

UNIVERSITY OF CALIFORNIA, LOS ANGELES
ASSURANCE OF COMPLIANCE WITH PUBLIC HEALTH SERVICE POLICY
ON HUMANE CARE AND USE OF LABORATORY ANIMALS

The University of California, Los Angeles (UCLA), hereinafter referred to as “institution,” hereby gives assurance that it complies 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, training, experimentation, and biological testing and related activities, hereinafter referred to as “activities,” involving live or dead, vertebrate animals which are conducted at this institution, or under the direction of any employee, student, or agent of this institution regardless of funding sources or location of the activity. This Assurance is also applicable to research conducted at another institution as a consequence of subgranting, subcontracting, or any other means of support provided by this institution.

"Institution" includes the following major components of UCLA:

- Division of Laboratory Animal Medicine (DLAM)
- Life Sciences Vivarium
- Franz Hall Vivarium
- Radiation Oncology Vivarium
- Warren Hall Vivarium
- UCLA Satellite facility – AIRCARE 1

II. INSTITUTIONAL POLICY

- A. This institution complies with all applicable provisions of the Animal Welfare Act (AWA) 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" and other applicable statutes and regulations concerning the care and use of laboratory animals.
- 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 makes 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.
- D. This institution has established and maintains 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 outlined in attached Appendix A.
- B. The qualifications, authority, and percent of time contributed by veterinarian(s) who participate in the program are:
1. Marcelo Couto, D.V.M., Ph.D. Director of the Division of Laboratory Animal Medicine (DLAM). Diplomate, American College of Laboratory Animal Medicine. Licensed and accredited in California. Received his D.V.M. from the University of Buenos Aires and his Ph.D. in Comparative Pathology from the University of California, Davis. 100% time commitment. Dr. Couto has a combined 26 years of clinical practice, residency, research, and laboratory animal experience. Dr. Couto is a voting member of the Chancellor's Animal Research Committee (ARC) and responsible for ensuring that the institution's animal facilities and veterinary care meet established standards.
 2. P. Timothy Lawson, D.V.M. Director, Consultation & Training, DLAM. . Licensed in Washington State. Diplomate, American College of Laboratory Animal Medicine. 100% time commitment. 34 years experience. His responsibilities include proving consultation and training to technicians and husbandry staff, and oversight of on-going building projects.
 3. Gregory Lawson, D.V.M. Director, Pathology & Lab Medicine, DLAM. Licensed and accredited in California. Received his D.V.M. from Oklahoma State University and his Ph.D. from the University of California, Davis. 100% time commitment. Completed residency in Comparative Pathology at UC Davis. Dr. Lawson has 10 years of private practice experience, and five years of research and laboratory animal experience. Dr. Lawson is a voting member of the Chancellor's Animal Research Committee (ARC). His responsibilities include medical care of all mouse and rat colonies, as well as pathology support services for the Division.
 4. Joanne Zahorsky-Reeves, DVM, Ph.D. Clinical Veterinarian. 10 years NIH-funded research involving laboratory animals, 4 years private practice, and 1 year in laboratory animal medicine. Ph.D. in Comparative and Experimental Medicine, University of Tennessee. Member of AVMA. 100% time commitment. Her responsibilities include clinical care of rodent colonies, research protocol review, training and support services for DLAM and the research community.
- C. The Chancellor or his designee (Vice Chancellor-Research) appoints the Institutional Animal Care and Use Committee - Chancellor's Animal Research Committee (ARC), which is qualified through the experience and expertise of its members to oversee the Institution's animal program, facilities, and procedures. The ARC consists of at least five members, and its membership meets the compositional requirement set forth in the PHS Policy at IV.A.3.b. Appendix B is

a list of the names, position titles, degrees, and other credentials of the ARC chairperson and members.

D. The ARC:

1. Reviews 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 ARC procedures for conducting semiannual program evaluations are as follows:

The semiannual program evaluations describe the nature and extent of the institution's adherence to the Animal Welfare Act (AWA), PHS Policy, the Guide and the institution's policies. The evaluations specifically identify any departures from the provisions of such policies, and review the reasons for each departure. Programmatic deficiencies are identified and handled in accordance with the procedures described in III.D.3.

The semiannual program evaluations include a copy of the recommendations to the Institutional Official regarding the animal facility inspections as described in III.D.2. The ARC also evaluates any changes or updates with respect to the following aspects of the animal program: (a) institutional components covered by the Assurance; (b) veterinary support; (c) ARC membership; (d) ARC procedures; (e) occupational health and safety program; (f) training or instruction of personnel involved in animal care, treatment or use; and (g) monitoring of investigators' compliance with approved protocols.

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

The ARC is responsible for inspecting all animal facilities including areas outside the Institution's core facility in which animals are housed for more than 12 hours, survival surgery areas and, when deemed necessary, specific surgery areas where non-survival surgery will be conducted. No ARC member will be excluded should he/she wish to attend a particular inspection and additional ad hoc consultants may be used as necessary. The inspection teams inspect all aspects of the facilities using the recommended standards as described in the Guide including: animal environment, housing, and management; veterinary medical care; and physical plant.

Deficiencies are identified and handled in accordance with the procedures described in III.D.3.

3. Prepares reports of the ARC evaluations as set forth in the PHS Policy IV.B.3. and submit the reports to the Vice Chancellor-Research. The ARC process for developing reports and submitting them to the Institutional Official are as follows:

The ARC conducts evaluations of the facilities and program, as described in III.D.1. & III.D.2. at least once every six months and submit these reports to the Vice Chancellor-Research Programs. The reports are reviewed, approved and signed by a majority of the ARC members and include any minority views. Semiannual reports categorize any deficiencies found during the review as either minor or significant. A significant deficiency is one that, in the judgment of the ARC or the Institutional Official, is or may be a threat to the health or safety of the animals. If any program or facility deficiencies are noted, the reports contain a reasonable and specific plan and schedule for correcting each deficiency. Any failure to adhere to the plan or schedule that results in a significant deficiency remaining uncorrected are reported in writing within 15 business days by the IACUC, through the Institutional Official, to the USDA and OLAW. Copies of the report are maintained by the Institution and made available to OLAW upon request.

4. Reviews concerns involving the care and use of animals at the Institution. The ARC procedure for reviewing concerns is as follows:

In accordance with the *ARC Policy for Reporting Allegations of Mistreatment or Other Noncompliance Issues* and the *ARC Policy on Investigating Allegations of Mistreatment or Other Noncompliance Issues*, concerns may be brought to the ARC's attention by any interested party including, but not limited to: the Veterinarian, the Associate Director- Animal Subjects Research, Biosafety Officer, Radiation Safety Officer, research personnel, University staff, or animal care technicians. The policy is available to all personnel on the ARC website and is discussed at various ARC-sponsored trainings and workshops. The policies state that there can be no threat or reprisal against anyone reporting perceived mistreatment or noncompliance. All complaints and relevant documentation are brought before the ARC following a preliminary investigation by the ARC staff on behalf of the ARC Chair. Verified violations and subsequent actions are reported to the Institutional Official, OLAW and USDA if applicable.

5. Makes written recommendations to the Vice Chancellor-Research Programs, regarding any aspect of the Institution's animal program, facilities, or personnel training. The ARC procedure for making recommendations to the Institutional Official is as follows:

The ARC makes recommendations as necessary for correcting and/or improving any aspect of the Institution's animal program, facilities, or personnel training. Recommendations are submitted to the Vice Chancellor in writing and include a description of the actions endorsed by the ARC to make such improvements or corrections and a suggested timetable for action. Recommendations forwarded to the Institutional Official are included in the semiannual program evaluations and the annual report to OLAW.

6. Reviews and approve, require modifications to (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 ARC procedures for protocol review are as follows:
 - a. The ARC evaluates all components related to the care and use of animals to determine that the proposed research and/or teaching protocols are conducted in accordance with institutional policies. In making this determination, the ARC confirms that the research project is conducted in accordance with the PHS Policy and the Animal Welfare Act insofar as it applies to the research project, and that the research project is consistent with the Guide, unless an acceptable justification for a departure is presented in writing. Furthermore, the ARC determines that the research protocol conforms with the Institution's Assurance and meets the following requirements:
 - i. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
 - ii. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless otherwise justified for scientific reasons in writing by the investigator.
 - iii. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.
 - iv. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian trained and experienced in the proper care, handling, and use of the species being maintained or studied.
 - v. Medical care for animals will be available and provided, as necessary, by a qualified veterinarian.
 - vi. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
 - vii. Methods of euthanasia will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.
 - viii. The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the

animals, and has provided a written narrative description of the methods and sources used to determine that alternatives were not available.

- ix. The investigator has provided a written assurance that the proposed research does not unnecessarily duplicate previous experiments.
 - x. No animal will be used in more than one major operative procedure from which it is allowed to recover, unless it is justified in writing for scientific reasons by the principal investigator, required as routine veterinary procedure, or conducted in order to protect the health or well-being of the animal as determined by the attending veterinarian.
- b. To obtain animal use approval investigators must submit an *Application to Use Laboratory Animal Subjects in Research and/or Teaching* and/or an *Application to Establish and/or Maintain a Breeding Colony* (in process of revision).

Prior to submission to the ARC, all new and renewal applications as well as addendum applications involving a change in experimental procedure are reviewed by veterinary staff in order to address animal care issues. Amendment submissions involving changes in funding, protocol title, location, personnel, co-investigator or principal investigator do not require pre-review prior to ARC review. Pre-review of continuation submissions are conducted by the Vice Chairs, except continuations involving a change or changes that may cause more than momentary or slight pain or distress to animals; such applications are referred to veterinary staff for pre-review. Investigators are requested to address all concerns raised during the pre-review prior to submission of the protocol to the ARC. Once the ARC receives an application, it is reviewed by the Chair or his designee and assigned either to Designated Member Review or Full Committee Review. Applications requiring Full Committee review include experiments involving the following:

1. Cats, dogs, and non-human primates;
2. Animals listed under USDA Pain Category E;
3. Biohazardous agents or radioactive materials, with the following exceptions:
 - a. Aldehyde compounds used for perfusion or as a post-mortem fixative;
 - b. Non-replicating viral and plasmid DNA vectors;
 - c. Ex vivo experiments;
 - d. Use of urethane;
 - e. Use of BrDu less than 12 hours prior to euthanasia;
 - f. Routine imaging of animals in core facilities, such as microPET in the Crump Institute or CHS B-floor imaging suites.

4. Experiments that may deleteriously affect animal health, including, but not restricted to:
 - a. Morbidity/"survival" experiments;
 - b. Prolonged physical restraint (>15 minutes) of an unanesthetized animal;
 - c. Food and/or water deprivation (>18 hours);
 - d. Neurological manipulations including status epilepticus models;
 - e. Physical methods of euthanasia without prior anesthesia;
 - f. Multiple survival surgeries, with the following exceptions:
 - i. Oocyte collection in frogs when consistent with the ARC Policy;
 - ii. Implantation and subsequent replacement or osmotic mini-pumps.
5. Requested exceptions to established ARC policies
6. New investigator-maintained survival surgery areas, and or new study areas to house mammals or frogs only
7. Adverse events (e.g., unexpected death due to experimental manipulations) not previously reported to the Committee

If a protocol is assigned to Full Committee Review, a copy of the application is distributed to all ARC members for review no later than five days prior to the next planned meeting. Approval of an application presented for Full Committee Review may only be granted after the following conditions have been met: (i) the application has been reviewed at a convened meeting of a quorum of the ARC; (ii) a majority of the quorum has voted to approve the application; and (iii) all modifications and corrections requested by the ARC have been made by the investigator. No member may participate in the ARC review or approval of a research protocol in which the member has a conflicting interest except to provide information as requested by the ARC; nor may a member who has a conflicting interest contribute to the constitution of a quorum when voting.

For applications that may be considered eligible for Designated Member Review, a list of research protocols are circulated once a week to all ARC members. Members are provided three working days following distribution of the list to indicate one of the following: 1) whether or not the application may be reviewed by designated members, with no response indicating lack of an objection, 2) whether the application is appropriate for designated member review with recommended modifications (indicated, and to be approved by the designated reviewer), or 3) whether Full Committee review of the application is required. Any member of the ARC may request Full Committee Review of those research protocols, and only one request is needed to require Full Committee Review. If Full Committee Review is not requested, the Chair reviews those research

projects and have the authority to require modifications (to secure approval) or indicate approval of those research projects. The Chair may also designate other qualified members of the ARC, such as the Biosafety Officer and the Campus Veterinarian, to review research projects that do not require Full Committee Review. Once all requested modifications have been made, an approval is issued. If a request for Full Committee Review is received after an approval for a given research application has been issued, the objections are presented for resolution at the next convened meeting.

In exceptional circumstances, the Chair, in consultation with the Campus Veterinarian or his designee, may request a shortened time frame of no less than two (2) working days for members to call for Full Committee Review following distribution of the application. ARC staff contact all voting members by phone to notify them of the shortened time frame, and the protocol is then submitted to the members via email. Members are requested to provide a response as to whether Full Committee Review is required. Any member of the ARC may request Full Committee Review of the protocol, and only one request is needed to require Full Committee Review. If Full Committee Review is not requested by the end of the predetermined time frame, the Chair reviews the protocol and has the authority to require modification (to secure approval) or indicate approval of the protocol. The Chair may also designate other qualified members of the ARC, such as the Biosafety Officer and the Campus Veterinarian, to review the protocol.

- c. The ARC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an activity or vote with the ARC.
7. Reviews and approve, requires modifications in (to secure approval), or withholds approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C. The ARC procedures for reviewing proposed significant changes in ongoing research protocols are as follows:

Prior to submission of a request for changes to experimental procedures in a previously approved protocol, investigators must submit the application via the on-line protocol tracking system for Pre- Review in order to address animal care issues. Investigators must address any concerns raised by the veterinary staff prior to submission of the application to the ARC. As noted above, amendment submission involving changes in funding, protocol title, locations, personnel, co-investigator, or principal investigator do not require pre-review prior to ARC review.

Following receipt of the application, the Committee reviews changes based on the requirements set forth in III.D.6. Written notification of ARC approval is required before significant changes can be made to an approved protocol.

Amendment applications are assigned either to Designated Member Review or Full Committee Review by the Chair or his designee. Amendment applications eligible for Designated Member Review are reviewed in accordance with the guidelines set forth in III.D.6.b.

8. Notifies investigators 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 ARC approval as set forth in the PHS Policy at IV.C.4. Notification are also sent to the Institution's designee responsible for verifying that extramurally funded applications and proposals involving the care and use of animals have been approved. The Institutional Official receives copies of all approved ARC meeting minutes.

If the ARC decides to withhold approval of an activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

9. Conducts continuing review of each previously approved, ongoing activity at appropriate intervals as determined by the ARC, including a complete review in accordance with the PHS Policy IV.C.1-4, at least once every three years. The ARC procedures for conducting continuing review are as follows:
 - a. The ARC conducts a continuing review of each previously approved protocol not less than once a year. Investigators seeking continuing approval are asked to: provide an update regarding the progress made toward achieving the scientific objectives of the protocol during the previous year; indicate the number of animals used during the previous year; describe any proposed changes to the approved protocols; and report adverse treatment effects or unanticipated problems.
 - b. The ARC conducts a complete *de novo* review (renewal) not less than once every three years. Investigators seeking renewal of a previously approved protocol submit a completed *Application to Use Laboratory Animal Subjects in Research and/or Teaching* via the on-line protocol tracking system. Renewal applications are subject to all review procedures as set forth in III.D.6. In addition, for renewal applications, investigators are also asked to provide an update regarding the progress made toward achieving the scientific objectives of the protocol during the previous approval period.
10. Is authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The ARC procedures for suspending an ongoing activity are as follows:
 - a. The ARC may suspend an activity that is previously approved if it determines the activity is not being conducted in accordance with the Institution's policy and applicable provisions of the Animal Welfare Act,

the Guide, or IV.C.1.a. - g. of the PHS Policy. The ARC shall suspend an activity only after review of the matter at a convened meeting of a quorum of the ARC and with the suspension vote of a majority of the quorum present.

- b. If the ARC suspends an activity involving animals, the Vice Chancellor-Research, in consultation with the ARC, shall review the reasons for suspension and take appropriate corrective action, and the action is reported with a full explanation to OLAW and the USDA, if appropriate.
 - c. Applications and proposals that have been approved by the ARC may be subject to further appropriate review and approval by officials of the Institution. However, those officials may not approve an activity involving the care and use of animals if the ARC has not already approved it.
- E. The individual authorized by this institution to verify ARC approval of the extramurally funded applications and proposals related to the care and use of animals is the Director of the Office of Contract and Grant Administration or his/her designee(s).
- F. The occupational health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals shall be comprised of the following components:

1. Occupational Health Care Facility

The Occupational Health Facility provides outpatient clinical services to all employees. The clinical staff is comprised of highly qualified doctors, physician assistants and nurses. Services made available through Occupational Health Facility or Emergency Medicine include: (a) pre-employment physical examinations and in-service physical evaluation; (b) diagnosis, treatment, documentation and follow-up of work-related illness or injury; and (c) immunizations. When the Occupational Health Facility is closed, employees are directed to the UCLA Emergency Medical Center for treatment.

Employees should immediately report all injuries and exposures to their supervisor and the Occupational Health Facility for the purposes of risk management. Injury reports are then forwarded to Insurance and Risk Management for a determination of the need for preventative action such as additional training.

2. Occupational Health and Safety Program

The Institution provides an occupational health and safety program that is consistent with federal, state and local regulations. All personnel involved in the care and use of research animals or their tissue must be enrolled in the program. The UCLA Health Protection Tracking System (HPTS) includes the

requirement for annual submission of the Medical History Questionnaire for review by the Occupational Health Facility. This mandate applies to all research, custodial, and contract personnel with access to animal housing areas, and individuals who handle animals or animal tissues. The ARC withholds approval for protocols in cases where research personnel do not have an approved MHQ filed within the year.

An abbreviated MHQ and zoonotic risk document for visitors is used to ensure that individuals who are not currently covered by the UCLA HPTS receive adequate information regarding zoonotic risks and required vaccinations. Investigators are also advised of the requirement for enrollment in the HPTS during inspections and protocol audits.

In most cases, effective use of good animal-care and occupational health and safety practices are sufficient to protect the health and safety of employees; however, in some cases, higher risk of occupational injury or illness may exist. In those cases, the determination of risk and need for health care services shall be the collaborative professional judgment of all interested parties including: the Campus Veterinarian who is familiar with zoonotic risks presented by the research animals; a specialist from the Office of Environment Health and Safety who is knowledgeable about occupational hazards common to animal care and use, as well as relevant hazard control strategies; a medical care provider from Occupational Health Care Facility; and the principal investigators who can assess the health risks associated with their planned experimental protocols. The type of participation in the occupational health and safety program depends upon various factors including: frequency and intensity of exposure; hazards associated with the animal(s) being handled; hazardous properties of agents used in research; individual susceptibility; and the occupational health history of previous employees.

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a. Division of Laboratory Animal Medicine (DLAM) and Outlying Vivaria Personnel

All vivaria personnel shall comply with the mandatory Standard Operating Procedures for the Occupational Health Program. (See attached Appendix C.)

b. Research Personnel

All personnel having contact with live animals shall be immunized for tetanus every ten years or following injury upon the advice of a physician. Personnel may be subject to specialized evaluations and/or immunizations,

depending upon the species and overall level of risk posed by contact with animals, including: annual Q-fever titers (female sheep); ova and parasite testing (non-human primates); rabies vaccination and follow-up titers; hepatitis B vaccination (non-human primates); and vaccinations and evaluations appropriate for infectious agent or recombinant DNA uses.

Routine medical surveillance may be required for research personnel who have animal contact as dictated by the various factors of exposure. Evaluations may include: medical history; physical examination; complete blood count (including differential white cell count); urinalysis; PPD skin test for tuberculosis (if negative prior history); and chest x-ray.

Personnel having contact with non-human primates shall have a TB test annually (or chest x-ray if known to be a positive reactor), have a pre-employment physical examination, be vaccinated against hepatitis B before working with these animals, and have a post-employment physical examination. Personnel who have no direct contact but occasional exposure shall have a TB test annually. The *Guidelines for the Cercopithecine Herpesvirus (B-virus) Exposure: Prevention and First Aid* are distributed to research personnel during species-specific training and are available to all animal handlers on the OPRS website at <http://www.oprs.ucla.edu/animal/occupational-health#>

3. Information Management

As noted above, the Office of Environment Health and Safety provides campus-wide access to a database, the UCLA Health Protection Tracking System, that provides information to animal users about the various components of the occupational health and safety program including: (a) animal handling requirements; (b) services provided by the Occupational Health Facility; (c) protocols for handling and reporting work-related injuries; (d) guidelines for protection from exposure to biohazards; and (e) information about the prevention of zoonoses transmission.

The Health Protection Tracking System tracks information for all personnel having significant contact with animals or animal tissue and the occupational health requirements for handling the specific species. If applicable, personnel are notified of required and/or recommended pre-employment immunizations and medical evaluations. The database also tracks continuing requirements (e.g., booster immunizations) required for personnel after they begin work with a specific animal species. Investigators are responsible for ensuring that follow-up medical evaluations or immunization boosters are completed in a timely fashion.

4. Procedures for Risk Assessment and Hazard Identification

The ARC has established the following procedures for conducting a health and safety review of research activities that involve infectious agents,

recombinant DNA molecules that are not exempt from the Federal guidelines, hazardous chemicals, and the use of ionizing radiation.

- a. The Radiation Safety Officer or his/her designee reviews all animal use applications involving ionizing radioactive materials. The ARC issues approval of animal activities involving radioisotopes only after the Office of Radiation Safety has provided written authorization of such activities.
- b. The Biosafety Officer or his/her designee reviews all animal use applications for the use of biohazards including: recombinant DNA molecules that are not exempt from the Federal guidelines, infectious agents, carcinogens, and highly toxic chemicals. The ARC approves animal activities involving hazardous agents only after the Biosafety Officer or his/her designee has authorized the use of such agents. For applications involving the use of infectious agents or recombinant DNA, the ARC issues approval of animal activities only after the use of such agents has been approved by the Institutional Biosafety Committee.
- c. Before authorizing activities involving radioactive materials or Biohazardous agents, the Radiation Safety Officer (or his/her designee) or the Biosafety Officer (or his/her designee) confers with the principal investigator and, in some cases, the Campus Veterinarian, to assess the potential risks involved and to ensure the placement of safeguards which minimize potential risks to research personnel and DLAM animal care technicians including: guidelines for the acquisition, transport, and handling of biohazardous materials; housing and special care requirements; periodic exposure surveillance; waste disposal management and cage cleaning practices; spill clean-up procedures; use of safety equipment and personal protective gear; any applicable occupational health and safety program requirements; appropriate containment in accordance with the Center for Disease Control and National Institutes of Health's Biosafety in Microbiological and Biomedical Laboratories (Latest Edition) or as deemed necessary by the Institutional Biosafety Committee (IBC); and bloodborne pathogen standard requirements (if applicable).

5. Training of Research Personnel

The principal investigator and facility supervisor are primarily responsible for overseeing the operational and day-to-day safety practices in the workplace. Supervisors are responsible for ensuring that their employees have acquired the necessary skills and information to work safely. Personnel at risk are provided with clearly defined procedures for conducting their duties and implementing the use of engineering controls, work practices, and personal protective equipment. If deficiencies are discovered, the supervisors provide on-the-job training until appropriate standards of proficiency are demonstrated.

The Division of Laboratory Animal Medicine (DLAM) and/or the Office of Environment, Health and Safety (Division of Radiation Safety or Division of Biological and Laboratory Safety), provide research personnel with one-on-one, laboratory, or additional training, as necessary, with respect to: prevention of zoonosis transmission; chemical safety; microbiologic and physical hazards (including those related to radiation exposure and allergies); handling of waste materials; personal hygiene practices; use and scavenging of anesthetic gases; and precautions to be taken under special circumstances (including pregnancy, illness, or decreased immunocompetence).

6. Equipment Performance

The Institution is responsible for certifying and monitoring safety equipment to ensure that it is capable of providing the necessary protection including: chemical fume hoods, autoclaves, and fire protection systems. All laminar flow, HEPA filtration devices are certified and maintained by the user or department through use of a private company contracted to certify and maintain these devices. The Institution assures that these devices are maintained and certified during inspection by the Animal Care and Use Committee of the animal use areas.

7. Emergency Procedures

The Institution has adopted and disseminated a campus-wide emergency response plan. The response team for the animal facility have rapid access to health and safety, veterinary and animal care personnel. The Institution periodically conducts drills to test the efficacy of the emergency response plan.

Each laboratory is required to keep accessible a copy of the UCLA Chemical Hygiene Plan, Laboratory Safety Manual, Biological Safety Manual, Laboratory Emergency Poster, and Radiation Safety Manual (as applicable) in the event of a spill or work-related injury.

G. The total gross number of square feet in each animal facility, the species of animals housed therein, and the average daily inventory, by species, of animals in each facility is provided in the attached Appendix D.

H. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment or use includes the following components:

The ARC ensures that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility is fulfilled in part through the provision of training and instruction to those personnel. Training and instruction is made

available, and the qualifications of personnel reviewed with sufficient frequency to fulfill the research institution's responsibilities.

1. Animal Care and Use Training Manual

All investigators involved in the care and use of animal subjects shall have access to a copy of the "UCLA Animal Care and Use Training Manual" (currently under revision). Investigators are required to keep a copy of the Manual in his/her laboratory for the use of all personnel. The manual is also available both in print and at the OPRS website <http://www.oprs.ucla.edu/animal/documents/pdf/training-manual.pdf>. It is anticipated that the revised version of the manual will be available by December 2006. Investigators are expected to review the Manual prior to completing an *Application to Use Laboratory Animal Subjects in Research and/or Teaching* and to ensure that all staff and students under their supervision are also familiar with the regulations and policies outlined in the Manual.

The Manual is a key component of the ARC's training program as it describes: (a) applicable regulations and policies governing the use of animal subjects; (b) animal acquisition, housing and husbandry practices; (c) the occupational health and safety program; (d) available veterinary care; (e) guidance on selecting the most appropriate animal models; (f) the availability and consideration of alternatives to the use of laboratory animals; and (g) ethical and humane considerations in the use of animals for research.

The Manual is also an important reference tool for animal researchers with its various supplements including: (a) Guidelines for the choice and utilization of tranquilizers, analgesics and anesthetics in laboratory animals; (b) the 2000 Report of the AVMA Panel on Euthanasia; (c) ARC guidelines of acceptable standards for various commonly used procedures involving animals; and (d) a copy of the Institution's Assurance of Compliance with PHS Policy on Humane Care and Use of Laboratory Animals.

2. Training for DLAM Animal Technicians

Training of DLAM staff is conducted by DLAM staff, and at formal classes conducted by other campus offices. Training conducted at meetings of the entire DLAM staff includes such areas as safety in the workplace, general zoonoses, and overall health surveillance of the colonies. Training at Senior staff meetings includes areas such as record keeping requirements, barrier and containment essentials, and paraveterinary functions including tail cutting in mice, blood collection, and timed mating techniques. Staff meetings for Animal Health Technicians include instruction in such areas as training of investigators and their staff, rodent rederivation procedures, and regulations pertaining to the research animal program.

Formal training in laboratory animal science in the form of scheduled

classes is conducted using the AALAS certification manuals. This is voluntary training, but is closely tied to career advancement. Additional formal training is conducted by the campus Environmental Health and Safety office and the Radiation Safety office.

Training of husbandry staff in day-to-day job duties is conducted by Senior staff.

3. ARC Animal Certification Program

The ARC has instituted a mandatory training program whereby research personnel involved in the care and use of laboratory animals shall be “certified” prior to working independently with animal subjects. The ARC maintains a database of all such personnel and a record of their certification status. The Office for Protection of Research Subjects (OPRS) also retains written documentation of each animal users completion of ARC Certification and DLAM training. To become certified, one must pass a written examination based upon the *UCLA Animal Care and Use Manual* and complete the appropriate species-specific training component. Participants who will be working with mice and/or rats are required to attend a handling and techniques lab session. The class begins with the viewing of a brief video followed by a discussion of topics such as recognition of pain and distress and proper euthanasia techniques. Rodent users have an opportunity to learn how to safely handle and restrain these animals and how to perform techniques such as giving injections and collecting blood.

In addition to completing the written exam and species-specific training, personnel who will be conducting survival surgery on any species are required to participate in an aseptic surgical technique class. This session begins with the viewing of a short video and a discussion on the importance of major points of aseptic surgery. Proper preparation of the surgeon, surgical instruments, and the animal patient is emphasized during the hands-on portion of the class.

Species specific training is required for each species a trainee will be handling and is accomplished by participating in a species-specific training session with the Division of Laboratory Animal Medicine (DLAM). The attending veterinarian assesses each trainee’s prior experience with the proposed animal model(s) and provide training accordingly. Trainees may be required to watch a video and/or attend a wet-lab demonstration of species-specific handling techniques and basic research procedures. Trainees who will be conducting surgery may be asked to watch a video and/or attend a wet-lab describing aseptic surgical techniques. If a trainee does not have any prior experience handling the proposed animal(s), the attending veterinarian provide hands-on training for the specific species.

If a previously certified person elects to work with a new species, he/she may be required to complete the training component as described above prior to being certified to work with the new species.

4. One-on-One Training Sessions for Investigators/Research Personnel:

One-on-one veterinary assistance or training is available upon the request by the investigator or the recommendation of the ARC. Frequently, during the review of an application, the ARC may designate the veterinarian to counsel an investigator and to ensure that he/she and his/her personnel involved in animal care, treatment, and use are experienced and qualified to conduct the research.

5. ARC Information and Training Workshops

The ARC regularly offers workshops dedicated to provide continuing training and instruction to the research community. Workshops may be dedicated to the following areas: (i) humane methods of animal maintenance and experimentation; (ii) the intent and requirements of the AWA, PHS Policy and Institution's policies governing the use of laboratory animals; (iii) the concept, availability, and use of research methods that limit the use of animals or minimize animal distress; (iv) the proper use of anesthetics, analgesics, and tranquilizers for specific animal species; and (v) the utilization of services (e.g., National Agricultural Library, Animal Welfare Information Center, and University of California Center for Animal Alternatives) available to provide information on appropriate methods of animal care and use or alternatives to the use of live animals in research.

IV. INSTITUTIONAL STATUS

As specified in the PHS Policy at IV.A.2., as Category 1, all of this institution's programs and facilities for activities involving animals have been evaluated and accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). All of this institution's programs and facilities for activities involving animals have also been evaluated by the ARC and are reevaluated by the ARC at least once every six months.

All ARC semiannual reports include a description of the nature and extent of this institution's adherence to the Guide. Any departures from the Guide are 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 contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the ARC evaluations are submitted to the Vice Chancellor- Research Programs. Semiannual reports of ARC evaluations are maintained by this institution and made available to the Office of Laboratory Animal Welfare (OLAW) upon request.

V. RECORDKEEPING REQUIREMENTS

- A. This institution maintains for at least three years:
1. A copy of this Assurance and any modifications thereto, as approved by PHS.
 2. Minutes of ARC 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 ARC approval was given or withheld.
 4. Records of semiannual ARC reports and recommendations (including minority views) as forwarded to the Vice Chancellor-Research Programs.
 5. Records of accrediting body determinations.
- B. This institution maintains records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the ARC for the duration of the activity and for an additional three years after completion of the activity.
- C. All records are accessible for inspection and copying by authorized Office of Laboratory Animal Welfare (OLAW) or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

- A. At least once every 12 months, the ARC, through the Vice Chancellor-Research or his/her designee, reports in writing to OLAW:
1. Any changes in the status of the institution, any changes in the description of the institution's program for animal care and use as described in this Assurance, or any changes in ARC membership. If there are no changes to report, this institution submits a letter to OLAW stating that there are no changes.
 2. Notification of the date that the ARC conducted its semiannual evaluations of the institution's program and facilities and submitted the evaluations to the Vice Chancellor-Research Programs.
- B. The ARC, through the Vice Chancellor-Research or his/her designee, provides 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 deviation from the provisions of the Guide.

3. Any suspension of an activity by the ARC.
- C. Reports filed under VI.A. and VI.B. above include any minority views filed by members of the ARC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Roberto Peccei, Ph.D.

Title: Vice Chancellor-Research

Address: University of California, Los Angeles
Chancellor's Office
2138 Murphy Hall
405 Hilgard Avenue
Los Angeles, CA 90095-1405

Phone: (310) 825-7943

Signature: *Roberto Peccei* Date: July 5, 2006

B. PHS Approving Official

Name: Denis Doyle
Director, Division of Assurances
Title: Office of Laboratory Animal Welfare
National Institutes of Health
Address: 6705 Rockledge Drive
RKL1, Suite 360, MSC 7982
Bethesda, MD 20892-7982

Signature: *Denis Doyle* Date: 7/11/06

C. Effective Date of Assurance 7/11/06

D. Expiration Date of Assurance 7/31/10