

UNIVERSITY OF CALIFORNIA, IRVINE
Assurance of Compliance with Public Health Service Policy
On Humane Care and Use of Laboratory Animals

A3416.01

February 2008

The University of California, Irvine, 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

- A. This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as "activities," involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this Institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or supported activity by this Institution.
- B. "Institution" includes the following branches and major components of the University of California, Irvine: All academic units at the campus (Irvine, California), including off-campus leased space, and all Medical Center (Orange, California) sites.
- C. When applicable, UCI Sponsored Projects staff will develop appropriate corresponding agreements to document subgranting or subcontracting of PHS-supported animal use activities and the transfer of all corresponding regulatory oversight responsibilities.

II. INSTITUTIONAL POLICY

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals ("Guide").

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

- A. The lines of authority and responsibility for administering the program and ensuring compliance with PHS Policy are demonstrated in the organizational charts provided as Attachment 1.
1. The UC Irvine Chancellor has delegated responsibility for compliance with all applicable regulations relative to the care and use of animals in research and teaching to the Vice Chancellor for Research.
 2. The Vice Chancellor for Research is designated as the Institutional Official (IO) of the animal program and is assisted in the discharge of this responsibility by the Associate Vice Chancellor for Research, the Institutional Animal Care and Use Committee (IACUC), the Attending Veterinarian and the Office of Research Administration.
 3. The IACUC reports directly to the Vice Chancellor for Research. Nominees for membership on the IACUC are submitted to the Vice Chancellor for Research who reviews the qualifications of the nominees and makes the appointments to the IACUC.
 4. The IACUC Chair is appointed by the Vice Chancellor for Research and is responsible for ensuring the IACUC performs its functions as outlined in the Animal Welfare Act, Animal Welfare Regulations, PHS Policy and this Assurance. The Chair serves as liaison with the IO on behalf of the IACUC. The Chair has the authority, on behalf of the IACUC, to halt any animal activity if the safety or welfare of an animal appears to be at risk, or if the work being performed on a project is not in accordance with the approved protocol. The Chair has the responsibility to address, in a timely fashion, any serious or repeated problems, concerns, complaints or allegations regarding the care and use of animals. The Chair evaluates the situation and makes recommendations for further action as appropriate.
 5. The Attending Veterinarian serves on the IACUC and is appointed by and reports to the Vice Chancellor for Research. The Attending Veterinarian directs the management of the campus animal facilities.
 6. The IACUC administrative staff report to the Vice Chancellor for Research through the Office of Research Administration (ORA). The ORA is the designated Office of Record for all federally mandated committee functions. The IACUC administrative staff are a resource for policy and program information and act as internal liaison between the IACUC and research investigators, University Laboratory Animal Resources, Sponsored Projects staff, Environmental Health and Safety, and other administrative and research units. With guidance from the Vice Chancellor (IO) and the IACUC, the IACUC administrative staff serves as administrative contact with external regulatory agencies and IACUC Administrators at other UC campuses and elsewhere to share interpretation of regulatory changes, institutional policy development, and overall awareness of animal program requirements and enhancements.

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

1. **Jeffrey Goodwin, D.V.M., Ph.D., Attending Veterinarian and Director, University Laboratory Animal Resources**

Dr. Goodwin received his B.S. and D.V.M. degrees and a Ph.D. in Veterinary Anatomy from Iowa State University and completed a postdoctoral training program in Laboratory Animal Medicine from the University of California at Davis. He holds memberships and is active in AALAS, ASLAP, and the AVMA. Dr. Goodwin's appointment at UCI is 100% time.

Dr. Goodwin has direct program authority for all animals at UCI, and the authority to implement the PHS Policy and the provisions of the Guide. Under the direction of the Institutional Official, Dr. Goodwin supervises housing and husbandry and ensures that adequate veterinary care is provided to all animals used for research, teaching and/or testing. His responsibilities with respect to adequate veterinary care encompass all aspects of animal well-being and the appropriate use of animals. They include supervising programs of disease detection, surveillance, prevention, diagnosis, treatment and resolution; the handling and restraint of animals; the use of anesthetics and drugs; methods of euthanasia; preoperative, operative, and postoperative care.

The Attending Veterinarian (or his designated appointee) is authorized to enter any place within the jurisdiction of UCI to conduct on-site inspections of animal facilities and animals to ensure that animal husbandry, sanitation practices, and animal health and research techniques are in compliance with relevant federal, state, local, and institutional requirements. The Attending Veterinarian is authorized to halt any animal activity if the safety or welfare of an animal is at risk or if the work being performed on a project is not in accordance with the approved protocol.

2. **Claire Lindsell, BVSc, MSc, PhD, DAACLAM, Assistant Director, University Laboratory Animal Resources**

Dr. Lindsell received a Bachelor of Veterinary Science (D.V.M. Equivalent) from Sydney University, Australia, a Master of Science degree in Theriogenology from the University of Saskatchewan, Canada, and a Ph.D. in Molecular Endocrinology from the University of Saskatchewan, Canada. Dr. Lindsell is a Diplomate of the American College of Laboratory Animal Medicine and holds membership in AALAS, ASLAP and LAWTE. Dr. Lindsell's appointment at UCI is 100% time.

The Assistant Director's responsibilities include veterinary pre-review of animal use protocols, alternate membership on the IACUC, voting membership on the Institutional Biosafety Committee, training and instruction of research personnel in the humane care and use of laboratory animals, shared after-hours veterinary coverage for the campus, oversight of ULAR's quality assurance program, clinical veterinary care of research animals, and backup to the Attending Veterinarian.

3. **Roger Geertsema, D.V.M., DACVPM, Associate Clinical Veterinarian**

Dr. Geertsema received his B.S. and D.V.M. degrees from the University of Minnesota. He is a diplomate of the American College of Veterinary Preventive Medicine and holds memberships in AALAS, ASLAP and the AVMA. Dr. Geertsema's appointment at UCI is 100% time.

The Clinical Veterinarian's responsibilities include clinical care of animals on campus, disease detection and surveillance, prevention, diagnosis, treatment and resolution. He provides training and instruction of research personnel in the humane care and use of laboratory animals, veterinary pre-review of animal use protocols, shared after-hours veterinary coverage for the campus, and backup to the Attending Veterinarian, as well as supervision of the Veterinary Care staff.

C. This Institution has established an IACUC, which is qualified through the experience and expertise of its members to oversee the Institution's animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy at IV.A.3.b. A list of the names, degrees, position titles, specialties, and institutional affiliations of the IACUC chairperson and all committee members is provided as Attachment 2.

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:
 - a. Program Evaluations are conducted at an additional meeting of the IACUC in January and July of each year. The program is evaluated on the basis of the Guide, the USDA Animal Welfare Regulations (AWRs), and UCI's Assurance of Compliance with PHS Policy, and AAALAC Program Description.
 - b. The IACUC Animal Program Review Checklist is used as a guide for review and report generation. Items noted on previous Program Evaluation reports are revisited, and new issues are added to the agenda for discussion and action as needed.
 - c. Any departure from the Guide, PHS Policy or the USDA AWRs is identified as either Minor or Significant (a significant deficiency is one which is or maybe a threat to the health or safety of animals). Each deficiency is given a reasonable and specific plan and schedule for correction.
 - d. In addition, suggestions for improvement to the program are discussed and implemented wherever possible. In some cases, additional fact finding, ad hoc subcommittee meetings and/or presentations to the IACUC may be required to complete the evaluations or recommendations.

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:
 - a. All IACUC members participate in semiannual facility inspections. Committee voting members are divided into subcommittees to inspect each facility. All animal study areas (as defined by USDA AWRs) and animal facilities, including satellite facilities where surgical procedures are performed (as defined by PHS Policy) are inspected at least once every six months. In addition, all animal facilities where non-surgical procedures are performed are visited not less often than once per year. In the event that a subcommittee cannot access a study area or animal facility during a regularly scheduled inspection, follow up visits are scheduled as needed.
 - b. Facilities are evaluated on the basis of the Guide, the USDA AWRs, and UCI's Assurance of Compliance with PHS Policy, and AAALAC Program Description. Laboratory staff and Principal Investigators are informed immediately of any deficiencies found; in most cases, a follow up email is sent, detailing the deficiency, the recommended course of action, and deadline for correction.
 - c. The Facility Inspection Form is used to inform researchers of inspection findings and deficiencies and convey other useful information. The form identifies the area reviewed, the departure from the Guide, and whether the deficiency is Minor or Significant (a significant deficiency is one which is or may be a threat to the health or safety of animals). Follow up contact by telephone and/or email is performed as needed.
 - d. The subcommittee reports are compiled by the IACUC administrative staff and brought to the full committee for review and approval. Each deficiency is given a reasonable and specific plan and schedule for correction.
3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3 and submit the reports to the Vice Chancellor for Research (IO). The IACUC process for developing reports and submitting them to the IO is:
 - a. Separate reports are prepared for the Program Evaluation and Facilities Inspection. Each report is prepared according to the OLAW sample format for the semiannual report to the IO.
 - b. The reports contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy.
 - c. Both reports identify any departures from the provisions of the Guide and PHS Policy and state the reasons for each departure.
 - d. Each report distinguishes significant deficiencies from minor deficiencies and contains a reasonable and specific plan for correction.

- e. Once approved by the full IACUC, reports are submitted to the IO. Special concerns may necessitate a follow-up meeting between IACUC representatives and the IO.
4. Review concerns involving the care and use of animals at the institution. The IACUC procedures for reviewing concerns are:
 - a. Complaints or concerns regarding the care and/or use of animals are directed to the IACUC administrative staff where they are documented and kept confidential.
 - b. An administrative audit then takes place to determine whether a possible occurrence of noncompliance warrants further attention. When an administrative audit reveals information that appears to substantiate an allegation of noncompliance with policies or regulations, all efforts are made to resolve the matter informally.

Possible outcomes of an administrative audit are:

 - dismiss allegation, or
 - achieve compliance with the cooperation of the Investigator, or
 - recommend review by IACUC Chair and, if necessary, the veterinarian, or
 - recommend review and action by the full IACUC.
 - c. All issues are brought to the attention of the IACUC. Compliance issues are a standard section of the monthly agenda. The IACUC promptly informs the Institutional Official of any serious or continuing noncompliance with the PHS Policy and/or the Guide, any serious deviation from the provisions of the Guide, and any suspension of an activity by the IACUC.
 - d. The IACUC, through the Institutional Official, promptly provides OLAW with a full explanation of the circumstances and actions taken with respect to any serious or continuing noncompliance with the PHS Policy and/or the Guide, any serious deviation from the provisions of the Guide, and any suspension of an activity by the IACUC. These reports include any minority views filed by members of the IACUC.
 - e. If requested, individuals who report animal welfare concerns and/or compliance issues will be apprised of the outcome via a written response from the IACUC.
5. Make written recommendations to the Vice Chancellor for Research (IO) regarding any aspect of the institution's animal program, facilities, or personnel training. The procedures for making recommendations to the IO are:
 - a. The IACUC submits written recommendations related to any aspect of the institution's animal program, facilities, or personnel training to the IO at the time of the Program Evaluation, when necessary.

- b. The IACUC Chair communicates regularly and meets with the Vice Chancellor for Research on an as needed basis to discuss issues and recommendations made by the IACUC. Written recommendations by the IACUC that occur between evaluations are presented promptly to the IO.
 - c. Regularly scheduled meetings of the Vice Chancellor for Research, the IACUC Chair, the Attending Veterinarian and Office of Research Administration staff facilitate communication between all parties charged with oversight and administration of the animal program. Additional meetings are scheduled as necessary.
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:
- a. Prior to implementing proposed research or teaching involving the use of live vertebrate animals, investigators must complete a protocol application and forward it to the IACUC staff. Administrative, veterinary and scientific pre-reviews are conducted; issues noted during pre-review are communicated back to the Principal Investigator for correction prior to the convened meeting.
 - b. All applications, with the exception of those outlined in 6.c. and 6.d. below, require full committee review, and are reviewed at a convened meeting with a quorum present. Decisions to approve, approve following modifications (table), or disapprove are made by a majority vote of the members present.
 - c. Research involving animals that are studied in their natural habitat without any invasive procedures and without harming or materially altering their behavior qualifies for designated review. Designated review consists of review by a subcommittee of the IACUC: one Committee member with expertise in the particular field of study, the Veterinarian, and IACUC Chair. All Committee members are notified of any designated review studies, provided with an electronic copy of the submission, and given the opportunity to participate in the review process and offer any concerns. If no member of the full committee has expressed a concern, the subcommittee members may approve the application. If any IACUC member feels full Committee review is necessary, the application will be placed on the agenda of the next scheduled IACUC meeting.
 - d. When animal research performed by or under the direction of UCI personnel is conducted entirely offsite at an OLAW-assured institution, UCI may accept registration of the off-site entity's IACUC approval in lieu of review and approval by the UCI IACUC. Registration of an off-site IACUC approval requires submission of the approved protocol and off-site entity's IACUC approval letter to the UCI IACUC for review by a subcommittee of one (e.g., the IACUC

Chair or designee). UCI reserves the right to limit, suspend or terminate the involvement of UCI personnel in studies approved by off-site entities. Off-site protocol registrations reviewed by subcommittee will be acknowledged at the next convened full IACUC meeting and appended to the minutes. Protocol registration dates coincide with the offsite location's approval period. All protocol modifications and annual renewals approved by the offsite entity's IACUC must be submitted by the investigator to UCI's IACUC in order to maintain UCI IACUC registration in good standing.

- e. The IACUC meets once each month at a convened meeting or as necessary to review proposals for the use of laboratory animals in research and teaching.
 - f. Prior to Committee review, each Committee member is provided with a copy of each of the protocols on the agenda and in sufficient time for adequate review prior to the meeting.
 - g. A primary and secondary reviewer is assigned for each protocol on the agenda. During the Committee meeting, the primary reviewer is responsible for leading discussion with regard to the proposed research as well as making a recommendation on behalf of himself/herself and the secondary reviewer for approval, approval following modifications (table), or disapproval.
 - h. If modifications are required, the Committee determines if review of those modifications can be assigned to a subcommittee (designated review) or must be returned for review to the full Committee at a convened meeting. The subcommittee is composed of at least the Chair or the primary and secondary reviewer of the protocol. The subcommittee has the authority to approve, require modifications in (to secure approval), or request full Committee review.
 - i. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest. IACUC members who are personally involved in the project are recused from the room during discussion and vote.
 - j. Any member who has a conflicting interest in the project under discussion is recused from the discussion and vote on that project, and does not contribute to the constitution of a quorum for that discussion/vote.
 - k. The IACUC may invite consultants to assist in the review of complex issues. However, consultants cannot vote with the IACUC, nor may they approve or withhold approval of an application.
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 changes in ongoing research projects are:

- a. Prior to implementing any change to an approved project, investigators must complete a Modification Request form. Changes include those in personnel, location, species, procedures, drugs, etc.
- b. All modifications containing "significant" changes as determined by the IACUC, with the exception of those outlined in 7.c. below, require full Committee review, and are reviewed at a convened meeting with a quorum present. Decisions to approve, approve following modifications (table), or disapprove are made by a majority vote of the members present.
- c. A Designated Review Subcommittee may review modifications containing significant changes as defined in 7.d. below. The Designated Review Subcommittee is appointed by the IACUC Chair and consists of one scientific IACUC member and one veterinarian. If additional expertise is needed, the Chair may appoint ad hoc members to assist in the review.
- d. The IACUC has established criteria for the types of significant protocol modifications suitable for Designated Review. These include minor increases in the number of animals allocated to the project (i.e., 10% or less of the originally approved allocation) refinements in or changes to the anesthesia regimen, addition of an AVMA approved euthanasia method, decrease in the invasiveness of a procedure, modification to decrease pain or distress, addition of a non-invasive procedure and any other changes deemed appropriate by the full IACUC.
- e. Modifications submitted for designated review are forwarded electronically to all IACUC members on Friday of the week they are submitted. IACUC members are given 5 business days to review modification requests, ask questions, and request additional clarifying information. During the review week, any IACUC member may call for full committee review of any given modification request by contacting the IACUC Administrator by a predetermined time. Modification requests thus referred are added to the agenda for the next regularly scheduled IACUC meeting and the Principal Investigator is notified.
- f. If no calls for full committee review are received, the modification will undergo designated review and can be approved by the subcommittee. Designated Review members will review the modification request and the entire protocol file during the review week. The subcommittee may request clarification from the investigator and approve the modification if warranted. They also may decide to refer the modification for full committee review at the next convened IACUC meeting. If the subcommittee requests full committee review, the IACUC Administrator will add the modification to the agenda of the next full IACUC meeting, inform the investigator in writing, and assign an IACUC member of the designated subcommittee as primary reviewer,

he/she is required to resubmit a new protocol for full *de novo* Committee review at a convened meeting.

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:
 - a. 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 USDA Animal Welfare Regulations, the Guide, the Institution's Assurance, or the PHS Policy.
 - b. The IACUC may suspend an approved protocol only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of the majority of the quorum present.
 - c. A letter is sent to the investigator with a copy to the Institutional Official advising them of the IACUC's decision to suspend. The investigator is given an opportunity to respond and correct the problems.
 - d. If the IACUC suspends an approved protocol 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 the USDA when applicable.
 - e. If the safety or welfare of an animal appears to be at risk, or if the work being performed on a project is not in accordance with the approved protocol, the IACUC Chair or Attending Veterinarian is authorized to halt animal activity until the situation can be brought to the attention of the full IACUC.

E. The individual(s) authorized by this institution to verify IACUC approval of those sections of the applications and proposals related to the care and use of animals is/are:

- Vice Chancellor for Research
- Assistant Vice Chancellor for Research Administration
- Office of Research Administration Directors
- Office of Research Administration Assistant Directors
- Office of Research Administration Administrators / Contract and Grant Officers / Sponsored Research Analyst

F. The Occupational Health Program for personnel who work in laboratory animal facilities or have frequent contact with animals is described below:

1. Program Overview
The Department of Environmental Health and Safety (EH&S) has responsibility for administering the Laboratory Animal Occupational Health Program (LAOHP), in coordination with the Office of Research Administration (ORA) and University Laboratory Animal Resources (ULAR). Mandated by federal requirements and external laboratory animal care

accreditation agencies, the primary goal of the LAOHP is to evaluate and, if necessary, address potential health risks that may be associated with the use of animals in the research environment. The LAOHP is coordinated and managed by the Occupational Health Program Coordinator, a registered nurse, in consultation with an Occupational Health physician.

2. Scope

All faculty, staff, visiting researchers and students who work directly with vertebrate animals or lab animal tissues (unfixed animal tissues or body fluids) and those who work in animal housing areas (animal care, Facility Management and contracted custodial workers) are required to participate in the LAOHP.

3. Program Description

All participants must submit a medical questionnaire to the Occupational Health Program Coordinator upon initiation of their work with animals at UC Irvine and annually thereafter.

All participants are informed of the inherent risk of zoonoses, allergies, and other hazards associated with lab animal contact. These topics also are covered in the ULAR orientation session that is required prior to vivarium access. Pamphlets and brochures on these topics are available throughout the vivaria and on the ULAR website.

If the employee or student works with or handles non-human primates, or pregnant or neonatal sheep, they must also attend specific training facilitated by ULAR. This training includes participation by UC Irvine's Biosafety Officer and others as required.

Animal protocols submitted for review by the IACUC are first assessed by EH&S for occupational health and other safety requirements. This assessment includes reconciliation with the LAOHP database to assure participation of all employees and students listed on animal protocol submitted to the IACUC each month. An annual reconciliation with the LAOHP database is conducted to assure participation of all ULAR, Facility Management, and contracted custodial workers.

4. Identification of Persons at Risk

As part of the protocol submission process, employees or students are directed to submit the medical surveillance information as follows:

- a. Employees or students complete the LAOHP Questionnaire, available on the EH&S website.
- b. The questionnaire is submitted to EH&S and assessed by Occupational Health Program Coordinator, following an established protocol. Medical questionnaires which indicate health concerns are referred for further assessment by a medical provider.
- c. Female employees or students who are pregnant or planning to become pregnant are advised to take additional precautions while working with animals. It is recommended that these individuals

discuss the pregnancy and work environment with their personal medical provider, supervisor, or the Occupational Health Program Coordinator. Information regarding reproductive health risks are included in EH&S Laboratory Core Safety Trainings.

5. **Exposure Control Methods**
The control of exposures to occupational hazards associated with animal research or handling is achieved through the application of engineering controls, work practices and the used of personal protective equipment. If engineering controls do not adequately control the exposure potential, work practices are modified to help minimize exposure potential. Personal protective equipment may be required as a last step for exposure control and is available at no cost to the program participant.
6. **Medical Surveillance of BSL 2 and BSL 3 Laboratories**
The Occupational Health Program Coordinator manages medical surveillance activities for researchers conducted in Biosafety Level 2 and 3 facilities that involve the release of organisms containing recombinant DNA. Appropriate referrals are made and records are maintained. No research requiring Biosafety Level 4 facilities is conducted at UCI.
7. **Medical Management of Injury or Illness**
A notification and medical treatment program is in place for accidents, including bites and scratches. For non-emergencies, the program participant is directed to immediately notify the supervisor of the work area and submit an on line Incident Report. Detailed information regarding referral procedures and locations is available on the EH&S website.
8. **Immunizations**
Tetanus immunization is recommended for all animal handlers in accordance with the guidelines of the federal Centers for Disease Control. The decision to provide other immunizations to employees or students is made when a recognized risk associated with the research or animal handling activity is identified during the protocol review process. If such occupational health services are indicated, they are provided at no cost to the employee.

Hepatitis B vaccine (HBV) is available to employees who are involved in research which may expose them to bloodborne pathogens or other potentially infectious materials.
- 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 as Attachment 3.
- H. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is:
 1. IACUC policies and guidelines are in place to assist researchers with protocol development and animal care, treatment and use, including guidelines for conducting alternative searches and determining and justifying the number of animals needed to obtain scientifically valid results. The IACUC policies and guidelines are posted on the UCI Website. Information

and updates pertaining to Institutional and IACUC policies and guidelines also is disseminated electronically to animal users via listserv.

2. Regularly scheduled classes on rodent and rabbit handling, aseptic rodent surgery and sterile surgical suite operations are offered by Veterinary Services. In addition to the regularly scheduled classes, Veterinary Services is available for individual instruction/consultation on topics such as animal handling, anesthesia, analgesia, new techniques, etc.
3. ULAR veterinarians provide protocol advice regarding specific techniques and procedures, such as anesthetic and analgesic use, assessment of pain and distress, and reporting of animal welfare concerns.
4. The animal husbandry staff participate in regularly scheduled educational seminars that range from review of the Laboratory Animal Care Course (Purina Mills, Inc.) to presentations by investigators discussing their particular research projects. The husbandry and veterinary technical staff are also encouraged to participate in local and national branches of AALAS, including attending regional and national meetings. Certification by AALAS is encouraged.
5. The IACUC requires all personnel working with animals to successfully complete the *Working with the IACUC* online training module offered by the Collaborative Institutional Training Initiative (CITI). This module covers core concepts for the responsible conduct of animal research and is required of all research personnel before they can be listed on an IACUC-approved protocol. Specific content includes an overview of animal welfare regulations, veterinary consultation, occupational health and safety (e.g., zoonoses and other animal hazards), and a thorough discussion of the “3Rs,” including recommendations for (a) minimizing the number of animals needed to obtain valid results and (b) refining procedures and techniques to minimize pain and distress in the animals. Additional CITI courses are required based on the actual species to be used and procedures to be performed, e.g., *Reducing Pain and Distress in Laboratory Mice and Rats*, *Aseptic Surgery*, *Working with Mice in Research Settings*, etc. In addition to the required CITI courses, classroom training and orientation provided by ULAR staff is required before access to campus vivaria is granted to research personnel.
6. Newly appointed IACUC members are required to complete the CITI module *Essentials for IACUC Members*.
7. The IACUC evaluates personnel qualifications, training and experience as part of protocol review and requires additional training when necessary. The Committee occasionally requires veterinary participation in initial procedures until all laboratory personnel become proficient. When this occurs, the veterinarian provides updates under the veterinary report at convened IACUC meetings. The IACUC also has approved guidelines for investigators to use when training inexperienced personnel in the use of live animals in their laboratories.
8. The Office of Research Administration offers a comprehensive, certificated training program, Research Administration Management Program (RAMP),

to meet the research administration needs of the campus. The goals of this program are to provide the campus with an improved understanding of regulations, policies, and procedures; to strengthen internal controls; and to provide staff and researchers with access to important resources and contacts when they need help. RAMP consists of 15 courses that are scheduled multiple times during the year at the main campus and Medical Center. In order to earn the RAMP certificate, participants are required to take a total of ten courses: seven required core courses designed to build competencies in basic research administration topics and their choice of three optional courses. One of the core courses is Ethical Care and Use of Animals. This course reviews the fundamental regulatory requirements and ethical principles for the care and use of animals involved in research, testing and teaching. Attendees learn about the protocol application and renewal processes, protocol management, animal purchasing, transportation and transfer issues, participation in the occupational health program, and available veterinary services.

IV. INSTITUTIONAL STATUS

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

All IACUC semiannual reports will include a description of the nature and extent of this institution's adherence to the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC evaluations will be submitted to the Vice Chancellor for Research. Semiannual reports of IACUC evaluations will be maintained by this institution and made available to the NIH Office of Laboratory Animal Welfare (OLAW) upon request.

V. RECORD KEEPING

A. This Institution will maintain for at least three years:

1. A copy of this Assurance, and any modifications thereto, as approved by PHS.
2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
4. Records of semiannual IACUC reports and recommendations (including

minority views) as forwarded to the Vice Chancellor for Research.

5. Records of accrediting body determinations.
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.
 - C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

IV. REPORTING REQUIREMENTS

- A. At least once every 12 months, the IACUC, through the Institutional Official, will report in writing to OLAW:
 1. Any change in the status of the institution (e.g. if the institution becomes accredited by AAALAC or AAALAC accreditation is revoked), any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, this institution will submit a letter to OLAW stating 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 Chancellor for Research.
- B. The IACUC, through the Institutional Official, will provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:
 1. Any serious or continuing noncompliance with the PHS policy.
 2. Any serious deviations from the provisions of the Guide.
 3. Any suspension of an activity by the IACUC.
- C. Reports filed under VI.A. and VI.B. above shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

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Date: 2/14/08

B. PHS Approving Official

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Date: 2-20-08

C. Effective Date of Assurance:
2-20-08

D. Expiration Date of Assurance:
2-28-12