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

I. APPLICABILITY
This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another location as a consequence of the subgranting or subcontracting of a PHS-conducted or supported activity by this institution. “Institution” includes the following branches and major components of Western University of Health Sciences: College of Osteopathic Medicine of the Pacific, College of Allied Health Professions, College of Pharmacy, College of Graduate Nursing, College of Veterinary Medicine, and Center for Drug Development.

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

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

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE
A. The lines of authority and responsibility for administering the program and ensuring compliance with this policy are as follows: The IACUC, the veterinarian, and the animal
facility manager report directly to the Vice President for Policy and Research, who shall serve as the Institutional Official for the purposes of this Assurance. The Vice President for Policy and Research reports directly to the Executive Vice President of Academic Affairs of the institution who in turn reports directly to the President/Chief Executive Officer of the institution.

B. The qualifications, authority, and percent of time contributed by the veterinarian who participates in the program is:

**Dr. Marcelo Couto**

Qualifications—
Ph.D., University of California, Davis (1990)
DVM, University of Buenos Aires Argentina (1978)
Board Certification by the American College of Laboratory Animal Medicine (1998)
California Veterinary License (9522) (1987)
University of California, Los Angeles, Associate Director (2004-) & Senior Clinical Veterinarian (2002-2004)
The Scripps Institute, La Jolla, CA, Associate Director for Comparative Medicine, Chief of Medicine and Surgery (1998-2001)
University of California, Los Angeles, CA, Senior Clinical Veterinarian (1993-1998)
UCLA Dept. of Medicine, Los Angeles, CA, Assistant Research Pathobiologist (1993-1994)
UCLA dept. of Medicine, Los Angeles, CA, Postdoctoral Fellow (Molecular and Cell Immunology) (1990-1993)
University of California, Davis, CA, Clinical Training-Internship & Residency Programs (Department of Reproduction) (1981-1986)

Authority—
A contractual arrangement has been established between the institution and Dr. Couto for him to serve as the attending veterinarian for the institution. Contracted duties, as stated in the agreement, include: (1) serve as veterinarian member of the IACUC, (2) serve in the capacity of attending veterinarian to the institution, (3) establish and monitor the institution’s program of veterinary care for animals used in research and teaching, (4) conduct regularly scheduled monthly visits to the animal care facility, (5) provide guidance and education to animal care personnel and researchers in the handling, immobilization, anesthesia, analgesia, tranquilization, euthanasia, and pre- and post-procedural care of animals, (6) provide veterinary care to animals housed in the animal care facility, and (7) monitor emergency, holiday, after-hours, and week-end veterinary care arrangements established by the institution. Dr. Couto has been granted access to the animal care facilities maintained by the institution and he has delegated authority to implement PHS Policy and the Guide.

Percent of time—
Estimated and contracted time for Dr. Couto in performance of the above duties represents 50 hours of service per year. Provisions in the contract allow for negotiating additional time as needed. Dr. Phillips serves as the back-up veterinarian for Dr. Couto. Dr. Phillips is a
full-time faculty member in our College of Veterinary Medicine, and is available in Dr. Couto’s absence.

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

D. The IACUC will:

1. Review at least once every six months the institution’s program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program evaluations are as follows: The IACUC Chair, Dr. Donald Walters, in consultation with the committee, shall schedule all program reviews every 6 months. The review team shall consist of at least 2 committee members. All members wishing to participate shall be included in the team. The team shall conduct a routine program review using a standardized format based on Office of Laboratory Animal Welfare (OLAW) Program Review Checklist templates.

2. Inspect at least once every six months all of the institution’s animal facilities, including satellite facilities, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows: The IACUC Chair, in consultation with the committee, shall schedule all facilities inspections every 6 months. Prior notification shall be given to the Vice President for Research to ensure access to all facilities. The inspection team shall consist of at least 2 committee members; all members wishing to attend shall be included in the team. Outside consultants on animal care, housing, medical care, etc., shall be invited as deemed necessary. The team shall conduct a routine inspection using a standardized format derived from the OLAW Review Checklist template.

   The IACUC shall maintain a list, map, and architectural drawings of and contact persons for all animal facilities on campus. This list shall contain itemized information specifically regarding central animal housing facilities, temporary (less than 12 hours) containment facilities, and surgical facilities. Details shall include room numbers, room use, species contained, last noted deficiencies, and corrective actions.

   During inspections, facility personnel shall be advised of apparent deficiencies. Their input shall be included in the IACUC’s assessment of the issue in question.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3, and submit the reports to Vice President for Policy and Research. The IACUC process for developing reports and submitting them to the Institutional Official is as follows: Notes from the inspection, along with completed checklists, shall be used to prepare a final report to the
Vice President of Policy and Research. The report shall include categorization (acceptable vs. minor vs. significant) according to United States Department of Agriculture (USDA) and PHS policy and regulations, a plan and timetable for correction of deficiencies, and contingencies if deficiencies cannot be corrected. The Vice President of Policy and Research shall contact relevant agencies when federally or independently funded projects are involved or impacted.

A quorum of the IACUC shall review, approve, and sign the final report. An addendum shall be added for minority views, if any. The report shall be presented to the Vice President of Policy and Research by the IACUC Chair. Annually, the Vice President of Policy and Research shall notify OLAW of inspection and final report dates, in a format acceptable to OLAW.

4. Review concerns involving the care and use of animals at the institution. The IACUC procedures for reviewing concerns are:

**Commitment**

The President, Executive Vice President of Academic Affairs, and Vice President for Research at the institution advocate the finest animal care and assure the public, researchers, employees, and students that there is a true desire to investigate allegations of mistreatment or noncompliance. The IACUC and veterinary staff fully support this philosophy. Under no circumstances shall reporting such instances be detrimental to an individual’s standing within the institution; indeed, this action is provided protection under the law (9 CFR, Part 2, Subpart C 2.32 (c)(4)). The complaint reporting procedure and contact names shall be posted in each facility conducting research on or housing research animals.

**Reporting procedure**

Placards shall be posted in and surrounding research laboratories and the laboratory animal facility (see Appendix B).

If an individual wishes to report any concern regarding animal mistreatment, noncompliance, or concern for human safety in research or teaching facilities, (s)he may contact the Vice President of Policy and Research, the IACUC Chair, the Campus Veterinarian, or the Campus Safety Officer for immediate action. Complainants are encouraged to fully document and sign their complaints. Every effort shall be made to protect the identity of complainants, but absolute anonymity cannot be guaranteed. Every complaint shall be taken seriously and reviewed by the IACUC.

**IACUC response to complaints**

Ideally, all complaints brought to the IACUC’s attention shall be documented and signed by the complainant. For undocumented complaints, the IACUC shall use its judgment on whether the complaint is of sufficient substance to proceed further. All documented and signed complaints shall be acknowledged as received, and when appropriate the complainant shall be informed of the outcome. The IACUC reserves the privilege to keep committee discussions and conclusions confidential.
IACUC procedures for the investigation of a complaint

The IACUC Chair shall designate an individual or subcommittee to handle allegations of mistreatment or noncompliance. All persons involved shall be informed of the purpose of the investigation, and those against whom the complaint is addressed shall be given the opportunity to explain their side of the issue. Results of investigations shall be documented and corrective actions recommended to the IACUC. When allegations result in an official IACUC investigation, the results shall be made available to all parties involved, including the Vice President of Policy and Research, who is ultimately responsible for taking corrective action.

Institutional Response

The institutional response shall depend on the nature of the investigative findings. The Vice President of Policy and Research, in consultation with the IACUC, has the power to impose sanctions on the investigator found responsible for any mistreatment or noncompliance. In serious cases, the IACUC is empowered by the USDA regulations and PHS policy to suspend a previously approved project. If the activity is supported by PHS funds, the IACUC through the Vice President of Policy and Research shall file a full report to Office of Laboratory Animal Welfare.

5. Make written recommendations to the Vice President of Policy and Research regarding any aspect of the institution’s animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are: Written recommendations as described in D.3. above shall be forwarded to the Institutional Official by email (copied to IACUC secretary) and interdepartmental mail (copied to IACUC secretary).

6. Review and approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C. The IACUC procedures for protocol review are:

The institution’s IACUC has a standardized animal protocol application that shall be submitted by all investigators who propose to conduct activities involving the use of animals. The IACUC shall meet on the second Friday of each month to review submitted protocol applications. Applications may be requested by faculty in computer template format or paper format from the Office of Vice President for Policy and Research. All applications shall be submitted to the Office of Vice President for Policy and Research no later than two weeks prior to the meeting at which it is to be reviewed.

In order to approve a proposed animal protocol application or proposed modifications in an ongoing approved protocol, the IACUC shall conduct a review and determine that the proposed protocol is in accordance with the Animal Welfare Act and PHS Policy, insofar as it applies to the research project, and that the protocol is consistent with the Guide, unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms with the institution's PHS Statement of Assurance and meets the following requirements:

1. Procedures with animals avoid or minimize discomfort, distress, and pain to the animals and are consistent with sound research design.
2. Procedures that may cause more than momentary or slight pain or distress to the animals shall be performed with appropriate sedation, analgesia, or anesthesia, unless the procedures are justified for scientific reasons in writing by the investigator.

3. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved shall be painlessly killed at the end of the procedure prior to recovery.

4. The living conditions of animals shall be appropriate for their species and contribute to their health and comfort. The housing, feeding, and non-medical care of the animals shall be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

5. Medical care for animals shall be available and provided as necessary by a qualified veterinarian.

6. Personnel conducting procedures on the species being maintained or studied shall be appropriately qualified and trained in those procedures.

7. Methods of euthanasia used shall be consistent with the recommendations of the American Veterinary Medical Association Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

Clear presentation of a proposal will assist the IACUC in its review. Preliminary discussions between the investigator and any IACUC member are encouraged and can help the investigator develop a proposal containing all the requisite information.

Prior to each monthly review cycle, IACUC members shall be provided with a list of animal protocol applications to be reviewed. Any member of the IACUC may obtain, upon request, full committee review of the applications. If full committee review is not requested, at least one member of the IACUC, designated by the Chair and qualified to conduct the review, shall review the application and shall have the authority to require modifications in (to secure approval) or request full committee review of the application. If full committee review is requested, approval of the application shall be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an application in which the member has a conflicting interest (e.g., is personally involved in the project), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum. Final review and discussion of an application shall take place at a regularly scheduled monthly meetings of the IACUC. The investigator may be invited to the meeting to answer any questions that may arise from this discussion which will aid in the final decision-making process. After a protocol has been reviewed by the full Committee, a designated reviewer conveys the comments and concerns of the full Committee to the investigator. The designated reviewer then decides if the investigator has adequately addressed the issues. If yes, the designated reviewer so informs the IACUC secretary and asks him/her to send the investigator a letter of approval. The
notice of this approval is then read into the minutes of the next meeting of the IACUC. If no, the IACUC Secretary informs the investigator of the issues yet to be resolved.

The IACUC 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 IACUC unless they are also members of the IACUC.

As a result of the review process, one of the following decisions shall be made by the IACUC:

1. Unqualified approval: The IACUC considers that all significant points have been addressed by the investigator. As a result of this approval, the investigator has permission to conduct the experiments on the number of animals described in the proposal.

2. Approval, pending clarification: The IACUC considers that there are significant points needing clarification. With satisfactory written responses to issues raised by the IACUC, the protocol shall be reclassified as an “Unqualified approval.”

3. Deferral: The IACUC considers that there is insufficient information available to make a determination, an absence of a quorum of members, or some other reason requiring deferral of consideration.

4. Disapproval: The IACUC does not permit the investigator to conduct experiments on animals under this protocol.

The IACUC has ultimate responsibility for the use of animals in research conducted at the institution. Disapproved proposals cannot be administratively approved by a higher authority. However, the opposite is not true; an IACUC approved proposal can be administratively disapproved by the Vice President for Research or the Executive Vice President of Academic Affairs for financial, facility-related, or other reasons.

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows: Modification of an existing approved protocol may be requested by the investigator. Examples of changes in a protocol that require submission of a modification request include, but are not limited to:

1. Change in the species of animal used for study

2. Change in the number of animals used for study

3. Addition of or changes in surgeries, protocols, etc., to be conducted on live animals.

The review and approval process for modification of a protocol is the same as that described above for full protocol application review.
8. Notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy at IV.C.4. The IACUC procedures to notify investigators and the institution of its decision regarding protocol review are as follows: Following review, the IACUC shall notify the investigator and the Office of Vice President of Policy and Research of its decision in writing. If the decision of the IACUC is other than unqualified approval, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing as per the general guidelines stated above. An investigator may revise and resubmit a proposal which has previously been disapproved.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy at IV.C.1-4 at least once every three years. The IACUC procedures for conducting review are as follows: The IACUC shall conduct continuing review of each previously approved, ongoing protocol at appropriate intervals (typically one year) as determined by the IACUC. A comprehensive review shall occur at least once every three years. Investigators shall be notified 60 days prior to the anniversary date of their approved protocol. For the yearly review process, the IACUC may request that the investigator provide a written narrative or submit an Annual Progress Report form, which can be obtained from the IACUC. All approved protocols expire 3 years from their dates of approval. At this time (actually, before the protocol expires in order to maintain continuity of the research), the investigator must resubmit the protocol as a new protocol which will then be reviewed as if for the first time by a quorum of the IACUC.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows: The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, or the institution's PHS Statement of Assurance. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, the Vice President for Policy Development and Research, in consultation with the IACUC, shall review the reasons for suspension and take appropriate corrective action. The institution shall also notify the sponsor.

E. The individual authorized by the institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals is the Vice President for Research.

F. The occupational health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals is as follows: Western University’s Injury and Illness Prevention Program which provides an overview of the University’s occupational health and safety program, including animal care personnel, is appended (Appendix C). It includes general policies and procedures regarding personal hygiene, handling hazardous materials, and personal protection. These general policies are supported by additional
information and training materials posted on the University’s Intranet. These deal with particular risks, including general office safety, laboratory safety, protocols for handling radioactive materials, etc.

All employees and students involved in research or educational projects involving animals are required to be up-to-date on their tetanus/diphtheria boosters. Veterinary medical students will also be required to show proof of immunity to rabies. Occupational health services are provided to University faculty and staff under a subcontract to Casa Colina, Inc. They provide a pre-placement medical evaluation that includes determining existing risks relative to allergy, physical limitations, immunocompromization, etc., and monitor employee health regarding zoonoses, hazards, etc. They also handle treatment of employees injured in the conduct of their duties with the University. Incident reports on all injuries or occupationally related diagnoses must be submitted by the employee to the University’s Office of Environmental Health and Safety. The IACUC office maintains the names and contact information on specialists in zoonotic diseases that the subcontractor can call upon should need arise. Students volunteering to work in laboratories with animal care responsibilities must access occupational health services through their regular medical provider.

Prior to job placement, individuals will receive general training in safe laboratory and animal use practices, including occupational health information. This training is repeated annually, and includes hygiene, sharps management, protective gear, decontamination practices, fume hood use, etc. Additional training to individuals in contact with animals will be provided by the Attending Veterinarian in the areas of allergies, zoonoses and special precautions for pregnancy and immune suppression by means of a handout. The Attending Veterinarian will be available to answer questions about the information contained in the handout. Several online programs that provide this kind of training are under review. In addition, advanced training in specific areas or animal species is required based upon the particulars of the position description. Based on the current and anticipated levels of research and teaching at Western University, the following hazards/risks have been identified: rat/mouse/guinea pig exposure (i.e., allergens, bites, scratches), infectious agents, chemical hazards (i.e., cleaning solutions), wet surfaces, bedding materials (i.e., cedar), anesthetic gases, flammable gases (O2), sharps, controlled substances, biohazards (i.e., tumor cells, etc.), nuclear radioisotopes, and machinery. The procedures for identifying and reporting risks are included in the Injury and Illness Prevention Program document. IACUC policies require that all individuals involved in the research project be identified in the IACUC protocol application and that documentation of appropriate training and experience of these personnel commensurate with their assigned duties be included in the submission.

The occupational health and safety program, as it relates to animal use and care, is reviewed semi-annually by the IACUC, the University’s Environmental Health and Safety officer, and the Vice President of Policy and Research. Based upon this review, improvements are recommended and implemented.
G. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein, and the average daily inventory of animals, by species, in each facility is provided in Appendix B.

H. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows: Training and instruction are available via the World Wide Web and the institution’s IACUC. The qualifications of personnel are reviewed when animal protocols are submitted and the level of training required is assessed. Training documentation for Level I and II shall be completed prior to activation of an Animal Care Protocol. Training is reviewed annually in conjunction with the Annual Review of the Animal Care Protocol.

All individuals working with vertebrate animals in research or education as part of their assigned responsibilities at the institution shall participate in Level I and II training administered by the IACUC.

Animal Care and Use Level I training includes institutional policies, federal regulations, and animal welfare, legal and ethical issues, the concept of the 3Rs, research issues, basic animal care/biology/techniques, occupational health and safety, and facility-specific issues. This requirement can be satisfied by several self-directed learning experiences and assessments. Satisfactory completion shall be certified and maintained on file.

Level II training includes species-specific training covering the care, handling, and research uses of the elected species. This requirement also can be satisfied by several self-directed learning experiences and assessments. Satisfactory completion shall be certified and maintained on file.

Level III training (advanced techniques, etc.) shall be required annually (one course) or as otherwise required by the IACUC.

We include training in the area of minimization of animal numbers but we do not teach them how to perform a power calculation. We inform them that a power calculation is one way they can justify to the Committee that they have indeed minimized the number of animals needed. There have been cases, however, when we have recommended to investigators experimental designs that would reduce the numbers of animals needed or asked the investigator to explain why such a design would not be appropriate for their study. We also cover the importance of using, whenever possible, methods that minimize pain and we inform investigators that this is an area that the IACUC gives close scrutiny to when considering whether or not to approve a protocol.

IV. INSTITUTIONAL STATUS

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

V. RECORD KEEPING REQUIREMENTS

A. This institution shall maintain for at least three years:

1. A copy of this Assurance and any modifications thereto, as approved by PHS.

2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.

3. Records of applications, proposals, proposed significant changes in the care and use of animals, and whether IACUC approval was given or withheld.

4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Vice President for Policy and Research.

5. Records of accrediting body determinations.

B. This institution shall maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

A. At least every 12 months, the IACUC, through the Institutional Official, shall report in writing to OLAW:

1. Any change in the status of the institution (e.g., if the institution becomes accredited by Association for Assessment and Accreditation of Laboratory Animal Care(AAALAC) or AAALAC accreditation is revoked), any change in the description of the institution’s program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, this institution shall provide OLAW with written notification that there are no changes.

2. Notification of the dates that the IACUC conducted its semiannual evaluations of the institution’s program and facilities (including satellite facilities) and submitted the evaluations to the Vice President of Policy and Research.
B. The IACUC, through the Institutional Official, shall provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS Policy.

2. Any serious deviations from the provisions of the Guide.

3. Any suspension of an activity by the IACUC.

C. Reports filed under VI.A. and VI.B. above shall include any minority views filed by members of the IACUC.
VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Steven J. Henriksen, Ph.D.
Title: Vice President for Research
Address: Western University of Health Sciences
         309 E. Second Street
         Pomona, California 91766-1854
Phone: (909) 469-5381
Fax: (909) 469-5694

Signature: ____________________________
Date: ________

B. PHS Approving Official

Name:
Title:
Address:
Phone:
Fax:

Signature: ____________________________
Date: ________

C. Effective Date of Assurance:

D. Expiration Date of Assurance: