DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-2803

June 27, 2007

Re: Animal Welfare Assurance
A3196-01 [OLAW Case 3N]

Dr. Roberto Peccei
Vice Chancellor for Research
University of California, Los Angeles
405 Hilgard Avenue
Los Angeles, CA 90024-1405

Dear Dr. Peccei,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 19, 2007 letter reporting the suspension of an animal activity at the University of California- Los Angeles (UCLA), following up on an initial telephone report on March 5, 2007. The Institutional Official (IO) took this action in response to the identification of multiple violations consisting of: housing mice in an unapproved location for up to three months; stacking multiple cages with mice for housing; using a room with minimal ventilation, no standard light cycle, no monitoring of temperature or humidity; housing mice under overcrowded conditions; failing to keep daily animal monitoring records; and failing to keep the area clean. The mice were administered carcinogens and staff failed to adhere to required safety procedures for personal protection and waste disposal. It was determined that the institutional veterinarian did not have access to the room and that the noncompliant activities were carried out by a graduate student with minimal supervision by the Principal Investigator (PI).

The immediate corrective actions consisted of relocating the mice to an authorized space, separating the overcrowded cages, and euthanizing some animals. The PI was counseled by the Institutional Animal Care and Use Committee and an audit was conducted of all of this investigator's studies. The actions required of the PI prior to lifting the suspension consisted of implementing regular laboratory staff meetings, retraining of investigative staff on biosafety issues, retraining the PI on research animal regulations, re-certifying the fume hood, and amending the protocol. The requirements were subsequently met to the satisfaction of the IACUC and the suspension was lifted however the IACUC will maintain enhanced oversight of this laboratory.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. OLAW understands that the protocol involved was not PHS-supported, but concurs that the incidents were serious and supports the actions taken by the IO and IACUC. The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals at UCLA are commendable and avoid the perception of a double standard.

Thank you for keeping OLAW apprised on this matter.

Sincerely,

Axel Wolff, M.S., D.V.M.
Director,
Division of Compliance Oversight

cc: William McBride, Ph.D., IACUC Chair
Kathy Wadsworth, Associate Director-Animal Subjects Research

UCLA
UNIVERSITY OF CALIFORNIA,
LOS ANGELES

ROBERTO PECCEI
Vice Chancellor for Research

Box 951405
Los Angeles, CA 90095-1405
phone: 310-825-7943
fax: 310-206-6030
rpeccei@conet.ucla.edu

June 19, 2007

Axel V. Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

RE: Final Report of Suspension of Activities
Animal Welfare Assurance A3196-01

Dear Dr. Wolff,

I am writing to provide you with a final report regarding a suspension of activities, which was initially reported to you by Associate Director Kathy Wadsworth on March 5, 2007, in accordance with PHS Policy IV.C.8[1]. The incident was initially reported to the Chancellor's Animal Research Committee (ARC) on February 27,2007 and involved multiple, serious violations of the ARC Policy on Maintaining Animals in Study Areas (attached). The protocol was not supported by federal funds, and did not involve USDA-covered species.

As Ms. Wadsworth informed you on March 5, 2007, a Specialist from UCLA's Office of Environment, Health and Safety (EH&S) inspected a study room in response to complaints from UCLA staff regarding an animal smell emanating from the room[2]. At that time, the EH&S Specialist noted that mice were housed in the room. When the Biosafety Officer questioned ARC staff about the room, it was noted that the room was

[1] PHS Policy IV.C.8, *"If the IACUC suspends an activity involving animals, the Institutional Official 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"*

[2] The EH&S Specialist gained access to the room via UCLA custodial staff.

approved as a "Research Area" (i.e., an area where animals are held for < 12 hours), but was not approved as a housing location.

On the morning of February 27, 2007, Associate Director Kathy Wadsworth contacted the Principal Investigator responsible for the room, to obtain entry to the room to confirm the EH&S Specialist's findings, and to permit DLAM husbandry staff to inspect the animals' health status. The PI informed Ms. Wadsworth that he did not have the key, but that the room was used by a member of his research staff ("Dr. E") who did have the key.

At 2:00 p.m. of the same day, Ms. Wadsworth, DLAM Executive Director Marcelo Couto, ARC Assistant Director Andrew Perkins, and a DLAM health technician, met with "Dr. E" to inspect the room. Upon entering the room, the following violations of ARC Policy and the *Guide for the Care and Use of Laboratory Animals* were noted:

- Approximately 46 cages of mice were stacked on the lab bench, many stacked three-high, impairing ventilation of the lower cages. "Dr. E" indicated that he had "solved" the ventilation problem by lifting the filter tops to allow more air in. Unfortunately, this resulted in the upper cages appearing precarious and possibly impairing function of the sipper tubes used to provide water to the animals[3].
- "Dr. E" indicated that the animals had been housed for 2-3 months in the room. Although he stated that the animals were monitored daily, there was no documentation to verify his claim[4].
- The room had near-zero ventilation, which produced a very strong odor. Further, the airflow in this room was such that odors and allergens were blown into the common corridor.
- Cages were stored amongst unknown/unlabeled chemicals[5].
- No standardized light cycle was in use[6].
- There was no monitoring of temperature/humidity[7].
- Many overcrowded cages, some of which were seriously overcrowded, were noted.
- Wire lids, filter tops, and other caging items were stored uncovered on the floor.
- The room was generally cluttered, dirty, and unsuitable for use as a housing area.

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[3] ARC Policy on Maintaining Animals in Study Areas: "*... provisions must be made to ensure that harmful or unacceptable concentrations of toxic gases, odors, or particles" do not accumulate in an animal's primary enclosure."*

[4] : "*Daily observation of animals must be recorded in the study area log."*

[5] : "*Hazardous biological, chemical, or physical agents must not be stored or used where animals are housed."*

[6] : "*Light in animal holding rooms should provide for adequate vision and for neuroendocrine regulation of diurnal and circadian cycles...A time-controlled lighting system should be used to ensure a regular diurnal cycle, and timer performance should be checked periodically to ensure proper cycling."*

[7] : "*Temperature and humidity must be monitored and recorded on a daily basis to ensure that adequate levels of these environmental factors are maintained in the study area."*

The inspection team was unable to obtain a definitive answer about whether the research staff had entered the vivarium barrier facility after working in this room. This was of significant concern due to issues of cross-contamination and infection within the animal vivarium. Additionally, "Dr. E" implied that All-Trans-Retinoic acid and Cadmium chloride were administered to mice in the unauthorized housing room. As such, it did not appear that appropriate precautions were taken by personnel involved in the care and use of the mice, including use of appropriate Personal Protective Equipment (PPE), and proper medical waste disposal for bedding and animal carcasses according to procedures established by EH&S. Moreover, the inspection team was not advised of the possible presence of carcinogens prior to entering the room. It was also unclear where "Dr. E" euthanized animals housed in the unauthorized housing room (the protocol indicates that euthanasia is to be conducted in a room which is off limits to animals that have been removed from the vivarium).

At the time of the inspection, "Dr. E" was advised of the following: 1) He was to identify animals that could be euthanized immediately; 2) All remaining animals were to be transferred to an appropriate animal room and all overcrowded cages separated no later than the next morning. DLAM staff confirmed that all animals were transferred to the animal room, and overcrowded cages separated that afternoon; 3) Existing experiments could be completed in the return room; however, per standard DLAM breeding policy, any new experiments must be carried out in the barrier facility and not in the return room.

In accordance with the ARC Policy on Authority of the Attending Veterinarian[8], DLAM Executive Director Couto suspended all animal activities in the unauthorized room. Due to the serious nature of the incident, as the Institutional Official for UCLA, I suspended all activities conducted under the protocol until such time that the ARC was able to conduct a full review of the circumstances relating to the incident. While I understood the disruption the suspension placed on the ongoing research, I believed this was the most appropriate action based on the concerns raised by the inspection team. In my letter of suspension to the Principal Investigator, I documented the findings of the inspection team, which led to my decision to suspend the protocol. I also expressed to the PI my concern that he did not have access to the room, nor did anyone else, most notably the Campus Veterinarian, which is a violation of ARC Policy[9].

In accordance with the ARC Policy on Investigating Allegations of Mistreatment or Other Noncompliance Issues[10], the investigator was offered the

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[8] ARC Policy on Authority of the Attending Veterinarian, *"the attending veterinarian may immediately stop research activities conducted under a protocol for humane reasons or protocol deviations pending ARC review of an incident.*

[9] ARC Policy on the Authority of the Attending Veterinarian: *"The attending veterinarian must have unrestricted access to all areas where animals are used or housed (including the vivarium, research laboratories, and research study areas)."*

[10] *"In every investigation, the person(s) against whom the complaint has been raised shall be given notice of the concern and provided an opportunity to address the allegations in writing."*

opportunity to address this incident. This matter, and the Principal Investigator's comments regarding the incident, were reviewed at the convened meeting of the ARC on March 12, 2007.

In his response, the PI affirmed that the mice were housed in the unauthorized room:

> *"It was done by a graduate student in an attempt to breed additional mice to hasten his experiments. The student was the only person with access to the room and knowledge of the extent of the conditions. Although the implication is that the conditions in the room were bad, it has determined by the reports from ["Dr. E"] that the breeding in the room was occurring at a much better rate than in the B-floor vivarium (number of litters maintained by females without cannibalization)."*

In response to the use of cadmium chloride, the PI stated:

> *"It may be true that the room was not approved by the IBC* [Institutional Biosafety Committee] *for administration of cadmium chloride, although I do not know if this is true, but the room was clearly approved for mouse experiments with radiolabelled cadmium (Cd-109). A Radiation Safety Officer inspected the facility for this purpose a number of years ago. It is my recollection, that this authorization was also deemed acceptable by the Biosafety Officer at the time, but I am unsure of this. The only person that had access to the room was a graduate student, who is a physician, and has knowledge of the toxicity of cadmium. Non-research personnel were not given access to the room. The cages from the room were taken to the same facility that cages are taken to from the vivarium room."*

In response to the perceived lack of oversight for the experiments conducted under the PI's approved protocol, he stated:

> *"I am willing to take responsibility for the lack of oversight and I am assuming that you will direct punitive measures accordingly. I admit that my style of management allows students a tremendous amount of freedom. However, it is not unusual for me to not have a key to a small room where research is occurring. Students frequently maintain the only key (except for the persons responsible for maintenance of the facilities) for such small research facilities. The room in question is a darkroom facility. It may be that I actually have a key to the room, but in fact I have dozens and dozens of keys in my office, and I was unable to locate and I am still unable to locate a key to that room."*

The Committee informed the PI that though they appreciated his willingness to take responsibility for the violations pertaining to this protocol, they continued to express serious concern regarding his reaction to the violations. Regarding his response to his justification for using the room for breeding purposes, the Committee expressed grave concern that these statements implied his support for the unapproved

housing, as well as his disregard for the policies and regulations pertaining to laboratory animal housing at UCLA. In the Committee's subsequent correspondence to the PI, they underscored that failure to adhere to applicable regulations is unacceptable regardless of the experimental outcome.

In response to the use of cadmium chloride in that room, the Committee reminded the PI that though the room was previously approved for use of *radiolabelled* cadmium (Cd-109), at the PI's request, the Radiation Safety Division surveyed the room on August 31, 2005 and removed Cd-109 from his radioactive material use authorization. The ARC was notified that the last shipment of Cd-109 was received by the PI on October 23, 2003, and the IBC had not inspected or approved the room for administration of cadmium chloride.

In response to the PI's comment regarding his "*style of management* [which] *allows students a tremendous amount of freedom,*" the Committee reminded the PI that the University, investigators and their research staff, and the ARC share a collective responsibility for the ethical conduct of research at UCLA. The Committee also reminded the PI that as Principal Investigator, he is responsible for upholding the federal, State and local policies and regulations governing the humane care and use of laboratory animals. The PI was also reminded that as Principal Investigator, he is accountable for ensuring that all personnel listed under his approved protocol(s) understand all procedures described therein and perform their duties in accordance with the aforementioned regulations and policies.

In order to understand the extent of the violations cited above, the ARC requested an audit of all of the PI's currently approved protocols. The audit took place on April 2 & 3, 2007, and involved a complete inspection of all animal facilities used to house his animals, and concluded with a meeting with the PI and his lab staff to determine their knowledge of the protocols and the applicable regulations and policies pertaining to his research. During the meeting, the PI and his staff demonstrated a thorough understanding of all aspects of the approved protocols, though it was clear that he and his staff required additional training in the use of biohazardous agents.

The Committee reviewed the results of the audit during the meeting held on April 9, 2007. They determined that additional actions were required prior to lifting the suspension of the study, including development of a corrective action plan to prevent future noncompliance. In order to assist the PI in developing an appropriate plan, the Committee requested that the following actions be included in the corrective action plan:

a. To improve communication within his lab, the ARC requested that the PI initiate regular, weekly lab meetings with his staff to discuss study progress, as well as to discuss issues and questions pertaining to the research.

b. Arrange a meeting between the PI, his staff, and the Biosafety Officer, to review the Agent Summary sheets for Cadmium Chloride and all-trans retinoic acid. During the meeting, the Biosafety Officer would also reviewed proper handing and storage of biohazardous agents, we well as proper disposal of any subsequent waste materials.

c. Re-inspection and re-certification of the fume hood in the investigator's lab.

d. Amend the protocol to include the investigator's lab as a research area, and indicate the use of the fume hood in that room.

The Committee also required that the PI and his research staff each undergo retraining in medical waste management, hazardous chemical waste procedures, and SPF barrier procedures, prior to lifting the suspension of the protocol. The PI was also required to undergo retraining in the applicable federal, State, and local laws and regulations pertaining to research involving vertebrate animals.

During the ARC meeting of April 25, 2007 the Committee reviewed the corrective action plan provided by the PI. As recommended, the PI and his staff completed most of the required retraining, and will conduct weekly lab meetings. The remaining actions to be completed included retraining in medical waste management, hazardous chemical waste procedures, and SPF barrier procedures, and re-inspection of the fume hood located in the PI's lab. As such, the Committee voted to lift the suspension of the study. The investigator was also notified that the suspension was lifted contingent upon his continued compliance with all federal, State and local policies and regulations governing the humane care and use of laboratory animals. The PI was also notified that the ARC will conduct periodic unannounced inspections of his laboratory and animal facilities, beyond the required semiannual inspections.

If you have any questions or concerns, please do not hesitate to contact me at (310) 825-7943.

Sincerely,

Roberto Peccei
Vice Chancellor for Research

Encl: ARC Policy on Maintaining Animals in Study Areas

cc w/o encl: Linda Rosenstock, Dean, School of Public Health
William H. McBride, Chair, ARC
Judith L. Brookshire, Director, OPRS
Kathy Wadsworth, Associate Director, Animal Subjects Research

University of California, Los Angeles
CHANCELLOR'S ANIMAL RESEARCH COMMITTEE (ARC)

Maintaining Animals in Study Areas

I. DEFINITIONS

Study Area: Any investigator-managed building, room, area, enclosure, or other containment site in which animals are housed for periods longer than 12 hours.

AWARs: USDA Animal Welfare Act Regulations

PHS Policy: Public Health Service Policy on Humane Care and Use of Laboratory Animals

The *Guide*: National Research Council *Guide for the Care and Use of Laboratory Animals* (http://www.nap.edu/readingroom/books/labrats)

II. FEDERAL REGULATIONS AND PRINCIPLES

The *US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, Principle VII* states that "the living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must 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." In accordance with this principle, the USDA AWARs and the *Guide* set standards that are mandatory for the environment, housing, and management of laboratory animals. These documents form the basis for ARC evaluation of animal facilities and study areas.

III. ARC REQUIREMENTS

In accordance with the USDA AWARs and PHS Policy, the ARC is required to conduct inspections of all animal facilities, including, but not limited to, areas where animals are maintained for periods longer than 12 hours, at least once every six months. Animals may be housed in study areas provided:

- Scientific justification for this arrangement is approved by the ARC. Please note that convenience is not considered acceptable justification for use of a study area. In cases where suitable housing is not available in the vivarium facilities, the ARC may rescind approval of any study area at such time as suitable vivarium housing becomes available.
- The study area is inspected and certified by the ARC at least once every six months. ARC certification of a study area is valid for a 6-month period after the date of inspection with the condition that acceptable standards are maintained.
- The Campus Veterinarian (x42571 or mcouto@mednet.ucla.edu) is notified when animals are brought to and removed from a study area in order to facilitate the identification of active

areas which require oversight by the ARC and DLAM.
NOTE: Investigators maintaining study areas located at the Sepulveda or West Los Angeles campuses of the VA Greater Los Angeles Healthcare System (VAGLAHS) must notify the VAGLAHS Veterinary Medical Officer when animals are brought to and removed from their study areas.

- Copies of study area logs are submitted to the Campus Veterinarian or designee on a monthly basis or at the end of the study period, whichever comes first (see Section IV.C.1).
- Ventilation in the study area is adequate as measured by Facilities Management (see Sections IV.A.4 and IV.C.3).
- The Campus Veterinarian or designee is given access (i.e., a key or combination) to the study area for evaluation of animal health and well-being (see Section V).

IV. GUIDELINES FOR ANIMAL ENVIRONMENT, HOUSING, AND MANAGEMENT

A. Animal Facility

1. Sanitation

The study area must have a regular sanitary maintenance schedule and must be kept clean, neat, and uncluttered. The *Guide* (p. 44) states that "all components of the animal facility…should be cleaned regularly and disinfected as appropriate to the circumstances and at a frequency based on the use of the area and the nature of likely contamination."

2. Food/Bedding Storage

Food and bedding materials must be stored in closed containers to avoid contamination and the potential spread of disease. Containers must seal so that vermin are excluded from the food and bedding being stored, and must be made of a material such that the container can be sanitized on a regular basis. It is important to note that, as stated in the *Guide* (p. 39), "contaminants in food can have dramatic effects on biochemical and physiologic processes, even if the contaminants are present in concentrations too low to cause clinical signs of toxicity."

If food is not stored in its original bag, its milling date (found on the bag seam) must be indicated clearly on the food container. If no milling date is listed on the food bag, label the bag with the date received. With proper storage, food can generally be used up to 6 months after the milling or receipt date. However, the shelf-life of food can be shortened by several factors, including temperatures above 21°C (70°F), humidity extremes, unsanitary conditions, light, oxygen, and pests. Furthermore, food with Vitamin C generally has a shelf-life of only 3 months.

3. Temperature and Humidity

Temperature and humidity must be monitored and recorded on a daily basis to ensure that adequate levels of these environmental factors are maintained in the study area.

Relative humidity should be maintained within 30 to 70%.
Unless special environmental conditions are approved by the ARC, the area temperature must be appropriate to the species (see table below). According to the *Guide* (p. 29-30), "the range of

daily temperature fluctuations should be kept to a minimum to avoid repeated large demands on the animals' metabolic and behavioral processes." Temperature extremes can affect research results, alter an animal's performance, or lead to clinical effects and death.

Recommended Dry-Bulb Temperatures for Common Laboratory Animals		
	°C	°F
Mouse, rat, hamster, gerbil, guinea pig	18-26	64-79
Rabbit	18-22	64-72
Cat, dog, nonhuman primate	18-29	64-84
Farm animals and poultry	16-27	61-81

4. Ventilation

Ventilation serves to "supply adequate oxygen; remove thermal loads caused by animal respiration, lights, and equipment; dilute gaseous and particulate contaminants; adjust the moisture content of room air; and, where appropriate, create static-pressure differentials between adjoining spaces" (the *Guide*, p.30). Although factors such as species, animal size, number of animals, type of bedding, and frequency of cage-changing can affect the minimum ventilation rate required, an acceptable general standard for a vivarium room containing the maximum animal density permitted by other constraints is 10-15 fresh-air changes per hour. Investigators' laboratories are frequently set up in space not designed to permit 10 – 15 fresh-air changes per hour. An acceptable general standard in such cases is that the maximum number of animals in a study area be reduced proportionately. Although lower or higher ventilation rates may be required in certain instances, provisions must be made to ensure that "harmful or unacceptable concentrations of toxic gases, odors, or particles" do not accumulate in an animal's primary enclosure.

5. Illumination

The *Guide* (p. 34-35) states that, "in general, lighting should be diffused throughout an animal holding area and provide sufficient illumination for the well-being of the animals and to allow good housekeeping practices, adequate inspection of animals---including the bottom-most cages in racks---and safe working conditions for personnel. Light in animal holding rooms should provide for adequate vision and for neuroendocrine regulation of diurnal and circadian cycles...A time-controlled lighting system should be used to ensure a regular diurnal cycle, and timer performance should be checked periodically to ensure proper cycling." Several factors should be considered when determining adequate illumination, such as light intensity and wavelength, duration and time of light exposure during the circadian cycle, animal pigmentation and light history, body temperature, hormonal status, age, species, sex, and animal stock/strain.

6. Noise

Unnecessary noise in the study area should be minimized. The *Guide* (p. 36) recommends that, "to the greatest extent possible, activities that might be noisy should be conducted in rooms or areas separate from those used for animal housing" and that "radios, alarms, and other sound

generators should not be used in animal rooms unless they are parts of an approved protocol or an enrichment program."

7. Hazardous Agents

Hazardous biological, chemical, or physical agents must not be stored or used where animals are housed.

8. Other

Doors must fit tightly within the frame to prevent escape of or injury to animals.

B. Animal Care and Husbandry

1. Daily Observation of Animals

In order to comply with federal requirements (USDA AWARs §2.33(b)(3) and the *Guide*, p. 46), animals must be observed daily, including weekends and holidays, by qualified personnel to assess their health and well-being. Daily observation of animals must be recorded in the study area log (see Section IV.C.a). Additionally, USDA AWARs §2.33(b)(3) requires that a mechanism of direct and frequent communication with the attending veterinarian exists so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed. Contact a Division of Laboratory Animal Medicine (DLAM) veterinarian at x42571 for animal health concerns. The on-call veterinary pager number (#96545) should be kept readily available in case of an after-hours veterinary emergency.

2. Food/Water

Adequate provisions for feeding and watering of animals must be made at all times. According to the *Guide* (p. 38), "animals should be fed palatable, uncontaminated, and nutritionally adequate food daily or according to their particular requirements." To avoid contamination, food must be stored properly and provided in feeders that are so placed to prevent contact of food with feces and urine.

Additionally, animals must have access to "potable, uncontaminated drinking water according to their particular requirements" (the *Guide*, p. 40). To avoid microbial cross-contamination, the *Guide* recommends either replacing water bottles or refilling them provided they are returned to the same cage from which they were removed. Watering devices should be checked daily to ensure proper operation and must be washed and sanitized at least weekly.

3. Cages/Bedding

The *Guide* (p. 42) states that "soiled bedding should be removed and replaced with fresh materials as often as is necessary to keep the animals clean and dry." Bedding changes can vary from daily to weekly depending on factors such as animal number and size, cage size, urinary and fecal output, and experimental conditions.

Cages must be cleaned and sanitized on a regular basis. The frequency of cage sanitation may vary depending on specific husbandry practices, such as bedding type, cage type and size, animal density, and frequency of bedding changes. Cages should be sanitized at least once a week.

C. Record-keeping

1. Study Area Log

Records of animal care, room maintenance, and environmental conditions are required to be posted in the study area and kept updated by responsible personnel. Attached is a sample study area log which can be modified as appropriate to the protocol and animal species. The format of the modified log should be kept on file and should accurately reflect the tasks performed and the frequency of each task as described in the Standard Operating Procedures (SOP) for the study area (see Section IV.C.2).

Copies of study area logs must be submitted to the Campus Veterinarian (924 Westwood Blvd., Suite 1050, Mail code 733646, or fax #40285) on a monthly basis or at the end of the study period, whichever comes first.

NOTE: Investigators maintaining study areas located in Franz Hall or Life Sciences may submit study area logs to either the Campus Veterinarian or their respective building's Vivarium Manager. Investigators maintaining study areas located at the VAGLAHS Sepulveda or West Los Angeles campuses must submit copies of study area logs to the Veterinary Medical Officer.

2. Standard Operating Procedures (SOP) for Animal Husbandry and Study Area Maintenance

A description of procedures for animal husbandry and study area maintenance must be submitted to the ARC (please see attached SOP form). The SOP must be kept on file and available for inspection by representatives of the ARC, the Campus Veterinarian, and regulatory agencies during normal business hours.

3. Room Ventilation

A copy of Facilities Management's report regarding room ventilation (exhaust and air exchange rate) must be submitted to the ARC. This document must be kept on file and available for inspection by representatives of the ARC, the Campus Veterinarian, and regulatory agencies during normal business hours.

V. VETERINARY ACCESS

The Campus Veterinarian must be given access (i.e., a key or combination) to the study area in order to ensure the provision of adequate veterinary care in accordance with federal requirements. Specifically, the USDA AWARs §2.33(a)(2) mandates that "each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use."

Furthermore, the *Guide* (p. 12) states that "adequate veterinary care must be provided, including access to all animals for evaluation of their health and well-being." In accordance with these requirements, the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International requires that "the attending veterinarian must have access to the institution's animals used in teaching and research."

NOTE: Investigators maintaining study areas located at the VAGLAHS Sepulveda or West Los Angeles campuses must provide the VAGLAHS Veterinary Medical Officer with a key or combination to their study areas.

A3196N

Initial Report of Noncompliance

Date: 3/5/07 Time: 12:10

Name of Person reporting: Kathy Wadsworth
Telephone #: 310 825 5227
Fax #:
Email:

Name of Institution: U of California - Los Angeles
Assurance number: A3196

Did incident involve PHS funded activity? No
Funding component: _____
Was funding component contacted (if necessary): _____

What happened? Suspension Animals found in non-approved room + were injected w/ non-approved compounds. Cages stickered w/ top of green sticker + had been in there for 2 days.

Species involved: mice
Personnel involved:
Dates and times:
Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____
IO suspended all activities

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #_____

Full Assurance Agreement Printout

Assurance Number: A3196-01
Prior Assurance Number: A1440
Institution Name: University of California - Los Angeles
Institution Address: Los Angeles, CA
Site: 00

Dates:
Conditional Data Due:
Effective: 07/11/2006
Expiration: 07/31/2010
AR Reporting Cycle: 01/2008
AAALAC Status: 1
PHS Grant / Contract #:
Last Modified: 2/20/2007 By: th

Chairman: William H. McBride, Ph.D.
Degree: Ph.D.
Title: Processor, Radiation Oncolgoy
Address: Office for Protection of Research Subjects
10945 Le Conte Ave. 1401
Los Angeles, CA 90095-1694
Phone: (310) 206-6308 Ext:
Fax: (310) 794-9565
Email: arc@oprs.ucla.edu

Official: Dr. Roberto Peccei
Title: Vice Chancellor for Research
Address:
405 Hilgard Avenue
Los Angeles, CA 90024-1405
Phone: (310) 825-7943 Ext:
Fax: (310) 206-6030
Email:

POC: Ms. Kathy L. Wadsworth
Title: Associate Director-Animal Subjects Research
Address:
Box 951694-1401 PVUB
Los Angeles, CA 90095-1694
Phone: (310) 206-6308 Ext:
Fax: (310) 825-3676
Email: kwads@oprs.ucla.edu