Animal Welfare Assurance for Domestic Institutions

Leland Stanford Junior University
(650) 721-6781
Stanford, CA 94305

A3213-01
THE LELAND STANFORD JUNIOR UNIVERSITY
ANIMAL WELFARE ASSURANCE
in accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals

I, Ann M. Arvin, M.D., as named Institutional Official for animal care and use at Leland Stanford Junior University, hereafter referred to as Institution, by means of this document, 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:

"Institution" includes the following branches and components of the Leland Stanford Junior University: 1) SLAC National Accelerator Laboratory; 2) Lucile Salter Packard Children's Hospital at Stanford; 3) Howard Hughes Medical Institute (at Stanford University); and 4) Stanford Hospital and Clinics.

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

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: **Attachment One**

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

The veterinarians carry out their duties as part of the program of the Veterinary Service Center (VSC). The VSC is a division of the Department of Comparative Medicine (DCM). Therefore, as indicated in this Assurance, section IIIA, the authority of the veterinarians is derived from the Board of Trustees, through the President, through the Provost, through the Dean of the Medical School, to the Chair of the Department of Comparative Medicine, to the veterinarians. The Attending Veterinarian also has a reporting relationship with the Institutional Official.

1) Professor and Chair, DCM; Director, VSC

Qualifications

- Degrees: DVM, LSU School of Veterinary Medicine, 1985; PhD in Neurobiology, UC-Davis, 1995; Diplomate, American College of Veterinary Internal Medicine (DACVIM), 1992.

- Training or experience in laboratory animal medicine and in the use of the species at the institution: Assistant Professor, DCM, 1995; Associate Professor, DCM, 2003; Professor, DCM, 2008; Director of Surgical Services; Associate Director of VSC and Attending Veterinarian (AV) 2006-2008; Professor and Chair of the DCM, Director of the VSC, 2009-present.

Responsibilities: Involved in general oversight, planning and administration of all areas of animal care and use. In addition to administrative responsibilities, provides clinical, teaching and research service.

Authority: Has direct program authority and responsibility for the Institution's animal care and use program, including access to all animals.

Time contributed to program: Full time employee. Percentage of time contributed: 100%.

2) Stephen Felt, Attending Veterinarian; Assistant Professor, DCM; Associate Director, VSC

Qualifications

- Degrees: DVM, University of Wisconsin, 1989; MPH, Uniformed Services University, 2003; Diplomate, American College of Veterinary Preventive Medicine (DACVPM), 2003; Diplomate, American College of Laboratory Animal Medicine (DACLAM), 2005.

- Training or experience in laboratory animal medicine and in the use of the species at the institution: Assistant Professor, DCM, AV, and Associate Director, VSC, 2008 to present.

Responsibilities: Dr. Felt has direct program authority and responsibility for the institution's animal care and use program, including access to all animals. Dr. Felt directs the Laboratory Animal Medicine Residency Program (currently three residents), supervises staff veterinarians, and provides clinical, teaching and research services. Also trains investigative staff, assists researchers with protocol preparation, performs protocol review, and is a voting member of the IACUC.

Time contributed to program: Full time employee. Percentage of time contributed: 100%.

3) Megan Albertelli, Backup Attending Veterinarian, Assistant Professor, DCM; Staff Veterinarian, VSC

Qualifications

- Degrees: DVM, Michigan State University, 1999; PhD, Human Genetics, University of Michigan, 2007; Diplomate, American College of Laboratory Animal Medicine (DACLAM), 2008.

- Training or experience in laboratory animal medicine and in the use of the species at the institution: Staff Veterinarian, VSC, 2007; Assistant Professor, DCM, 2009 to present.

Responsibilities: Oversees large animal clinical services and provides clinical, teaching and research support. Serves as the backup AV, having delegated program authority and responsibility for the institution's care and use program, including access to all animals. Also trains investigative staff, assists researchers with protocol preparation, performs protocol review, and is an alternate member of the IACUC.

Authority: Has delegated responsibility for the Institution's animal care and use program, including access to all animals.

Time contributed to program: Full time employee. Percentage of time contributed: 100%.

4) Professor, DCM and Director of Necropsy Services, VSC

Qualifications

- Degrees: DVM, University of Tennessee, 1985; PhD in Comparative and Experimental Medicine, University of Tennessee, 1995; Diplomate, American College of Veterinary Pathologists (DACVP), 1996.

- Training or experience in laboratory animal medicine or in the use of the species at the institution: Assistant Professor, DCM, 1997; Associate Professor, DCM, 2003; Professor, DCM, and Director of Necropsy and Clinical Diagnostic Services, VSC, 2008; Professor, DCM and Director of Necropsy Services, 2011 to present.

Responsibilities: Oversees postmortem and histologic examinations for diagnostic or research purposes, and provides investigator training and consultation.

Authority: Has direct responsibility for the Institution's diagnostic pathology support services.

Time contributed to program: Full time employee. Percentage of time contributed: 100%.

5) Staff Veterinarian and Assistant Director of Rodent Health Surveillance, VSC

Qualifications

- Degrees: DVM, University of California at Davis, 2003; Resident in laboratory animal medicine, UCLA, 2006; Diplomate, American College of Laboratory Animal Medicine (DACLAM), 2007.

- Training or experience in laboratory animal medicine and in the use of the species at the institution: Staff Veterinarian and Assistant Director of Rodent Health Surveillance, VSC, 2008 to present.

Responsibilities: Helps oversees the VSC rodent health surveillance program and provides clinical, teaching and research support services. Also trains investigative staff, assists researchers with protocol preparation, performs protocol review, and is an alternate member of the IACUC.

Authority: Has delegated responsibility for the Institution's animal care and use program, including access to all animals.

Time contributed to program: Full time employee. Percentage of time contributed: 100%.

6) Assistant Professor, DCM and Director Clinical Diagnostic Services, VSC

Qualifications

- Degrees: DVM, University of California, Davis, 2001; PhD in Comparative Pathology, University of California, Davis, 2011; Diplomate, American College of Veterinary Pathologists (DACVP), 2007.

- Training or experience in laboratory animal medicine or in the use of the species at the institution: Assistant Professor, DCM, and Director Clinical Diagnostic Services, VSC, 2011 to present.

Responsibilities: Oversees VSC diagnostic laboratory services and provides clinical, teaching and research services.

Authority: Has direct responsibility for the Institution's diagnostic laboratory support services.

Time contributed to program: Full time employee. Percentage of time contributed: 100%.

7) Senior Research Scientist, DCM and Staff Veterinary Pathologist, VSC

Qualifications

- Degrees: BVSc University of Sydney, 2000; Diplomate, American College of Veterinary Pathologists (DACVP), 2007.

- Training or experience in laboratory animal medicine or in the use of the species at the institution: Companion Animal Veterinarian, 2001; Veterinary Pathologist, NSW Department of Primary Industry, 2002; Resident/Post-Doctoral Fellow in Veterinary Anatomic Pathology, The Animal Medical Center/Weill Medical College of Cornell University/Rockefeller University/Memorial Sloan-Kettering Cancer Center, 2003; Staff Pathologist, The Animal Medical Center, 2006; Senior Research Scientist, DCM and Staff Veterinary Pathologist, VSC, 2008 to present.

Responsibilities: Provides technical support for researchers, diagnostic pathology support to the VSC, and participates in laboratory animal medicine resident training.

Authority: Has delegated responsibility for the Institution's diagnostic pathology support services.

Time contributed to program: Full time employee. Percentage of time contributed: 100%.

8) Assistant Professor, DCM; Staff Veterinarian and Director of Rodent Health Surveillance, VSC

Qualifications

- Degrees: PhD in Ecology, University of California, Davis, 1979; DVM, University of Tennessee, 2004; Diplomate, American College of Laboratory Animal Medicine (DACLAM), 2008.

- Training or experience in laboratory animal medicine and in the use of the species at the institution: Postdoctoral training in Endocrinology, Developmental Genetics, Immunology, and Molecular Biology at Memorial Sloan-Kettering Cancer Center, NYC (1979), Pasteur

Institute, Paris, France (1986), and Howard Hughes Medical Institute, University of California, San Francisco (1987); Assistant Professor in Cell Biology, Vanderbilt University, 1990; Laboratory Animal Medicine Residency, Massachusetts Institute of Technology, 2004; Assistant Professor, DCM and Director of the Rodent Health Surveillance Program and the Mouse Cryopreservation/Rederivation Service, VSC, 2008-present.

Responsibilities: Provides direct clinical care, teaching and research services. Oversees the Rodent Sentinel Program; supervises Mouse Cryopreservation and Rederivation Program; participates in Laboratory Animal Residency Program; trains investigative staff, assists researchers with protocol preparation, performs protocol review, and is voting member of the IACUC. Also participates as an alternate member of Administrative Panel on Biosafety and ex-officio member of the Administrative Panel on Stem Cell Research Oversight.

Authority: Has delegated responsibility for the Institution's animal care and use program, including access to all animals.

Time contributed to program: Full time employee. Percentage of time contributed: 100%.

9) Assistant Professor and Director of Anesthesia, Pain Management, DCM

Qualifications

- Degrees: DVM, Faculty of Veterinary Sciences, Chulalongkorn University, Thailand, 1995; Clinical Resident in Anesthesiology and Pain Management, MS, Washington State University, College of Veterinary Medicine, 2001; PhD, Comparative and Molecular Biosciences (Pain Management), University of Minnesota, College of Veterinary Medicine, 2008; Diplomate, American College of Veterinary Anesthesiologists (DACVA), 2012.

- Training or experience in laboratory animal medicine and in the use of the species at the institution: Assistant Professor, DCM, 2009 to present.

Responsibilities: Oversees anesthesia and surgical support services and provides direct clinical care, teaching and research services.

Authority: Has delegated responsibility for the Institution's animal care and use program, including access to all animals.

Time contributed to program: Full time employee. Percentage of time contributed: 100%.

10) Staff Veterinarian, VSC

Qualifications

- Degrees: DVM, Ecole Nationale Veterinaire d'Alfort (ENVA), France 1999. MBA, Sorbonne, 2003, Diplomate, American College of Laboratory Animal Medicine, (DACLAM), 2009. Individual has completed a Lab Animal Medicine residency at an ACLAM-accredited program (Stanford University), and has successfully passed the DACLAM Boards. This individual is in the process of completing an Educational Commission for Foreign Veterinary Graduates (ECFVG) certificate program and will remain under the supervision of an AVMA-recognized veterinarian until successful completion of the ECFVG program.

- Training or experience in laboratory animal medicine and in the use of the species at the institution: Small Animal Clinician, 1999; Product Manager, Omega Pharma, 2001; Rodent Health Coordinator, DCM, 2004; Postdoctoral Fellowship in Laboratory Animal Medicine, DCM, 2006; Staff Veterinarian, VSC, 2008 to present.

Responsibilities: Supports the clinical service functions of the VSC with experience in laboratory animal medicine, particularly fish and amphibians; and supervises the VSC

veterinary technicians. Also trains investigative staff, assists researchers with protocol preparation, performs protocol review, and is an alternate member of the IACUC.

Authority: Has delegated responsibility for the Institution's animal care and use program, including access to all animals.

Time contributed to program: Full time employee. Percentage of time contributed: 60%.

11) Veterinary Resident, VSC

Qualifications

- Degrees: Texas A&M University College of Veterinary Medicine 2010; ACLAM Training Fellowship in Comparative Medicine, DCM, Stanford University, 2011-2014.
- Training or experience in laboratory animal medicine and in the use of the species at the institution: Postdoctoral Fellowship in Laboratory Animal Medicine, DCM, 2011 to present.

Responsibilities: Supports the clinical service functions of the VSC.

Authority: Has delegated responsibility for the Institution's animal care and use program, including access to all animals.

Time contributed to program: Full time fellow. Percentage of time contributed: 100%.

12) Veterinary Resident, VSC

Qualifications

- Degrees: DVM, College of Veterinary Medicine at Cornell University, 2009; MBA;ACLAM Training Fellowship in Comparative Medicine, DCM, Stanford University, 2011-2014.
- Training or experience in laboratory animal medicine and in the use of the species at the institution: Postdoctoral Fellowship in Laboratory Animal Medicine, DCM, 2011 to present.

Responsibilities: Supports the clinical service functions of the VSC.

Authority: Has delegated responsibility for the Institution's animal care and use program, including access to all animals.

Time contributed to program: Full time fellow. Percentage of time contributed: 100%.

13) Veterinary Resident, VSC

Qualifications

- Degrees: Western University of Health Sciences College of Veterinary Medicine, 2010; MS, Biology, Stanford University 2006; IACUC Training and Compliance Specialist, UCSF, 2011; ACLAM Training Fellowship in Comparative Medicine, DCM, Stanford University, 2012-2015.
- Training or experience in laboratory animal medicine and in the use of the species at the institution: Postdoctoral Fellowship in Laboratory Animal Medicine, DCM, 2011 to present.

Responsibilities: Supports the clinical service functions of the VSC.

Authority: Has delegated responsibility for the Institution's animal care and use program, including access to all animals.

Time contributed to program: Full time fellow. Percentage of time contributed: 100%.

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. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations. **Attachment Two**.

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:

a) The IACUC will conduct semiannual reviews of the University's Program for Laboratory Animal Care and Use at convened meetings utilizing the sample "Semiannual Program Review Checklist," the most recent edition of the *Guide*, the Policy, and as applicable, 9 CFR Chapter I, subchapter A, as a basis for evaluation. The "Semiannual Program Review Checklist" is distributed to the IACUC well in advance of the convened meeting.

b) During these convened meetings, IACUC members will evaluate selected program items from the checklist, categorize any program deficiencies as minor or significant, and will develop a plan and schedule for correction for any deficiencies.

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:

a) The IACUC will inspect every six months all of the University's animal facilities, including satellite holding facilities and areas in which surgical manipulations are performed, using the most recent edition of the *Guide*, the Policy, and as applicable, 9 CFR Chapter I, subchapter A, as a basis for evaluation. The sample "Semiannual Facility Inspection Checklist" is used for conducting facility inspections.

b) Facility inspections are conducted with at least two IACUC members inspecting all facilities where USDA-covered species are housed or studied, and IACUC members and/or ad hoc consultants inspecting areas where non-USDA covered species are housed or studied. All IACUC members are invited to participate in semiannual facility inspections, or other evaluations of the facilities.

c) Facility inspection findings are presented at convened IACUC meetings.

3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

a) A majority of the IACUC members review and sign the IACUC semiannual evaluations report after it has been presented at a convened IACUC meeting; the IACUC then submits reports to the Institutional Official via the IACUC office.

1. The IACUC will develop reports of the IACUC evaluations, addressing the requirements outlined in the sample format for the "Semiannual Report of the Program Review and Facility Inspection" for the Institutional Official, and as applicable, 9 CFR Chapter I, subchapter A. This report lists the dates when program evaluation and facilities inspections were conducted, provides any minority views or contains a statement that there were no minority views.

2. The IACUC will identify and discusses departures from the *Guide*, the Policy, and as applicable, 9 CFR Chapter I, subchapter A, during their program evaluations, facilities

inspections and protocol review. Any departure is designated in IACUC records and if new, reported to the Institutional Official in the IACUC evaluations report.

3. The IACUC will ensure through their facility inspection and program evaluation processes that any deficiencies are characterized as significant or minor, and assigns reasonable and specific plans and schedules for the correction of each deficiency.

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

   a) The IACUC will facilitate and enable individuals to report concerns involving animal care and use by: 1) posting the telephone number for reporting concerns in multiple locations throughout the main animal facilities where the majority of animal users pass through, and in animal use areas; 2) posting information on how to report concerns on the IACUC website; and 3) providing information in the general animal care and use seminar on how to report concerns. Anyone reporting concerns related to the care and use of animals may do so anonymously.

   b) The IACUC will review all concerns involving the care and use of animals with safeguards to protect the individual's identity, and if needed, appoints a subcommittee to perform an IACUC investigation; the IACUC will review any subcommittee findings at a convened meeting and take appropriate action, if warranted, up to and including suspension of a protocol.

   c) The IACUC will report concerns and related IACUC findings and recommendations via the IACUC Chair, Attending Veterinarian, or IACUC office to the Institutional Official.

5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

   a) The IACUC will evaluate, usually by subcommittee, a particular aspect of the University's animal program, facilities, or personnel training.

   b) Written recommendations developed by the subcommittee will be reviewed and approved by the IACUC at a convened meeting.

   c) IACUC-approved reports of written recommendations are submitted to the Institutional Official via the IACUC office.

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:

   Receipt of protocols and initial screening: Protocols are received in the IACUC office (on-line electronic protocol management system, hereafter referred to as "eProtocol"). IACUC staff perform an initial screening of all protocols for completeness and adherence to animal welfare standards, and write routine comments to comply with federal regulations and University policies/practices.

   Notification of members: A list of protocol activities is made available to all IACUC members in eProtocol (prior to any IACUC action). IACUC members are notified via an email from eProtocol when they have been assigned IACUC protocols to review.

   Distribution: Protocol activities are made available in eProtocol for IACUC review as either: 1) full committee review, or 2) designated member review (descriptions below under "Methods of Protocol Review"), based on established criteria. All IACUC members have full on-line access to the proposed research protocols to be reviewed, or they may request a written description of those protocols from the IACUC office. As long as no member requests

full committee review of a research protocol that meets the criteria for designated member review, the protocol becomes eligible for review and approval by the designated member review process, as described below.

Meeting Conduct: The IACUC meets at least monthly; the IACUC proceedings are confidential. A quorum of the IACUC must be present to conduct its business. Alternates are encouraged to attend all meetings. All agendas and minutes are sent to all IACUC members, and a copy is sent to the Institutional Official.

Methods of protocol review

a) Full committee review:

Protocol activities that have been referred for Full Committee Review are assigned to IACUC reviewers, (a minimum of two IACUC members); the IACUC staff assigns other expert reviewers to protocols when applicable, e.g., Radiation Safety when a project involves radioisotope use and/or Biosafety when a project involves a biological agent or recombinant DNA vectors.

1. The IACUC and expert reviewers review the protocol in the eProtocol system.
2. IACUC reviewers submit their comments and requests for modification to the IACUC office within eProtocol.
3. The IACUC office reviews all comments and requests for modification that are received for consistency and any duplication, and then sends the comments and requests for modification to the Protocol Directors.
4. Protocol Directors are notified via an auto-generated email that comments have been sent on the protocol. All comments and requests for modification are sent without referencing the author, thus preserving IACUC reviewer anonymity. Comments and requests for modification are sent out with a request for response within three business days.
5. Upon receipt of the Protocol Directors' responses to the comments and requested modifications to the protocol, the IACUC staff reviews the responses and modifications, then forwards responses and modifications to the IACUC reviewers. If additional questions arise, or further modifications need to be made, another round of comments is generated and sent to the Protocol Directors for their response. This process is repeated as often as necessary, until all reviewer questions have been answered and requested modifications to the protocol have been made. The protocol is then assigned to a convened IACUC meeting agenda.
6. At least 5 days prior to any convened meeting, a list of all protocol activities is sent to all IACUC members via an auto-generated email list. Complete written descriptions of these protocols are available to all IACUC members within the eProtocol system.

Designated Member Review (DMR) procedure for modifications subsequent to Full Committee Review (FCR):

A protocol assigned to FCR will be presented at a convened meeting by IACUC reviewers and/or discussed collectively at the meeting with direction from the IACUC Chair, prior to a vote to approve, with or without further modifications to secure approval, or withhold approval. If approval is withheld, the IACUC will provide written notification to the Protocol Director, and will provide the Protocol Director with an opportunity to respond in person and/or in writing. If substantive modifications are required, the IACUC will vote to return the modified protocol for FCR, or send the modified protocol for DMR, as described below in the DMR section. If DMR is selected, then all IACUC members will have the modified research protocol available to them. As long as no member requests FCR, the modified protocol becomes eligible for review and approval by the DMR process. All IACUC members have agreed in advance, in writing, that the quorum of members

present at a convened meeting may decide to use DMR subsequent to FCR when a 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.

b) Designated Member Review (DMR):

All IACUC members are provided a list of proposed research protocols eligible for DMR via an auto-generated email list. Complete written descriptions of these protocols are available to all IACUC members within the eProtocol system. As long as no member requests FCR of a research protocol that meets established criteria for DMR by the end of the predetermined time period (three days or more), the protocol becomes eligible for review and approval by the DMR process. Once it is determined that the protocol is eligible for review via the DMR process, then the reviewer(s) assumes the responsibility for the full committee in granting unanimous approval, requiring modification, or sending the protocol for full review. In an emergency situation, the predetermined time period for review may be shortened, but the procedures for designated review will be followed.

Protocols eligible for DMR will be assigned to at least one IACUC member, designated by the IACUC Chair (or the Vice Chair in their absence) as qualified to conduct the review. Other expert consultants may be assigned when applicable (e.g., Radiation Safety when a project involves radioisotope use and/or Biosafety when a project involves a biological agent or recombinant DNA vectors), but only an IACUC designated reviewer is authorized to take action on the protocol.

1. The IACUC designated reviewer(s) and expert consultant(s) review the protocol in the eProtocol system.
2. IACUC reviewers submit their comments and requests for modification to the IACUC office within eProtocol.
3. The IACUC office reviews all comments and requests for modification that are received for consistency and any duplication, and then sends the comments and requests for modification to the Protocol Directors.
4. Protocol Directors are notified via an auto-generated email that comments have been sent on the protocol. All comments and requests for modification are sent without referencing the author, thus preserving IACUC reviewer anonymity. Comments and requests for modification are sent out with a request for response within three business days.
5. Upon receipt of the Protocol Directors' responses to the comments and requested modifications to the protocol, the IACUC staff reviews the responses and modifications, then forwards responses and modifications to the IACUC reviewer(s). If additional questions arise, or further modifications need to be made, another round of comments is generated and sent to the Protocol Directors for their response. This process is repeated as often as necessary, until all reviewer questions have been answered and requested modifications to the protocol have been made. All IACUC designated reviewers assigned to a particular protocol review identical versions of the protocol, including all comments and modifications. All reviewers must be aware of and agree to the modifications, before indicating the protocol activity is ready for approval, or that full committee review is needed. Designated review may not result in withholding of approval.

Conflicts of Interest: Protocol activities that disclose a potential Investigator Conflict of Interest or potential Institutional Conflict of Interest are referred to the appropriate campus entities for follow up review.

The IACUC requires members to decline participation in any type of IACUC review and/or voting in which the member has a conflicting interest. The definition of Conflict of Interest includes participation in the project, involvement in competing projects, a financial interest, a personal relationship, or other situation giving rise to a conflicting interest as defined in the

"Guidelines for APLAC Members on Conflicting Interests" (available on the IACUC website). Any member having a conflicting interest must leave the meeting during the discussion of and vote on the protocol. No member leaving the room because of a conflicting interest or any other reason will be counted as part of the quorum for any vote taking place while the member is out of the room.

Voting: The IACUC requires a quorum to conduct its business. Voting occurs after IACUC review and deliberations at a convened meeting. An approval vote of a majority of the quorum present is needed for any IACUC action.

The IACUC may invite consultants to assist in the review of complex issues. Consultants may not vote on an activity.

Alternate Processes/Procedures for Review:

Special Meetings: In an emergency situation, the predetermined time period for a review may be shortened, but the procedures for designated review or full committee review, including access to all materials, will be followed as described above. If needed, telecommunication devices may be used by IACUC members to facilitate participation in a special meeting. Telecommunication participation will only be conducted by methods consistent with the OLAW published "Guidance of the Use of Telecommunication for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals."

Procedures for Reviewing Personnel Changes: Any proposed change in an ongoing activity that involves the addition or removal of personnel other than the Protocol Director will be eligible for administrative approval by the IACUC office staff following an appropriate review mechanism. The review will be performed in accordance with the NIH Guide for Grants and Contracts NOT-OD-03-046, and will ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in applicable occupational health and safety programs, and meet other criteria as required by 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: The IACUC processes significant changes for IACUC review under either: Full Committee Review or Designated Member Review, as described 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:

   a) The IACUC notifies Protocol Directors and the Institutional Official by auto-generated email reports of IACUC decisions regarding protocol review.

   b) If approval is withheld, the IACUC will provide written notification to the Protocol Director and a statement of the reasons for its decision, and will provide the Protocol Director with an opportunity to respond in person and/or in writing.

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:

   The IACUC monitors ongoing activities through their post-approval monitoring program, including:

a) veterinary walk-throughs or veterinary assignments to animal use areas where protocol activities take place;

b) assignment of protocols (during protocol review process) for specific veterinary or IACUC Compliance Manager in-person monitoring; this monitoring is followed up by subsequent reporting during IACUC meetings;

c) IACUC semiannual inspections and follow-up visits.

The IACUC procedures for conducting continuing review of each previously approved, ongoing activity require at least annual review of USDA- and PHS-covered species activities, and a complete (de novo) review of those activities at least once every three years.

a) Protocol Directors must complete a standard form containing basic protocol information (within the eProtocol system) and submit to the IACUC office in order for the IACUC to conduct an annual review of each previously approved, ongoing activity. Any proposed significant changes to the currently approved protocol would need to be approved by the IACUC prior to implementation.

b) The IACUC performs a complete review of each previously approved protocol, at least every three years (within the eProtocol system), ensuring that it conforms to the *Guide*, PHS Policy, and as applicable, 9CFR Chapter I, subchapter A, under either: Full Committee Review or Designated Member Review, as described above.

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

a) suspension of any protocol or approved activity involving animals after review of the matter at a convened meeting of a quorum of the IACUC, and through a vote of a majority of the quorum present;

b) review of the reasons for suspension with the Institutional Official and implementation of appropriate corrective action;

c) submission of a full report to the Institutional Official, who then submits a written report to OLAW for PHS-supported research, USDA, and other relevant entities.

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

1) The Laboratory Animal Occupational Health Program (LAOHP) is administered through Stanford's Department of Environmental Health & Safety (EH&S) in the onsite Stanford University Occupational Health Center (SUOHC), in close cooperation with the VSC and the IACUC. The LAOHP provides information and safeguards for personnel working with laboratory animals and hazardous agents in the following areas:

a) PERSONNEL HYGIENE includes the provision or requirement of appropriate clothing depending on the area in which animal care personnel are working, or species they are working with, such as: gloves, safety glasses or face shields, disposable gowns or jumpsuits, masks, hoods/hair covers, booties or shoe covers, hearing protection, chemical resistant aprons, steel-toed boots, and steel mesh or leather gloves. Appropriate protective equipment and/or clothing are provided at the entrance to all biohazard containment rooms. Dedicated work clothing may be worn outside a facility in some circumstances if the employee is in transit to another campus facility, but work clothing is not be worn home, or from home; no eating/drinking is allowed in any animal housing or procedure areas.

b) HAZARDOUS AGENT HANDLING

1. **Biohazardous Agent Use**

Oversight is provided by the Administrative Panel on Biosafety (APB) through the Biosafety Manager who is part of the University's EH&S program. The APB is responsible for the review of this institution's teaching projects, research activities and facilities involving the acquisition, use, storage and disposal of biohazardous agents. The Biosafety Manager, SUOHC and EH&S industrial hygiene professionals work closely with the veterinary staff to provide training in the safe handling and management of biological and chemical hazard agents used in studies with laboratory animals. Detailed biosafety requirements and safety procedures are contained in the Biosafety Manual (revised 2010) available on-line at the EH&S website, or in hard copy from the EH&S offices. Additionally, the Biosafety Manager (or qualified designee) is an IACUC member and the Attending Veterinarian (or qualified designee) serves on the APB to review the prospective use of hazardous agents and outline safeguards for affected personnel. Biohazardous projects involving animals can only be performed in areas approved by the Attending Veterinarian. Stanford has special containment suites for projects involving specific biohazardous agents, and access to these facilities is granted only upon VSC approval of the appropriate protocols that detail how the biohazard agent will be handled and disposed of, and what safeguards will be followed by research personnel.

2. **Ionizing and Non-ionizing Radiation**

Possession and use of radioisotopes must be authorized under the radioactive materials license issued to Stanford University by the State of California. All machines that produce ionizing radiation for which State registration is required must be registered centrally through EH&S. All projects must comply with pertinent regulations and relevant terms of licenses. The Administrative Panel on Radiological Safety (APRS) monitors compliance with regulations, license conditions and policies utilizing the Health Physics staff of EH&S. All regulated radiation activities are subject to approval by the APRS and are subject to inspection by the Health Physics staff. Detailed policies and procedures governing the acquisition, use and disposal of radiation sources are found in the Radiation Safety Manual (updated 2010), available on-line or from Health Physics. The Manager of Health Physics, i.e., the Radiation Safety Officer (RSO), is designated in all licenses. The RSO may deny or withdraw approval to use a radiation source where an imminent threat to health and safety, noncompliance or unsafe practice is found, pending review by the APRS.

3. **Chemical Agent Use**

Stanford has developed and implemented a written Chemical Hygiene Plan that is directed at controlling exposures to hazardous chemicals in laboratories. The Plan sets forth procedures, equipment, personal protective equipment, and practices that are capable of protecting employees from health hazards presented by hazardous chemicals used in laboratories and are capable of keeping chemical exposures below regulatory limits. The plan is administered through the Department of Environmental Health and Safety (EH&S). Managers and supervisors of researchers, animal care technicians, and husbandry/cage washing staff are responsible, with assistance from SUOHC and EH&S, for evaluating the potential exposures risks of hazardous chemicals/drugs to staff during chemical preparation, animal dosing, and cage handling and washing. A guidance document entitled "Animal Research Protocols Involving Hazardous Chemicals" addressing the use of known or suspect carcinogens, reproductive toxins, or other highly toxic substances and nanomaterials in laboratory animals, along with operation specific exposure controls for occupational exposures to hazardous chemicals in chemical preparation, chemical administration, animal care and transport, and cage cleaning have been developed and are available on the EH&S webpage. Whenever agents administered to laboratory animals by research personnel are potentially hazardous, the Facility Operations Manager and/or the Attending Veterinarian discuss the aspects of safety and containment with both the research staff and the animal care staff.

c) PERSONNEL PROTECTION for personnel working with laboratory animals includes the issuance of appropriate clothing either as part of their employment or at their request. The provision of appropriate facilities for maintaining personal hygiene, first aid equipment, and training in safe techniques including emergency responses in the event of an incident is also provided. This institution has policies in place for the use of biologic, chemical, and physical agents; these policies are viewable via the EH&S website at http://www.stanford.edu/dept/EHS/prod/.

d) PREEMPLOYMENT MEDICAL EVALUATION is required for all Veterinary Service Center employees as a condition of employment.

e) REQUIRED IMMUNIZATIONS is managed by the Medical Director of the SUOHC who reviews LAOHP health questionnaires and determines what immunizations are necessary. Immunization requirements may include tetanus, hepatitis B, rubeola, vaccinia virus, etc., depending upon the specific circumstances, identified risk factors and determined medical need.

f) PREVENTIVE MEDICINE PROGRAM is managed by the Medical Director of the SUOHC who reviews LAOHP questionnaires and determines what follow up is needed. A medical records database in EH&S provides the ability to manage occupational health information for personnel. Pertinent and specific occupational health and safety information can be distributed directly to the animal handler/users. In-service information and training on preventive medicine issues are also periodically provided.

g) ZOONOSIS SURVEILLANCE is managed by screening animals for select pathogens during the procurement process and routine testing following arrival to our facility. This institution has appropriate quarantine facilities and procedures in place to prevent zoonoses. All personnel working with animals are provided general information on zoonotic agents and personnel working with higher-risk species (e.g., nonhuman primates, pregnant sheep) are required to receive additional species-specific safety-related training.

h) PROCEDURES FOR REPORTING AND TREATING INJURIES include instructing personnel involved in emergency situations to determine whether it is life threatening or not. If it is, they dial 911 or activate the nearest fire alarm if a phone is unavailable. Appropriate authorities, including the Protocol Director, are notified. For a situation that isn't life threatening, medical treatment and follow-up are sought as needed through the SUOHC. EH&S is consulted for clean-up assistance in instances involving hazardous materials. Personnel are instructed to report accidents/exposures to their supervisor as soon as possible. Injuries are treated by SUOHC medical professionals during office hours (Monday-Friday 8:00 a.m. to 5:00 pm) or in the Stanford Hospital Emergency Room during weekends or nights. The Medical Director of SUOHC remains on-call to assist ER staff with the management of occupational illness/injuries as needed. An investigation team consisting of an industrial hygienist, chemical safety specialist, chemical waste specialist, environmental specialist, Biosafety Officer, radiological safety specialist, occupational health professional, and fire marshal is available as appropriate for follow up.

i) COVERED PERSONNEL are faculty, staff, students and visiting scholars who work directly with vertebrate animals, unfixed animal tissues or body fluids, and those who work in animal housing areas. Personnel participate via a risk-based program. The level of participation is dependent upon their level of risk through their assignment to Risk Category 1, (RC1), or Risk Category 2 (RC2).

   1. Risk Category 1 is considered higher risk and encompasses VSC employees, other dedicated animal care staff, and individuals who work with nonhuman primates (including unfixed tissue and bodily fluids), hoofed mammals (e.g., swine, goats, sheep, and cows), wild rodents, and certain field studies. Specific risk factors are variable and dependent upon specific uses and handling identified in the animal care

and use application. Personnel in RC1 must complete and submit a LAOHP questionnaire prior to IACUC approval of an individual to work on a protocol. Each LAOHP questionnaire will be evaluated by the occupational health professional to determine the level of potential exposure and whether further steps are necessary.

2. Risk Category 2 is for all individuals involved in protocols that do not fall within the RC1 participation group. All individuals in this group are provided with risk information, educational materials and periodic updates on health and safety issues associated with the particular animal species or research material with which they work. These individuals are strongly encouraged to complete the LAOHP questionnaire, but the LAOHP questionnaire completion and submittal is optional for members of the RC2 participation group.

j) PROCEDURES FOR HAZARD AND RISK ASSESSMENT involves input from: the Medical Director of the SUOHC who reviews the LAOHP questionnaires and performs the medical evaluation; the IACUC by review of the protocol; VSC by review of equipment, protective clothing and procedures; and EH&S by evaluation of specific and general risk factors.

k) TRAINING OF PERSONNEL, e.g., on ZOONOSES, ALLERGIES, HAZARDS, SPECIAL PRECAUTIONS FOR PREGNANCY, ILLNESS, IMMUNE SUPPRESSION is provided through targeted in-service training and information programs, seminars and education programs by the SUOHC staff and other specialized personnel. These programs, in addition to educational materials sent via email, emphasize the specific risks associated with different types of research with laboratory animals and provide guidance to research and support personnel on appropriate methods of exposure control and protection.

l) SPECIAL PRECAUTIONS FOR PERSONNEL WORKING WITH NONHUMAN PRIMATES, e.g., TUBERCULOSIS SCREENING, TRAINING AND PROCEDURES FOR BITES AND SCRATCHES, and EDUCATION REGARDING MACACINE HERPESVIRUS 1 (formerly *Cercopithecine herpesvirus* 1 or Herpes B) are managed by requiring that personnel actively working with nonhuman primates be classified in RC1 risk category, be screened annually for tuberculosis, and participate in training specific to the prevention of illness/injury with this species. Each nonhuman primate housing area is equipped with injury/exposure kits. Follow up and treatment procedures specific to nonhuman primate exposure have also been developed and disseminated to personnel actively working with nonhuman primates. Additionally, both the SUOHC and the Stanford Emergency Department have special and specific medical Standard Operating Procedures to follow for evaluation and treatment of nonhuman primate bites/scratches.

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. **Attachment Three**

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

ANIMAL CARE STAFF

1) Training of VSC animal care personnel consists of in-house continuing education instruction by VSC staff members, Stanford faculty members, and guest speakers using monthly departmental meetings as the primary forum. Presentations are made on various husbandry, veterinary care, health and safety, and animal research-related topics.

2) VSC staff participate in a matrix of relevant Stanford training courses based on their duties, including the Animal Care and Use Training Program, Working Safely with Nonhuman Primates, health and safety courses, supervisory courses, etc. The Departmental Human Resources Manager, Training and Compliance Coordinator, Assistant Operations Manager and hiring Supervisor coordinate a new employee orientation process which identifies training needs and supports new employees through the on-boarding process.

3) VSC staff participate in a comprehensive training program using Standard Operating Procedures (SOPs). SOPs cover relevant VSC functions (i.e., animal husbandry, veterinary care, diagnostic and pathology procedures, administrative procedures, occupational health and safety, computer operations, etc.). All SOPs for the VSC are centralized, both in hard copy and electronic form. Both current and historical files are maintained.

4) Participation in the Northern California Branch (NCB) of AALAS is encouraged for animal care personnel, including workshops and symposiums. VSC animal care personnel take advantage of AALAS Learning Library accounts available through the branch. AALAS certification is strongly encouraged and the VSC offers AALAS ALAT certification training on site. Personnel also participate in local NCB AALAS-sponsored Technician Certification training courses.

SCIENTIFIC/RESEARCH STAFF

1) **General**

Training in all topics in 9CFR, Part 2, Subpart c, section 2.32(c) is provided either as part of formal or organized training sessions described below or is available in the form of individualized training sessions given on an as-needed basis as indicated during the protocol review process.

This institution provides faculty/staff/student access to AGRICOLA and the online resources available through AWIC/NAL. Trained librarians within the School of Medicine library are available to assist with literature searches, and advice can also be obtained from the faculty and staff of the Department of Comparative Medicine (DCM) who have experience with literature searches for alternatives to the use of animals, as well as methods and refinements to limit animal pain and distress.

Available resources on research or testing methods that minimize the number of animals required to obtain valid results can be found on the IACUC website. Faculty, staff, and students can also request a biostatistical consultation with biostatisticians at the Stanford Center for Clinical and Translational Education and Research (Spectrum).

2) **Specific Training Courses (required per IACUC protocol)**

a) <u>Animal Care and Use Training Program</u>
This training program is an introduction to the care and use of animals in research and teaching at Stanford University. All faculty, staff and students who will be involved in the use of laboratory animals are required to complete this training. The program was launched as a web-based course in 2011 and consists of reviewing a training module and passing a quiz. The content is a customization of the AALAS Learning Library course, "Working with the IACUC" and includes the following lessons:

- Working with the IACUC
- Endpoint Criteria
- Animal Housing
- Federal Mandates
- Introduction to Surgery & Anesthesia
- Prolonged Restraint
- The Veterinary Consultation
- Antibody Production
- Euthanasia
- The Animal Use Protocol
- Collecting Blood Samples
- Using Human Patient Care Areas
- Alternatives to the Use of Animals
- Personnel Training & Experience
- Making Post-Approval Changes

- Avoiding Unnecessary Duplication
- Occupational Health & Safety
- Reporting Misuse, Mistreatment, or Non-compliance
- USDA Pain/Distress Categories
- Using Hazardous Agents in Animals

b) Working Safely with Nonhuman Primates (NHPs)
All individuals who come in contact with NHPs and/or their unfixed tissues or body fluids as part of an animal research protocol are required to attend this training seminar. Individuals are not given access to primate areas until this course is completed and they have received clearance from the Stanford University Lab Animal Occupational Health Program (LAOHP) to work with NHPs. The lecture course may be taught to small groups or individuals. The course outline is shown below:

- Bacterial, viral and protozoal pathogens that may infect humans
- Human diseases that can be anthroponotic
- Proper handling of NHPs and appropriate personal protective equipment
- Procedure for dealing with a bite, scratch, needlestick or other exposure involving primates
- Proper waste disposal and decontamination procedures
- Stanford's Plan to Promote the Psychological Well-Being of NHPs

c) Working Safely with Pregnant and Neonatal Sheep
All individuals who may come into contact with pregnant or neonatal sheep housed at Stanford (i.e., potential for Q Fever exposure) must attend a training seminar. Individuals are not given access to pregnant sheep areas until this course is completed and they have received clearance from the Stanford LAOHP to work with pregnant or neonatal sheep. There have not been any pregnant or neonatal sheep housed on the Stanford campus in over three years and we don't anticipate having any in the near future. Stanford research personnel conduct these studies at collaborating institutions (i.e., UC Davis) and must enroll in Stanford's LAOHP (including annual respirator fit-test training at Stanford for clearance to wear an N95 particulate respirator). They are also given general information on Q fever from the Stanford Occupational Health Center as well as the collaborating institution.

d) Working Safely with Biohazardous Agents in Laboratory Animals
In 2010, Stanford implemented a new training program entitled "Working Safely with Biohazardous Agents in Laboratory Animals". This program includes an online component (courtesy of the American Biological Safety Association) and face-to-face meetings with laboratory, biosafety, veterinary, husbandry and training personnel. All laboratories that initiate new biohazard work in animals at Stanford are required to complete this training. Additionally, the training is being offered to laboratories which began in vivo biohazard work prior to 2010.

e) Stem Cell Research Building Animal Facility Orientation
The orientation to this restricted access mouse barrier facility consists of a web-based course followed by a small group facility orientation tour. Completion of this training program is required for anyone requesting access to the Stem Cell Research Building Animal Facility.

f) Small Animal Imaging Facility Training
Rodent care and anesthesia training is provided monthly for new In Vivo Imaging System (IVIS) users and as needed for MRI users (approximately quarterly). Training topics include: protocol compliance, transportation, handling and restraint (physical and/or chemical), anesthesia and monitoring, and post-anesthetic recovery. Approximately 100-120 individuals receive this training annually.

3) **Additional Courses Offered:**

The following courses are not generally required, unless requested by the IACUC, but are available to all Stanford faculty, staff, students and affiliates.

a) Mouse Handling and Basic Techniques Workshop
In this hands-on workshop, researchers learn to handle mice, assess health, and perform basic blood sampling and dosing techniques. In addition, they learn about appropriate, approved methods of anesthesia and euthanasia. The workshops are limited to twelve students and are scheduled at least once per month.

b) Rodent Aseptic Surgery Techniques Workshop
This hands-on workshop instructs researchers on Stanford's rodent aseptic surgery technique guidelines, how to set up and maintain sterile technique when performing rodent surgery, how to choose appropriate instrument sterilization methods, and provides instructions on surgical wound closure techniques, including suture patterns. This is primarily a dry lab, using materials in place of live animals. The class size is limited to eight and the workshop is offered at least once per month.

c) Mouse Breeding Workshop
This hands-on workshop instructs researchers on mouse reproductive physiology and behavior, mouse breeding systems, and weaning criteria according to Stanford's guidelines for housing and weaning mice. The didactic portion is followed by a wet-lab where students receive practice in sexing pups, checking for plugs in bred females, and performing tail biopsies for genotyping. This workshop is limited to twelve students and is currently scheduled on a monthly basis.

d) Rat Handling and Basic Techniques Workshop
In this hands-on workshop, researchers learn to handle rats, assess health, and perform basic blood sampling and dosing techniques. In addition, they learn about appropriate, approved methods of anesthesia and euthanasia. The workshops are limited to twelve students and are scheduled on an as needed basis, usually quarterly.

e) Introduction to Stereotaxic Surgery in Rodents
This workshop includes demonstration and hands-on practice for basic stereotaxic surgery technique in rodents. Topics include identifying brain coordinates, setting up and using the stereotaxic device, and aseptic technique. This workshop is limited to four students and is currently scheduled on an as needed basis.

f) Compassion Fatigue and the Use of Animals in Research
This seminar is designed to assist all members of the research team in understanding some of the common feelings that workers in the field of animal care and research may experience. The seminar acknowledges that kindness and concern for animals are desirable characteristics for workers in this field, and provides suggestions and resources for managing human emotions and providing workplace support in the care of laboratory animals. This seminar is offered at least quarterly.

g) VSC AnimalTrax Computer Lab
This hands-on computer lab for researchers reviews requisitions, transfers, bar-coded cage card stickers, and reporting using the AnimalTrax electronic animal ordering, billing and census system. For those users with a financial role, there is a special version of the class with a financial focus that goes over PTA management in AnimalTrax. This course is scheduled on an as needed basis.

4) **Other Training Methods:**

a) Email Lists
Both the IACUC and the VSC maintain email lists to proactively provide researchers information on a variety of topics including compliance updates, upcoming training opportunities, changes in policies, facility maintenance schedules, etc. The IACUC email list, Lab Partners, includes at least one representative from each PI's lab. The VSC maintains email lists that target researchers using specific species or facilities.

b) Individual Training
VSC veterinary staff provide individual (one-on-one) hands-on training on a variety of research procedures. Documentation of this training is maintained by the VSC. Animal husbandry personnel also provide individual training to research staff on various aspects of animal facility operation.

c) Reference Materials
Reference materials (books, journals, newsletters, bibliographies, videos, brochures, etc.) are maintained in the DCM library. Items are cataloged and available for review by DCM personnel and other individuals. The DCM library comprises over 1,000 volumes and employs a part-time medical librarian who maintains the library and performs literature searches.

d) Web Resources
The VSC maintains a website (http://vsc.stanford.edu) that includes information on VSC resources, policies, training opportunities, etc. The Office of the Dean of Research maintains a website (http://labanimals.stanford.edu) that provides information on institutional policies and practices. EH&S maintains a website (www.stanford.edu/dept/EHS) that provides information on safety, health and environmental practices and procedures.

IACUC MEMBERS

1) New members appointed to the IACUC are provided an introductory training session that includes information pertinent to responsibilities of the committee in regards to animal care and use (e.g., federal regulations, PHS requirements, University policy, and the concerns of the public). Supplementary reference information that is provided to new committee members can be found on the IACUC website and includes regulatory information and University policies and practices.

2) Additional training is provided at regularly convened meetings in the form of discussions or as presentations on specific topics (e.g., regulatory updates, NHP enrichment strategies).

3) IACUC members are sponsored by the University to attend local and National meetings on IACUC-related topics.

4) IACUC members are requested to complete the online Animal Care and Use Training Program.

5) An agenda item at IACUC meetings is reserved for IACUC member education. Typically, laboratory animal welfare articles, regulatory updates, and conference announcements are presented.

Stanford University supports continuing education of staff by providing partial or full reimbursement of the cost of job-related courses, seminars and workshops. The Stanford Training and Registration System (STARS) is a campus-wide learning management system that maintains centralized training records of most Stanford-sponsored training. This centralized system facilitates promotion of VSC training programs and documentation of training participation by research and VSC personnel.

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 1 — 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.

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, Dr. Ann M. Arvin
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, Dr. Ann M. Arvin
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: Ann M. Arvin, M.D.	
Title: Vice Provost and Dean of Research	
Name of Institution: Leland Stanford Jr. University (Stanford University)	
Address: *(street, city, state, country, postal code)* c/o Stanford University Research Compliance Office 1501 S. California Avenue, MC 5579 Palo Alto, CA 94304	
Phone: (650) 721-6781	Fax: (650) 736-7077
E-mail: sonja.wallace@stanford.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: 06/17/2013

V

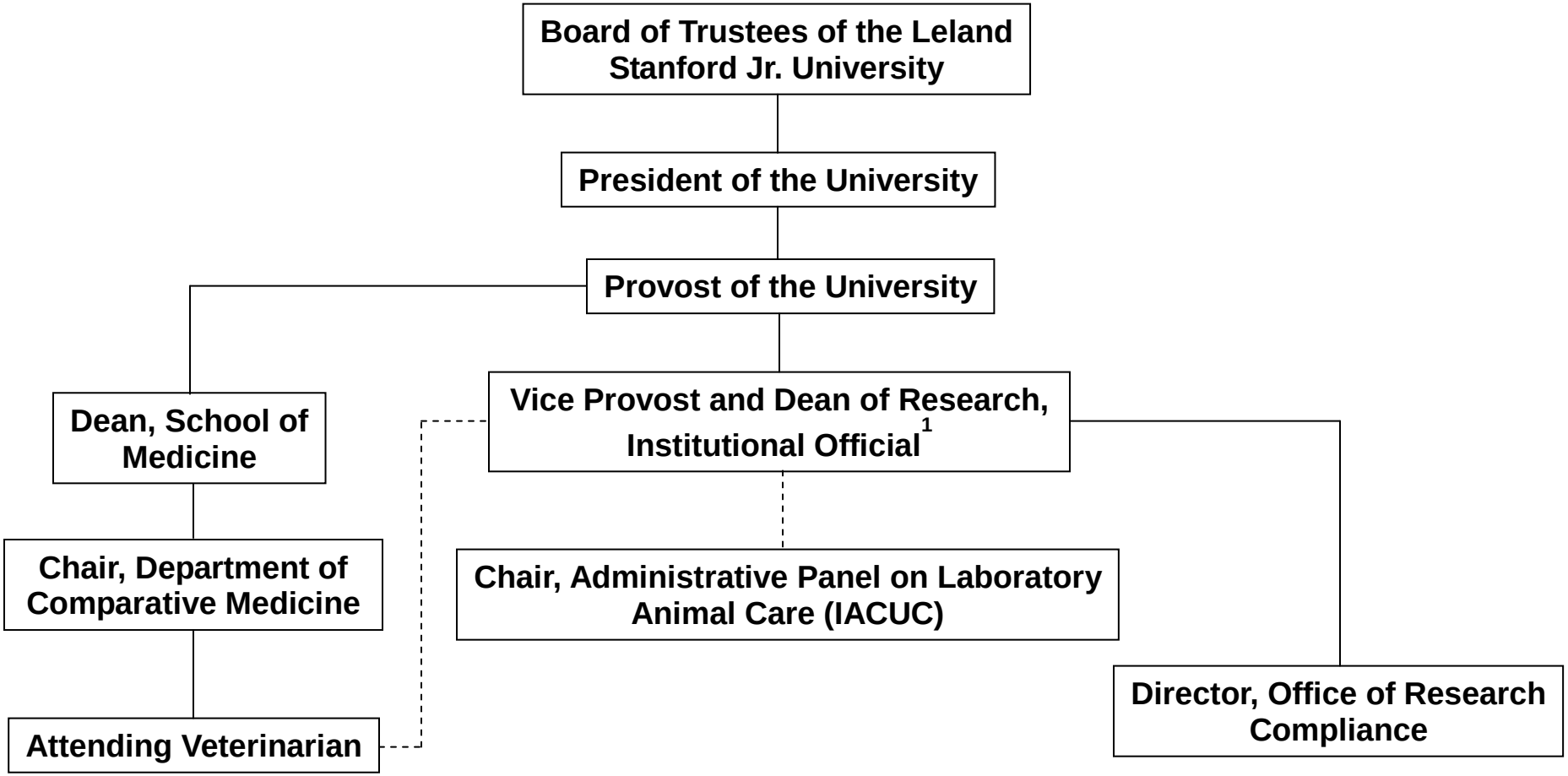
B. PHS Approving Official *(to be completed by OLAW)*

Dr. Venita B. Thornton, D.V.M., M.P.H.
Office of Laboratory Animal Welfare (OLAW)
National Institute of Health
6705 Rockledge Drive
RKL1, Suite 360- MSC 7982
Bethesda, MD 20892-7982
Phone: (301) 469-7163 Fax: (301) 915-9473

(7)

Signature: Venita B Thornton	Date: June 17, 2013
Assurance Number: A 3213-01	
Effective Date: June 17, 2013	Expiration Date: May 31, 2017
Effective Date:	Expiration Date:

Authority and Responsibility for Stanford's Animal Care and Use Program



[1]The "Institutional Official" responsible for Stanford's Program of Animal Care and Use has been designated, in writing, by the President of the University with the authority to appoint IACUC members. The dotted line represents direct access to the IO through standing or ad hoc meetings where the AV and IACUC Chair clearly and regularly communicate the program needs.