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University
OF HEALTH SCIENCES

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Office of the Institutional Animal Care and Use Committee

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August 22, 2019

Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive
RKL 1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982

Colleagues,

The Institutional Official for Western University of Health Sciences has recently changed, as has some of our veterinary support staff and the membership of our IACUC. These changes are reflected in our following, revised, Animal Welfare Assurance for Domestic Institutions (D16-00558 (A3989-01)). We look forward to hearing from you regarding your approval of these changes.

Sincerely,

Donald E. Walters, Ph.D.
Chair, Institutional Animal Care and Use Committee
Western University of Health Sciences
309 East Second St.
Pomona, CA 91766

**Western University of Health Sciences
D16-00558 (A3989-01)
Animal Welfare Assurance for Domestic Institutions**

I, Devendra K. Agrawal, Ph.D., Senior Vice President for Research & Biotechnology, as named Institutional Official (IO) for animal care and use at Western University of Health Sciences (WesternU), 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, HHS, and/or NSF. This Assurance covers only those facilities and components listed below.

A. The following are branches and components over which this Institution has legal authority. Included are those that operate under a different name:

- Western University of Health Sciences, Pomona, CA
 - College of Osteopathic Medicine of the Pacific
 - College of Allied Health Professions
 - College of Pharmacy
 - College of Graduate Nursing
 - College of Veterinary Medicine
 - College of Dental Medicine
 - College of Optometry
 - College of Podiatric Medicine
 - College of Biomedical Sciences
 - Center for Advancement of Drug Research and Evaluation
- Western University of Health Sciences, Lebanon, OR

B. The following are other institution(s) or branches and components of another institution: None

The Institution understands that only those entities listed in this section will be entitled to use the Assurance number for grant and contract submissions to PHS agencies.

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 the 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 shall maintain a program for activities involving animals according to the most recent edition of 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 (sub-award) 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, both at the Pomona, CA, and Lebanon, OR, campuses, are as follows: The IACUC, the veterinarians, the Director of Animal Resources at the Pomona campus and the Coordinator of Animal Resources at the Lebanon campus report directly to the Senior Vice President for Research & Biotechnology who shall serve as the IO for the purpose of this Assurance. The IO reports directly to the President/Chief Executive Officer of the Institution.
- B. The qualifications, authority and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

1) Marcelo A. Couto, DVM, PhD, DACLAM (Institutional Veterinarian; Attending Veterinarian for Pomona Campus)

Qualifications:

- Degrees: Ph.D., Comparative Pathology, University of California, Davis (1990)
DVM, University of Buenos Aires Argentina (1979)
Board Certification by the American College of Laboratory Animal Medicine (1998)
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Couto was the Executive Director (Retired), Division of Laboratory Animal Medicine (DLAM) at the University of California, Los Angeles (UCLA), where he directed a large and complex, multi-species, lab animal program and served as a

Campus Veterinarian from 2006-15. Dr. Couto is presently the Institutional Veterinarian for the Pomona, CA, and Lebanon, OR, campuses and he has served as the Attending Veterinarian for the Pomona campus since 2003. Species housed at these facilities include rodents, shrews, chickens and zebrafish. Dr. Couto provides clinical, surgical, regulatory and training support for the animal research enterprise. His past experience includes Director, Preclinical Research, Guidant Corp, St. Paul, MN (2001-02) where he provided administrative, clinical, surgical, regulatory, and training support for a large animal facility focusing on development and testing of cardiovascular devices; Associate Director for Comparative Medicine, Chief of Medicine and Surgery, The Scripps Research Institute, La Jolla, CA (1998-2001) where he provided administrative, clinical, surgical, regulatory, and training support for a large and complex, multi-species lab animal program.

- Authority: **Dr. Marcelo Couto** is the Institutional Veterinarian for WesternU's Pomona, CA, and Lebanon, OR, campuses and has IO-delegated program authority and responsibility for the Institution's animal care and use program including access to all animals at both campuses. Dr. Couto also serves as the Attending Veterinarian for the Pomona, CA, campus.
- Time contributed to program: Estimated and contracted time for Dr. Couto in performance of his duties as Institutional Veterinarian and Attending Veterinarian represents approximately 260 hours of on-site service per year with provisions in the contract for additional time as needed. Extensive off-site involvement includes phone and e-mail consultation with PIs, staff and administrators, protocol review and other activities associated with the animal research enterprise.

2) Dr. Gagandeep Kaur serves as the back-up veterinarian for Dr. Couto.

Qualifications:

- Degrees: Bachelor of Veterinary Science and Animal Husbandry, Punjab Agricultural University, India, July, 2005
DVM, Educational Commission for Foreign Veterinary Graduates, 2009
Ph.D. Physiology (Neurophysiology), Kent State University, Kent, OH, 2009
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Kaur is an Assistant Professor of Physiology at WesternU and has four years of experience working with Syrian hamsters obtained during her dissertation research. She also has IACUC-approved protocols working with dogs, cats and laboratory mice and she spent three years in private practice at Stow Kent Animal Hospital in Kent, Ohio, working with dogs and cats. Dr. Kaur reports to Dr. Couto.

3) Dr. Heather Sidener, DVM, DACLAM (AV for Lebanon Campus)

Qualifications:

- Degrees: DVM, College of Veterinary Medicine, Washington State University (2000)
B.S., University of Alaska, Fairbanks, AK (1995), Biology Cum Laude
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Following her Bachelor of Science degree, Dr. Sidener received her DVM degree at the Washington State University, College of Veterinary Medicine, in 2000. With this training, Dr. Sidener served as small animal clinician at Sacajawea Health Care for Pets, Federal Way, WA, and Magnolia Veterinary Hospital, Seattle, WA (2000-2004); Lab Animal Resources Support Supervisor and Veterinary Services Supervisor at SNBL, Everett, WA (2005-2012); and currently as Department Head, Clinical Medicine Unit at the Oregon National Primate Research Center in Beaverton, WA, since 2012.

Authority:

Dr. Heather Sidener has IO-delegated program authority and responsibility for the Institution's animal care and use program at the Lebanon, OR, campus where she serves as the Attending Veterinarian and has access to all animals there. Dr. Sidener reports directly to Dr. Marcelo Couto, the Institutional Veterinarian.

Time contributed to program: Estimated and contracted time for Dr. Sidener in performance of her duties as Attending Veterinarian at the Lebanon, OR, facility represents 40 hours of on-site service per year with provisions in the contract for additional time as needed.

- 4) **Dr. Brandy Dozier, DVM, DACLAM** serves as the back-up veterinarian at the Lebanon campus and reports directly to Dr. Sidener.

Qualifications:

- Degrees: DVM, Virginia-Maryland College of Veterinary Medicine (2012)
B.S., Roanoke College, Salem, VA (2002); Major – Biology Cum Laude
- Training or experience in laboratory animal medicine: Dr. Dozier is currently Assistant Veterinarian, Clinical Medicine Unit, at the Oregon National Primate Research Center in Portland, OR, and has complete internship and externship programs at the National Heart, Lung, and Blood Institute, Bethesda, MD; Wake Forest University Primate Center, Winston-Salem, NC; and Eastern Virginia Medical School, Norfolk, VA.

C. The IACUC at this Institution is properly appointed in accordance with PHS Policy IV.A.3.a. and is qualified through 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 names, degrees, profession, titles or specialties and institutional affiliations (see Appendix A).

D. The IACUC shall:

1. Review at least once every six months the Institution's program for humane care and use of animals, using the most recent edition of the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows: The IACUC Chair, in consultation with the committee, shall schedule all program reviews at least every six months. The review team shall consist of at least two committee members. All IACUC members are invited to participate in the semiannual program review. The team shall conduct a routine program review using a standardized format based on the Office of Laboratory Animal Welfare (OLAW) Program Review Checklist template.
2. Inspect at least once every six months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the most recent edition of 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 at least every six months. All IACUC members are invited to participate in the semiannual facility inspection.

The inspection team shall consist of at least two committee voting members; all members wishing to attend are 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.

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 according to PHS Policy at IV.B.3. Notes from inspections, along with completed checklists, shall be used to prepare final reports to the IO. A quorum of the IACUC shall review, approve and sign the final report. A quorum is defined by IACUC Policy 2016-054, "Establishing a Quorum and Voting", as a simple majority (50% + 1) of the voting members of the IACUC. If the IACUC has an odd number of members, the number of members that must be present to constitute a quorum shall be determined by taking half of the total number of voting members and rounding up to the next whole number + 1. Official business requiring a vote shall not be conducted unless a quorum, as defined above, is present. Members who recuse themselves shall not contribute to a quorum. If a recusal results in the loss of a quorum, any business under consideration that led to the recusal shall be tabled until a quorum is present. A simple majority of votes

by the voting members present and eligible to vote shall determine a decision. The committee Chair contributes to the quorum but shall not vote except to break a tie.

An addendum shall be added to the report for minority views. If there are no minority views, it shall be so stated in the report. The IACUC Chair shall present the final report to the IO. The reports shall include categorization of any deficiencies (acceptable vs. minor vs. significant) according to USDA and PHS policy and regulations, a plan and timetable for their correction and contingencies if deficiencies cannot be corrected. If a deficiency is noted during the facilities inspection, the IACUC shall identify on the report the person responsible for correcting the deficiency. This person shall then be contacted in writing by the Director of Animal Resources or the IACUC Chair and informed of the deficiency. A reasonable and mutually agreeable timeline for correction shall be established at this point. The Director of Animal Resources shall then notify the IACUC Chair when the deficiency is corrected and the Chair shall note this date on the report. If the deficiency is not corrected by the stated deadline, the IACUC Chair shall so notify the IO for further action. If a deficiency is noted during the program evaluation, the IACUC Chair shall bring the issue before the IACUC for discussion and recommendations. These recommendations shall then be presented, in writing, to the IO for corrective action. The report shall also identify any IACUC-approved departures from the provisions of the most recent edition of the *Guide*, the PHS Policy or the Animal Welfare Act regulations along with a statement of the reasons for each departure. The IO shall contact relevant agencies when federally or independently funded projects are involved or impacted. Annually, the IO 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 as follows:

Commitment:

WesternU's President, Provost and IO 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 containing phone and e-mail contact information for the IO, the IACUC Chair, the Attending Veterinarian and the Director of Animal Resources are posted in and surrounding research laboratories and in various locations throughout our four vivaria at both campuses. Any person who wishes to report a concern regarding animal mistreatment, noncompliance or concern for human or animal safety in research or teaching facilities may contact any one of the persons named on the placard either in person or anonymously online or by phone. Complainants are encouraged to fully document their allegations. Persons wishing to file an anonymous report are encouraged to use the anonymous "Report Button"

prominently posted on the IACUC's website (<http://www.westernu.edu/research/regulatory-affairs/research-iacuc/>). If a person filing a report identifies himself or herself in the report, every effort shall be made to ensure their anonymity to prevent retribution from the accused or other interested parties. All complaints shall be taken seriously and carefully reviewed by the IACUC whether or not a subsequent investigation is launched. If feasible and subject to the complainant's wishes (or agreement), the IACUC may solicit additional information from the complainant or the accused parties.

The IACUC, in consultation with the IO, shall use its judgment to determine whether an allegation is sufficiently substantive and meritorious of a full investigation. In all cases, however, the complainant shall be kept apprised of the status of any ongoing investigation but shall not be privy to IACUC deliberations, conclusions or the nature of any punitive actions taken against the offending parties.

IACUC response to complaints:

The IACUC shall request that non-anonymous complaints be documented in writing and signed by the complainant. If the complainant refuses to do so, the IACUC shall make a written record of the complaint and note the refusal of the complainant to provide a written, signed statement. In either case, the IACUC shall use its judgment on whether or not 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 status of the complaint. 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 the investigation 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 the appropriate parties, including the Vice President for Research & Biotechnology who is ultimately responsible for taking corrective action.

Institutional response:

The institutional response shall depend on the nature of the investigative findings. The IO, 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 IO shall file a full report with OLAW.

5. Make written recommendations to the IO regarding any aspect of the Institution's animal program, facilities, or personnel training. Written recommendations as described in D.3., above, shall be forwarded to the IO by email (copied to the IACUC secretary) and interdepartmental mail (copied to the IACUC secretary). Additional written recommendations

from the IACUC to the IO, outside of the semiannual reports, are made as situations warranting such communications arise. The IACUC Chair and the Attending Veterinarian routinely meet with the IO, typically every Wednesday. At these meetings, the IO is apprised of any circumstances that may require his consultation, support or intervention. These additional communications shall be appropriately documented.

6. Review and approve, require modifications to secure approval, or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy at IV.C.1-3. The IACUC procedures for protocol review are as follows:

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 project, and that the protocol is consistent with the most recent edition of the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to 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 (AVMA) Guidelines for the Euthanasia of Animals 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 are provided with a list of animal protocol applications to be reviewed along with copies of the entire protocols. Any member of the IACUC may obtain, upon request, full committee review (FCR) of the applications.

If FCR 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. Final review and discussion of an application shall take place at a regularly scheduled monthly meeting 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.

FCR may result in one of the 3 outcomes listed below:

1. 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. Modifications required to secure approval: A proposal may require modifications to secure approval for one of the following reasons:
 - a) The IACUC considers that substantive changes must be made to secure approval or that there are significant points needing clarification before approval can be granted. This outcome correlates to the PHS Policy outcome referred to as “modifications required in (to secure approval)”. The IACUC has established a written policy that all IACUC members have agreed to that authorizes the quorum of members present at a convened meeting to decide by unanimous vote to use designated member review (DMR) subsequent to FCR when modification is needed to secure approval. The written policy also stipulates that any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. The modified protocol shall be reviewed using either FCR or DMR as determined by a majority vote of the members present at the convened meeting and following the processes as described in this document.
 - b) There is insufficient information available to make a determination.
 - c) There is some other reason requiring deferral of consideration.
3. 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, an IACUC-approved proposal can be administratively disapproved by the IO or the President/Chief Executive Officer for financial, facility-related or other reasons.

If the quorum present at the convened meeting requires minor, administrative, changes or corrections to a protocol, such changes shall be made in accordance with WesternU's IACUC Policy 2014-048 (below), "Changes to Approved Protocols", and the National Institutes of Health NOT-OD-14-126.

IACUC Policy 2014-048:

Changes Requiring Committee Review

The following significant changes in an IACUC-approved protocol must be submitted to the IACUC and approved either by Full Committee Review (FCR) or Designated Member Review (DMR) as described in PHS Policy IV.C.2.

- from non-survival to survival surgery
- resulting in greater pain, distress or degree of invasiveness
- in housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC
- in species
- in study objectives
- in Principal Investigator (PI)
- that impact personnel safety

Administrative Changes in Consultation with the Veterinarian

The following significant changes may be handled administratively in consultation with the Attending Veterinarian (AV) at either campus; i.e., per Veterinarian Verification and Consultation (VVC). In these instances, the AV is serving as a subject matter expert to verify that compliance with IACUC-approved policies is appropriate for the animals involved.

Consultation with the AV must be documented. The AV may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-approved policies.

- Change in diet, provided that the new diet does not create a new change in animal health status.
- Blood and tissue collection for genotyping:
 - 1) Change between approved methods of blood collection (route, frequency, volume) as stated within IACUC Policy 2014-004 "Blood Collection"
 - 2) Change between tissue types for genotyping according to IACUC Policy 2014-028 "Genotyping Rodents".
 - 3) Collection of additional tissue after euthanasia.
 - 4) Non-invasive collection of urine, saliva, feces or other specimens.
- Anesthesia, analgesia, sedation or experimental substances. Changes in anesthetic, analgesia or sedation regimens must be in accordance with the IACUC's approved Laboratory Animal [Formulary](#) per IACUC Policy 2017-056 or appropriately documented

by the AV if the dose, dosing frequency or duration of administration differs from the Formulary.

- Euthanasia to any method approved in the latest version of the [AVMA Guidelines for the Euthanasia of Animals](#)
- Duration, frequency, type or number of procedures performed on an animal
- Procedures:
 - 1) Change to study timelines as long as animal health is not expected to deteriorate.
 - 2) Addition of special husbandry or nursing care as prescribed by a veterinarian.
 - 3) Addition of pre-defined Pain Category C behavioral tests to approved protocols that already include behavior testing provided that there is an IACUC-approved Standard Operating Procedure (SOP) for the behavioral test to be added and that the request is documented in the protocol.
 - 4) Variations to previously approved surgeries that do not increase the invasiveness or expected outcomes.

Administrative Changes Not Requiring Consultation with the Veterinarian

As stated in the National Institutes of Health notice [NOT-OD-14-126](#), “A significant change that may be handled administratively according to existing IACUC policies without additional consultation or notification is an increase in previously approved animal numbers.” Pursuant to this Notice, it is the policy of WesternU’s IACUC that an increase in animal numbers shall be permitted provided that the following conditions are met:

- The request must be submitted by the Principal Investigator, in writing, to the IACUC Secretary or to the IACUC Chair.
- The request must include a detailed explanation of why the additional animals are necessary based on the original study objectives.
- A justification for the numbers of additional animals requested must be provided.
- The study objectives, as described in the approved protocol, must remain the same.

As noted above, a change in the original study objectives, or any change in protocol that impacts animal welfare, will require the request to be submitted to the IACUC for review and approval. Such changes may not be administratively approved. The only persons authorized to administratively approve an increase in animal numbers are the IACUC Chair and, in the Chair’s absence or unavailability, the Vice-Chair, and Attending Veterinarian.

Once approved, the amendment request, along with the IACUC’s approval, shall be attached to the end of the approved protocol and kept on file in the IACUC Office.

Other changes that may be made administratively without further consultation include:

- correction of typographical errors
- correction of grammar

- contact information updates
- changes in personnel other than the PI (However, there must be an administrative review to ensure that all such personnel are appropriately trained, qualified, enrolled in the occupational health and safety program and meet any other criteria as required by the IACUC.)

Once approved, the IACUC secretary shall 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 FCR is not requested, at least one member of the IACUC, designated by the Chair and qualified to conduct the review, shall be appointed to conduct a DMR of the applications. The reviewer shall convey his/her comments and concerns to the investigator, in writing, who then responds, in writing, to each concern. The DMR then decides if the investigator has adequately addressed the issues. If yes, the DMR 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 DMR informs the investigator of the issues that need to be resolved.

DMR may result in one of the following outcomes:

1. Approval: The designated reviewer(s) 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. Modifications required to secure approval: A proposal may require modifications to secure approval for one of the following reasons:
 - a) The DMR considers that substantive changes must be made to secure approval or that there are significant points needing clarification before approval may be granted. This outcome correlates to the PHS Policy outcome referred to as “modifications required in (to secure approval)”. The modified proposal will be re-reviewed by the DMR who will then decide if the investigator has adequately addressed the issues. If yes, the DMR 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 DMR informs the investigator of the issues yet to be resolved.
 - b) There is insufficient information available to make a determination.
 - c) There is some other reason requiring deferral of consideration.
3. Refer back to the IACUC for FCR: DMR may **not** result in disapproval. When more than one DM reviewer is appointed, if either reviewer feels that the protocol is not approvable, it must go back to the IACUC for FCR.

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. 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.

7. Review and approve, require modifications to (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy at IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are described above in Part III. D. 6.
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. Following review, the IACUC shall notify the investigator 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 at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

Conduct annual reviews by DMR, as described in Part III.D.6, of each previously approved, ongoing activity covered by PHS Policy. For the yearly review process, the IACUC may request that the investigator provide a written narrative or complete and submit an Annual Progress Report form that can be obtained from the Office of the IACUC. Any member of the IACUC may obtain, upon request, FCR of the annual report.

Continuing review of previously approved ongoing activities is also accomplished by means of the IACUC's post-approval monitoring (PAM) program as described in IACUC Policy 2016-055, "Post-Approval Monitoring":

The PI shall be notified at least one month in advance, either by the IACUC Secretary or the IACUC Chair, that one or more of their protocols will be audited. A meeting date and time will be selected when the PI and as many other research personnel as possible that are named in the protocol are available. The protocol audit will be conducted in the PI's office, laboratory or other available space. This does not, however, preclude spot inspections for cause.

Prior to meeting with the PI, Monitors (voting members of the IACUC) will familiarize themselves with the selected protocol(s) and any amendments or attachments. Using the Post-Approval Monitoring Checklist as a guide, Monitors will highlight areas of interest and formulate questions that they may have.

Exit Briefing: At the conclusion of the audit, the Monitor shall discuss the observations with the PI and other available research personnel named in the protocol to confirm that the observations are accurate. The PI and research personnel may offer additional information at this time. However, Monitors do not have the authority to approve or disapprove any changes in processes or procedures. They cannot negotiate an outcome. That authority belongs only to the IACUC.

The Monitor(s) shall report the findings of the audit at a convened meeting of the IACUC. If corrective actions are needed, the IACUC shall meet with the PI to discuss any action(s) to be taken, recommendations for improvement, a timeline for correction of any deficiencies and/or follow-up inspections, if needed. The PI will receive a copy of the final report(s) which will be filed in the corresponding protocol folder(s).

Protocol Selection Criteria: Protocols will be selected for PAM based on the following criteria:

- Principal Investigator (PI) history (e.g. past non-compliance issues)
- Multiple survival surgeries involved
- Food/water restriction involved
- Prolonged physical restraint involved
- Pain category D protocols (pain or distress; drug relieved)*
- Pain category E protocols (pain or distress; no relief provided)
- Protocols requiring housing of animals outside of a vivarium
- Recommendations based on concerns from Animal Care Staff
- Reports from other personnel (e.g. faculty, students, laboratory technicians, etc.)

*Protocols in pain categories D and E will receive higher priority for review than protocols in pain category C, although all protocols are subject to audit regardless of the pain category.

All approved protocols expire 3 years from their dates of approval per PHS Policy IV.C.1-5. Investigators shall be notified of the impending expiration of their protocol 60 days prior to the actual expiration date. To continue work on a protocol beyond the expiration date, the investigator must resubmit the protocol as a new protocol for review and approval, prior to expiration of the original protocol, which shall then be reviewed as if for the first time by FCR or DMR as described in Part III.D.6.

10. Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. 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 PHS Policy, Animal Welfare Act, the most recent edition of 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 IO in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report

that action with a full explanation to OLAW and other authorities, as applicable. The Institution shall also notify the sponsor.

IACUC oversight at the Lebanon, Oregon, campus is provided by appointing their Attending Veterinarian and one or more of their research scientists engaged in animal research to the University's IACUC. For real time audio and visual communication, IACUC meetings are streamed between campuses using Haivision Mako HD which has been in use at both campuses for several years. The Attending Veterinarian, Animal Facility Manager and IACUC member(s) at the Lebanon site shall be responsible for day-to-day oversight of animal activities at that campus and for conducting semiannual program and facilities reviews. The results of these reviews shall be combined with the reviews from the Pomona campus into a single semiannual review document and submitted to the IO as required. Any issues at the Lebanon site shall be brought to the IACUC Chair who will bring them before the full committee for open discussion and resolution.

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 posted on the University's intranet as part its Injury and Illness Prevention Program and on the IACUC's website. Prior to working with or around animals or animal tissues, faculty, students and staff, including facilities and safety personnel, must enroll in WesternU's Occupational Health and Safety Program which consists of completing a Risk Assessment Form and an on-line training course on Occupational Health and Safety. The Risk Assessment Form requests health information pertaining to allergies, physical limitations, immunocompetence, etc. This form contains protected health information (PHI) and is appropriately handled in accordance with HIPAA. Completed forms are submitted to and reviewed by a licensed nurse practitioner employed by the WesternU's Student-Employee Health office. After assessing the level of risk, the nurse practitioner shall forward a Health Clearance Form to the IACUC Chair with one of the following recommendations: 1) "I am not aware of any restrictions to this patient accepting such a position"; 2) "I believe that this patient may accept such a position but with the following restrictions"; 3) "The applicant should not accept such a position because the risks are unacceptably high". This form must be completed and submitted to the Student-Employee Health Office annually or more often as necessary.

Students enrolled in academic programs at WesternU are required to be up-to-date on their tetanus/diphtheria boosters as a condition of their acceptance into their program and are, therefore covered should they wish to participate in research or educational projects involving animals at the Lebanon, OR, and Pomona, CA, campuses. Veterinary medical students will also be required to show proof of immunity to rabies. Other than this, students volunteering to work in laboratories with animal care responsibilities must access occupational health services through their regular medical provider

Employees or visiting faculty who are uncertain of their immunization status may be referred to occupational health and safety experts at one of the facilities listed below with whom the University contracts for evaluation. If it is determined that immunization is warranted, WesternU shall cover the costs. These facilities provide additional occupational health and safety medical services to University faculty and staff in Pomona as needed and their name, address and contact information is posted inside each vivarium. The clinical staff of these facilities consists of highly qualified doctors,

physician assistants and nurses. Employees at the Pomona campus injured in the conduct of their duties with the University may be initially treated at the University-owned medical center on campus. Follow-up treatment, if required, is provided either by one of the listed facilities or the employee's primary care physician. Students may receive initial treatment at the University's medical center and follow-up treatment by their primary care physician. At the Lebanon campus, employees and students may be initially treated at the Samaritan Lebanon Community Hospital a block from campus with follow-up treatment provided by their primary care physician. Incident reports on all injuries or occupationally-related diagnoses at either campus must be submitted by the employee to the University's Office of Environmental Health and Safety (EH&S). The program is monitored by the IACUC and the Student-Employee Health Office.

Contracted Facilities:

<u>Pomona/Rancho Cucamonga:</u>	Dedicated Occupational Health Center - Ontario Medical Center, Ontario, CA After-hours/Urgent Care – Ontario Medical Center, Ontario, CA Hospital Services/After-Hours Care – Ontario Medical Center, Ontario, CA
<u>Van Nuys:</u>	Dedicated Occupational Health Center - Panorama City Medical Center, Panorama City, CA After-hours/Urgent Care - Panorama City Medical Center, Panorama City, CA; Santa Clarita Medical Offices, Santa Clarita, CA Hospital Services/After-Hours Care – Panorama City Medical Center, Panorama City, CA
<u>Los Angeles:</u>	Dedicated Occupational Health Center – West Los Angeles Medical Center, Los Angeles, CA After-hours/Urgent Care - West Los Angeles Medical Center, Los Angeles, CA Hospital Services/After-Hours Care – West Los Angeles Medical Center, Los Angeles, CA
<u>Rancho Mirage:</u>	Provider: Catlett, Steven, MD, Santa Rosa del Valle Medical Group, Palm Desert, CA

Prior to job placement, individuals shall receive general training in safe laboratory and animal use practices, including occupational health information. This training is repeated annually and includes hygiene, sharps management, personal protective equipment (PPE), decontamination practices, fume hood use, etc. Additional training to individuals in contact with animals shall be provided by the Attending Veterinarians in the areas of lab animal allergies (LAA), zoonoses and special precautions for pregnancy and immune suppression, by means of a handout. The Attending Veterinarians shall be available to answer questions about the information contained in the handout. 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 WesternU, the

following hazards/risks have been identified: rat/mouse/guinea pig exposure (e.g., allergens, bites, scratches), infectious agents, chemical hazards (e.g., cleaning solutions), wet surfaces, bedding materials (e.g., cedar), anesthetic gases, flammable or combustible gases (e.g., O₂), sharps, controlled substances, biohazards (e.g., recombinant DNA, tumor cells, etc.), 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 care and use, is reviewed semi-annually by the IACUC and the University's EH&S officer. Based upon this review, improvements are recommended and implemented.

- 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.
- G. The training or instruction available to scientists, animal technicians, students and other personnel involved in animal care, treatment or use at the Lebanon, OR, and Pomona, CA, campuses is available via the University's on-line IACUC 101 Training Program, the IACUC itself and the World Wide Web. The qualifications of personnel are reviewed when animal protocols are submitted and the level of training required is assessed. Training documentation 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 training administered by the IACUC. Animal Care and Use 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. Species-specific training covers the care, handling and research uses of the elected species. Advanced techniques training and species-specific training at the Pomona, CA, campus and at the Lebanon, OR, campus may be arranged upon request with the respective Attending Veterinarian for each campus with refresher training as required by the IACUC.

Training in the area of minimization of animal numbers is provided to scientists, animal technicians, and other personnel involved in animal care, treatment, or use (including the IACUC members). However, specific instructions on how to perform a power calculation are not provided. Personnel are informed that a power calculation is one way to justify to the IACUC that the number of animals needed has indeed been minimized. There have been cases, however, when the IACUC has recommended experimental designs that would reduce the numbers of animals needed or have asked investigators to explain why such designs would not be appropriate for their studies. The importance of using, whenever possible, methods that minimize pain is also covered noting that this is an area that the IACUC gives close scrutiny to when considering whether or not to approve a protocol.

To serve on the IACUC, each member is asked to attend an IACUC 101 training session sponsored by the OLAW. A copy of each member's Certificate of Attendance is kept on file in the Office of the IACUC. In addition, each member is provided with a copy of the most recent edition of the Guide and the American Veterinary Medical Association's Guidelines on Euthanasia. They are also directed to the Animal Welfare Act, the PHS Policy on Humane Care and Use of Laboratory Animals and the OLAW/ARENA IACUC Guidebook. A copy of the approved Animal Welfare Assurance is also provided to each committee member. The Attending Veterinarian provides additional guidance and training as needed. By way of continuing education, members are provided with copies of articles from professional journals and websites of professional organizations that deal with issues surrounding the care and use of animals in research and teaching, including social and political issues. These issues are often discussed in open forum at regularly scheduled meetings of the IACUC.

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 six months and will be re-evaluated by the IACUC at least once every six months according to PHS Policy IV.B.1.-2. Reports have been and shall continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports shall include a description of the nature and extent of this Institution's adherence to the PHS Policy and the most recent edition of the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports shall distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports shall contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations shall be submitted to the IO. Semiannual reports of IACUC evaluations shall be maintained by this Institution and made available to OLAW upon request.

This Institution is Category Two (2) – not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). Reports of the most recent IACUC's semiannual evaluations (program reviews and facility inspections) shall be submitted to OLAW along with the Animal Welfare Assurance.

V. Recordkeeping Requirements

- A. This Institution shall maintain for at least three 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, 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 view) as forwarded to the IO.
 5. Records of accrediting body determinations.

- B. This Institution shall maintain records that related 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. This Institution's reporting period is the calendar year (January 1 – December 31). The IACUC, through the IO, shall submit an annual report to OLAW by January 31st of each year. The report shall include:
 - Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
 - Any change in the description of the Institution's program for animal care and use as described in this Assurance
 - Any change in the IACUC membership
 - 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 IO.
 - Any minority views filed by members of the IACUC
 - If there were no changes in the program then the report will indicate that there were no changes.
- B. The IACUC, through the IO, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
 - Any serious or continuing noncompliance with the PHS Policy
 - Any serious deviations from the provisions of the most recent edition of the Guide
 - 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: Devendra K. Agrawal, Ph.D.
Title: Senior Vice President for Research & Biotechnology
Address: Western University of Health Sciences
309 E. Second Street
Pomona, California 91766-1854

Phone: (909) 469-7040

Email: dagrawal@westernu.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:

 Aug 21, 2019

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

Name: Jane. J. Na

Title: Veterinary Medical Officer

Address: 6705 Rockledge Drive RKL1, Suite 360,
Bethesda, MD 20892

Phone: (301)702-1922

Fax: (301) 451-5609

Signature:

Date

Assurance Number: D16-00558 (A3989-01)

C. Effective Date of Assurance: December 1, 2017

D. Expiration Date of Assurance: November 30, 2021

Appendix A

MEMBERSHIP OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Date: 6/1/17

NAME OF INSTITUTION: Western University of Health
Sciences ASSURANCE NUMBER: D16-00558 (A3989-01)

Chairperson Name, Title, and Degree/Credentials		Business Address, Phone, Fax, and Email of Chairperson		
Name: Donald Walters		Address: 309 East 2 nd Street, Pomona, CA 91766		
Title: Manager, Research Regulatory Affairs				
Degree/credentials: Ph.D.		Phone: 909 469-5592	Fax: 909 469-5693	Email: dewalters@westernu.edu
Name of Member*	Degree/Credentials	Position Title		PHS Policy Membership Requirements**
Marcelo Couto	DVM, PhD, DACLAM	Institutional Vet & Attending Vet for Pomona campus		Veterinarian
Member 2 (Vacant)				
Member 3	Ph.D.	Associate Professor		Scientist
Member 4 (non-voting)	B.S.	Animal Facilities Manager		Nonscientist
Member 5	Ph.D., DVM	Associate Professor		Scientist; Veterinarian
Member 6	DDS	Professor		Scientist
Member 7	Ph.D.	Associate Professor		Scientist
Member 8	BA	Librarian		Nonaffiliated/ Nonscientist
Member 9	Ph.D.	Associate Professor of Philosophy,		Nonaffiliated/ Nonscientist
Member 10	Ph.D.	Associate Professor		Scientist
Member 11 (non-voting)	B.S.	IACUC Secretary		Nonscientist
Member 12	DVM	Attending Vet for Lebanon campus		Veterinarian
Alternate Voting Members				
Member 5A	Ph.D.	Associate Professor		Scientist
Member 7A	Ph.D.	Associate Professor		Scientist
Member 10A	Ph.D.	Professor		Scientist

* Non voting members must be so identified

** **Veterinarian:** a veterinarian will direct or delegate program responsibility

Scientist: a practicing scientist experienced in research involving animals.

Nonscientist: a member whose primary concerns are in a non-scientific areas (e.g., ethicist, lawyer, member of the clergy).

Non-affiliated member: a member who is not affiliated with the institution in any way other than as a member of the IACUC, and who is not a member of the immediate family of a person who is affiliated. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting attending veterinarian may not be considered non-affiliated.