



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
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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  
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October 3, 2008

Re: Animal Welfare Assurance  
A3196-01 [OLAW Case 4C]

Dr. Roberto Peccei  
Vice Chancellor for Research  
University of California, Los Angeles  
Box 95405, 2147 Murphy Hall  
Los Angeles, CA 90024-1405

Dear Dr. Peccei,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 22, 2008 letter reporting the suspension of an animal activity at the University of California- Los Angeles, following up on an initial telephone report on June 12, 2008. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee/Animal Research Committee (IACUC/ARC) took this action in response to repeated instances of noncompliance. Specifically, the investigator failed to contact veterinary staff regarding surgical complications, failed to document complications in the medical records, failed to perform or document pre-operative animal exams, failed to maintain complete anesthetic records, failed to contact the veterinarians for input in treating the chinchillas, failed to contact the veterinarian for a medical emergency which resulted in a chinchilla's death, and failed to contact the veterinarian prior to conducting surgery.

The corrective action plan submitted by the investigator requires investigative staff to contact a veterinarian for animal emergencies and extended post-operative recovery periods, to maintain completed and accurate medical records, to contact a veterinarian prior to conducting surgery for provision of oversight, to conduct surgeries early in the day and week, and to work with the veterinary staff to enhance the peri-operative procedures. The investigator was reminded that all significant changes to a protocol must be approved by the IACUC prior to implementation and that open communication must be maintained with the veterinary staff. The IACUC accepted the corrective actions and lifted the suspension. The funding component was notified about the suspension.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate having been informed about this matter and find no cause for further action by this Office.

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  
MaryAnn Gray, Assistant Provost

September 22, 2008

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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 suspension of activities investigated by the Chancellor's Animal Research Committee (ARC). This matter was initially reported to you via phone by Associate Director Kathy Wadsworth on June 12, 2008, in accordance with PHS Policy IV.C.8<sup>1</sup>. The research involved in the noncompliance was funded by NIH grant # 1 RO1 DC005801. USDA-covered species were used in the aforementioned research.

As Ms. Wadsworth informed you, the ARC was notified June 11, 2008 of repeated allegations of noncompliance, that resulted in the Campus Veterinarian suspending all activities involving chinchillas conducted by the investigators and members of his laboratory<sup>2</sup>. In accordance with the ARC Policy, Investigating Allegations of Mistreatment or Other Noncompliance Issues, the investigator was provided an opportunity to address the following allegations:

- Reported failure to contact the veterinary staff when complications from surgery arose
- Complications not documented in the surgery records
- Required pre-operative exam of the animals not done or not documented
- Anesthetic or procedure records missing or incomplete

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<sup>1</sup> 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"

<sup>2</sup> 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."

- Improperly treating chinchillas without veterinary consultation
- Failure to page the attending veterinary in an emergency situation that resulted in death of a chinchilla.
- Repeated failure to honor the veterinarians' requests to be notified prior to subsequent surgeries

The ARC reviewed the actions that lead to the veterinary suspension, as well as the investigator's response, during the convened meeting of June 16, 2008. While the ARC appreciated the investigator's cooperation during the investigation and in his thorough response to the allegations, the Committee determined that additional information and clarification was required prior to lifting the veterinary suspension order. As such, the Committee voted to continue the suspension of the protocol, pending a meeting between the investigator and the Campus Veterinarian scheduled for June 17, 2008. The investigator was asked to submit a corrective action plan following this meeting to detail the procedures that will be taken to ensure full compliance with University and Federal requirements concerning provision of veterinary care and maintenance of complete surgical and post-operative records, and interactions with veterinary staff.

The Committee reviewed the investigator's revised corrective action plan during the convened meeting of June 30, 2008. The plan outlined the steps that would be taken to ensure adequate communication with the veterinary staff and to maintain complete medical records for the chinchilla experiments. The Committee found the plan to be acceptable, and as such, voted to lift the suspension of the protocol. The approved plan is summarized below:

- a) Laboratory staff will contact a veterinarian in cases where the post-operative recovery period exceeds 1 hour in duration, and in the event of any emergency situations (including those such as resuscitation which must be undertaken by his staff immediately).
- b) All animal records will include documentation of the pre-operative examination, complete details of all anesthetics administered, and any instances of prolonged recovery from anesthesia.
- c) The investigator will notify veterinary staff of future surgeries to ensure that veterinary oversight can be provided.
- d) To ensure adequate observation time during normal working hours, the investigator will make every attempt to conduct procedures in the morning and to avoid conducting surgeries on Fridays.
- e) The veterinary staff will continue to work with the investigator to evaluate potential changes to the anesthetic regimen, and to identify any husbandry or health maintenance concerns that may predispose the animals to anesthetic complications.

The Committee agreed that the corrective actions outlined above were acceptable and, if followed, would avoid further problems. However, the investigator was reminded that continued approval to resume the studies is contingent upon the following:

- a) Surgical procedures must be conducted in the mornings unless deemed acceptable by the attending veterinarian.
- b) The veterinarian must be notified in advance of any planned surgery.
- c) Any changes to the protocol resulting from the veterinarian's evaluation of the anesthetic regimen must be submitted to the ARC for approval prior to implementation.

Finally, the Committee underscored that proactive cooperation between the research team and the veterinary staff is critical to identifying and resolving animal health problems and to improving the success of the research experiments. The investigator was also reminded that failure to ensure proper communication with the veterinary staff could subject UCLA to citation and fines by the U.S. Department of Agriculture, and can place the University's entire research program at risk. As such, the investigator was informed that failure to communicate with the veterinarian as described above may result in immediate suspension of his approved protocols.

In accordance with PHS Policy IV.C.7 and USDA Animal Welfare Regulations §2.31(d)(7), this suspension is being reported to, or has been reported to, the NIH Office of Laboratory Animal Welfare (OLAW), the U.S. Department of Agriculture, and to the UCLA office responsible for notifying the funding agency.

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

cc: Maryann Gray, Assistant Provost  
William McBride, Chair, ARC  
Judith L. Brookshire, Director, OPRS  
Kathy Wadsworth, Associate Director, Animal Subjects Research



# Initial Report of Noncompliance

Date: 6/12/08

Time: 1:40

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

Name of Institution: UCLA  
 Assurance number: A 3196

Did incident involve PHS funded activity? Yes  
 Funding component: \_\_\_\_\_  
 Was funding component contacted (if necessary): \_\_\_\_\_

What happened?  
*Not suspend all animals under PHS at University Health  
 well & report to animal. Not yet contacted - are  
 required to.*

Species involved: *canine*  
 Personnel involved:  
 Dates and times:  
 Animal deaths:

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY  
 Case # \_\_\_\_\_

