicated animal facilities personnel are qualified; and that occupational health and safety requirements for personnel have been met. If problems are noted, plans for correction are approved, noted in the minutes (thereby being reported to the IO), and corrective action is assured by the Chair and facility Manager and reported to the IO. The Sample Semiannual Program Review Checklist—Veterinary Medical Care is the guide for the Attending Veterinarian's preparation of a report of the status of veterinary medical care. The report concerns procedures for preventive medicine, animal procurement and transportation, surgery, control of pain or distress, procedures for euthanasia, and the storage and control of drugs. The IACUC reports the results to the Manager, the Chair and the IO at least once every six months, or more frequently as needed.

2. Inspect at least every six months all of the institution's animal facilities, including satellite facilities, using the Guide as a basis for evaluation. The IACUC procedures for conducting the semiannual facility inspections are guided by the Sample Semiannual Inspection Checklist. The inspection is conducted by the Attending Veterinarian after each IACUC meeting, and at other intervals as needed. The Attending Veterinarian is ordinarily accompanied by the facility Manager and the IACUC Chair, and other Committee members who wish to attend. The IACUC reports in writing to the IO, the Chair, and the Manager within ten days of the visit, but reports matters requiring immediate attention at once verbally to the Manager or Chair. Any deficiencies noted on the inspection will be identified as minor or major and include a plan and schedule for correction. Any locations where animals are to be housed for more than twenty-four hours will be inspected by the Attending Veterinarian and the Manager of the facility in advance.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to the IO. The IACUC process for developing reports and submitting them to the IO is to summarize the results of all discussions in the minutes of each meeting and in the report from the Attending Veterinarian provided after each facility inspection. These reports will note any departures from the Guide, include major and minor deficiencies, and list a plan for correction.

4. Review concerns involving the care and use of animals at the institution. The IACUC procedures for reviewing concerns are as follows. Any suspected misuse should be reported to the Chair, the Attending Veterinarian or any other member of the IACUC or the IO. The Chair will initiate a review, intervening immediately to stop any improper activity. The Committee will be notified of the nature of any valid complaint, and the result of investigation and action. At the request of any Committee member, the matter may be brought to the entire Committee for discussion. The IO will be notified of all complaints, and of the outcome of any investigation. Verified violations and subsequent actions will be reported to the IO, OLAW and, when a regulated species is involved, to the USDA. SFSU's Human Resources policy and the California Whistleblower Protection Act protect an individual's identity and shield the individual from reprisal, retaliation, threats or coercion for reporting such information. The IACUC adheres to these policies.

5. Make written recommendations to the IO regarding any aspect of the institution's animal program, facilities, or personnel training. The procedures for making recommendations to the IO involve one of the following procedures: (1) Recommendations are written in the form of a letter from the Chair to the IO. (2) The Chair may elect to include the recommendations or other information in the minutes of a meeting, and will notify the IO by electronic mail or telephone that a particular item requires attention. (3) The recommendation may be made by electronic mail.

6. Review and approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C. The Institution's policies are detailed in "Review of Applications and Proposals" below.

Review of Applications and Proposals

a. **Standard Review:** Each IACUC member shall be provided with a copy of applications and proposals to be reviewed. Any member of the IACUC may upon request obtain full committee review of an application. If full committee review is not requested, the Chair and/or the Attending Veterinarian shall be authorized by the committee to review the application and approve, require modifications (to secure approval) or request full committee review of a proposal. If full committee review is requested, approval may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an application or proposal 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 Attending Veterinarian and the Chair shall review all protocols, including those that do not require full committee review (registered protocols).

b. **Off-Campus Research:** Research conducted off campus, but submitted to the University as a grant proposal or for student research credit, must be filed with the SFSU IACUC on SFSU forms. If the project has received approval at an institution with a valid OLAW Assurance, a copy of this approval must be submitted with the IACUC forms. When this research involves an institution that does not have a valid OLAW Assurance and the research is not PHS funded, an appropriate official at the host institution will be notified of the application and the committee's actions regarding the application.

c. **Wild Animals:** The IACUC will review all proposals involving collection of wild animals brought into campus facilities for study and observation. These animals must be appropriately quarantined and housed in quarters separate from laboratory animals. The Attending Veterinarian or the Animal Facilities Manager may deny entry if the animals may pose a danger to personnel or laboratory animals.

- d. Animals in situ (field, zoo, aquarium, natural environment): Research on animals in situ that involves simple field observation with no impact on either animals or their environment and does not require wildlife agency or other permits must be registered with the IACUC, but does not require full IACUC review. A description of the activities and the precautions taken to ensure that no adverse impact on the study animals or their environment will occur; documentation that permits are not required; animal course completion certificate, and a signed Applicant Assurance will be required for registration. All other in situ animal research must be submitted to the IACUC for Standard Review with all appropriate wildlife permits included.
- e. Avian Embryos: Research involving avian embryos that will be sacrificed prior to 3 days before hatching does not require full IACUC review, but must be registered with the IACUC. A complete Avian Embryo Use Summary form and a signed Applicant Assurance will be required for registration. (See attached Policy for the Use of Avian Embryos)
- f. Animal Products: Research involving animal products taken directly from live animals by or under the direction of the PI must be approved by the IACUC. For non-PHS funded research only, obtainment of customized antibodies from a bona fide vendor with an IACUC does not require full IACUC review, but must be registered with the IACUC. Research involving solely the use of museum specimens or specimens that someone else has gathered does not require full IACUC review, but must be registered with the IACUC. A description of the study; a letter from the source authorizing access to the samples and indicating that the samples were collected appropriately; animal course completion certificate; and a signed Applicant Assurance will be required for registration.
- g. Research Conducted by non-SFSU Affiliates: Research conducted by individuals working on campus but not affiliated with SFSU will be reviewed by the IACUC.
- h. Consultants: The IACUC may invite consultants to assist in the review of protocols if they involve specialized expertise or complex issues. Consultants may not approve or withhold approval of an application or proposal and may not vote with the IACUC.
- i. Notification: The IACUC will notify investigators in writing of its decision to approve or withhold approval of those sections of applications or proposals related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an application or proposal, it shall 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. (See also section 8.)
- j. Periodic Review: The IACUC shall conduct continuing review of applications and proposals covered by this policy at appropriate intervals as determined by the IACUC, but not less than once every three years. Investigators shall complete a renewal form annually to: verify active status; verify that activities were conducted in accordance with the approved

protocol; describe any proposed departures from the approved protocols; provide information about animal usage and progress to date; and provide information about activities projected for the upcoming year. Any proposed changes deemed to be significant would then be brought before the IACUC for its consideration and documented as an official IACUC action. Minor changes can be approved by the Chair and the Attending Veterinarian. (See also section 7.) Full committee review of protocols shall occur at least every three years.

Research on species that are under USDA regulation must be reviewed annually. (See also section 9.)

k. Modification or Revocation: The IACUC may revoke approval or request alteration of an approved protocol at any time.

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C. Investigator-initiated changes in ongoing research are reported to the Chair of the IACUC and the Attending Veterinarian to determine whether a modification in protocol or a new protocol is required. If the requested modifications are minor, such as the addition of a new trained staff member, the Chair, in consultation with the Attending Veterinarian, may approve an administrative change. If there are significant changes in the use of animals or in the number of animals to be used, or in other aspects of the protocol, the Chair will notify the investigator that Committee approval is required. The investigator must describe and fully justify the modifications in writing. The investigator's request will be circulated to all IACUC members, who may request a full Committee review or may allow the Chair and Attending Veterinarian to act on the request. If the Chair or any committee member deems it necessary, a complete new protocol must be filed. If a letter is used as a modification to an existing protocol, the letter becomes a part of the protocol file. The Committee will be notified of all administrative actions taken.

8. Notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy at IV.C.4. The IACUC procedures to notify investigators and the institution of its decisions regarding protocol review are to provide a letter or email message to the investigator and the IO stating the approval date, approval number (a local tracking number) and expiration date for the protocol.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy at IV.C. 1-4. at least once every three years. Investigators shall complete a review form annually to: verify active status; verify that activities were conducted in accordance with the approved protocol; describe any proposed departures from the approved protocols; provide information about animal usage and progress to date; and provide information about activities projected for the upcoming year. Any proposed changes deemed to be significant would then be brought before the IACUC for its

consideration and documented as an official IACUC action. Minor changes can be approved by the Chair and the Attending Veterinarian. Full committee review of protocols shall occur at least every three years. Research on species that are under USDA regulation must be reviewed annually.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. When a problem arises, the Chair may stop activities immediately by notifying both the investigator and the IACUC members (including the IO) of the situation. If the problem is not deemed critical, the Chair may allow activities to continue pending the outcome of a Committee investigation. The investigator will be informed of the complaint and invited to provide the committee with a written explanation or a proposed change in protocol. By a majority vote of a quorum of committee members at a convened meeting, the activity may be reinstated, or the activity may be suspended indefinitely. If the IACUC needs to suspend a previously approved activity, the IO 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 and, if a regulated species, to the USDA.

E. The individuals authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals are the IACUC Chair and the IO.

F. The occupational health and safety program for personnel who work in the animal facility or have contact with laboratory animals, "Occupational Health Program for Individuals with Animal Contact, SFSU", is appended. In addition, the policies and procedures for Biohazardous Materials Handling Procedures (Biology Department), Hazardous Waste Management Procedures (Biology Department), Autoclave Operation Procedures (Biology Department), Teaching New Employees about Safety (College of Science and Engineering), and Safety and Hazardous Materials at COSE (College of Science and Engineering) are appended. Waste disposal is handled by an outside contractor which picks up waste and incinerates it. Student Health Services provides first aid for animal bites during their regular hours (8:30-5:45 Mon-Thurs, 8:45-4:45 Fri). Off-site 24 hour/7 days per week medical services are provided by St. Francis Memorial Hospital, 1150 Bush Street, SF, at the Franciscan Treatment Room (Telephone: 415.353-6305). University police can contact off-campus paramedics and they have emergency medical technicians on staff to assist individuals in case of an emergency (Telephone: 415.338-2222).

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

H. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is detailed below.

- 1) All individuals using animals for research or involved in animal care should be appropriately trained. Appropriate training will be determined by the Attending Veterinarian in consult with the IACUC and Chair. The Animal Facility Manager provides group and/or individual instruction in humane practices of animal care and use. Instruction in specialized procedures is provided by the Attending Veterinarian or qualified consultants. All investigators must complete the SFSU on-line animal subjects training course or an equivalent course at another institution at least once every three years, and provide the IACUC with a copy of the Certificate of Completion of this course with their protocol submission. Among the topics covered in this course are federal mandates, alternatives, avoiding duplication, methods to minimize pain or distress, occupational health and safety, and reporting requirements.
- 2) Videotapes and reading materials, which include items such as animal care and use techniques, consideration of non-animal alternatives, and minimizing the number of animals used, are available in the Biology Stockroom. Investigators should document completion of the review of these educational materials to the IACUC in writing.
- 3) Familiarity with the SFSU IACUC policy and Federal guidelines is required of all users. Copies of these policies are available from the Office for the Protection of Human and Animal Subjects, in the Biology Stockroom and at the SFSU IACUC web site (www.sfsu.edu/~protocol).

IV. INSTITUTIONAL STATUS

As specified in the PHS Policy at IV.A.2, as Category 2, all of this institution's programs and facilities, including satellite facilities, for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months in accord with IV.B.1. and 2. of the PHS Policy, and reports prepared in accord with IV.B.3. of the PHS Policy.

All IACUC semiannual reports will include a description of the nature and extent of this institution's adherence to the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where 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 evaluations will be submitted to the IO. Semiannual reports of IACUC evaluations will be maintained by this institution and made available to the Office of Laboratory Animal Welfare (OLAW) upon request.

V. RECORD KEEPING REQUIREMENTS

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

1. A copy of this Assurance and any modifications thereto, as approved by 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 Dr. Jaylan Turkkan, Associate Vice President for Research and Sponsored Programs and Professor of Psychology.
 5. Records of accrediting body determinations.
- B. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.
- 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. At least once every 12 months, the IACUC, through the IO, will report in writing to OLAW:
1. Any change in the status of the institution (*e.g., if the institution becomes accredited by AAALAC or AAALAC accreditation is revoked*), any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, this institution will provide OLAW with written notification that there are no changes.
 2. Notification of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to Dr. Jaylan Turkkan, Associate Vice President for Research and Sponsored Programs and Professor of Psychology.
- B. The IACUC, through the IO, will provide the OLAW promptly 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 shall include any minority views filed by members of the IACUC.