



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

August 11, 2008

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

Roberto Peccei, Ph.D.
Vice Chancellor for Research
Office of the Chancellor
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 23, 2008 letter concerning an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California, Los Angeles (UCLA). According to the information provided, OLAW understands that the Chancellor's Animal Research Committee (ARC) was notified on April 10, 2008 that mice had been found dead or moribund following surgery performed by an inexperienced and unsupervised surgeon. In addition, the surgeon had not given the animals antibiotics as required. Although the PI was subsequently asked by the ARC Associate Director Kathy Wadsworth to provide a more experienced lab member to oversee the surgical procedures, on April 16, 2008 two more mice were found dead or moribund following unsupervised surgery by the same inexperienced surgeon. This activity was not federally funded.

Corrective actions consisted of the PI being informed that the surgeon must stop performing survival surgeries pending a review of the events. The PI was also asked to develop a corrective action plan. That plan consisted of the surgeon observing mouse procedures performed by the principal microsurgeon until he is able to demonstrate proficiency, and that all staff will be reminded to follow all required procedures, including antibiotic administration. After a telephone conversation between this Office and Ms. Wadsworth, it is further understood that the surgeon will undergo additional training while under observation by a veterinarian.

OLAW understands that the protocol involved was not PHS supported, but also concurs that the incident warranted reporting. The actions taken by the UCLA ARC appear appropriate for the incident. 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.

Box 951405, 2147 Murphy Hall
Los Angeles, CA 90095-1405
phone: 310-825-7943
fax: 310-206-6030
rpeccei@conet.ucla.edu

June 23, 2008

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: Report of Incident of Noncompliance
Animal Welfare Assurance A3196-01**

Dear Dr. Wolff:

I am writing to provide you with a final report regarding an incident of noncompliance involving failure of a Principal Investigator to adequately train and monitor a new surgeon, as required by ARC Policy and The Guide for the Care and Use of Laboratory Animals¹. The incident involved a non-USDA covered species and was not supported by Federal funds.

The Chancellor's Animal Research Committee (ARC) was notified on April 10, 2008 of instances in which animals were found dead or moribund following an April 9, 2008 transplant surgery, performed by a surgeon who disclosed to veterinary staff that he was inexperienced in performing major survival surgery in mice. When asked by veterinary staff, the surgeon also admitted that he had not provided antibiotics as required by the approved protocol and by ARC Policy. Additionally, the ARC was informed, and the surgeon confirmed, that he had performed the survival surgeries by himself.

In response to the above, ARC Associate Director Kathy Wadsworth contacted the Principal Investigator on April 11, 2008 to request that he ask a more experienced lab member to oversee the surgical procedures until the new surgeon is able to demonstrate proficiency. Additionally, Ms. Wadsworth suggested that the lab develop a perioperative checklist of required medications in order to avoid such incidents from occurring in future surgeries.

¹ The Guide for the Care and Use of Laboratory Animals (p. 14): *Investigators, technical personnel, trainees, and visiting investigators who perform animal anesthesia, surgery, or other experimental manipulations must be qualified through training or experience to accomplish these tasks in a humane and scientifically acceptable manner.*

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However, on the morning of April 16, 2008, the ARC was again notified of two (2) mice found dead or moribund following unsupervised surgery performed by the above referenced surgeon.

On April 17, 2008, the ARC sent an initial query to the Principal Investigator regarding the continued failure to adequately supervise and train the surgeon. Following consultation with the Campus Veterinarian and the ARC Chair, the Principal Investigator was informed that since it is unclear whether the surgeon is capable of performing survival surgery in an acceptable manner, the surgeon must stop performing survival surgery transplant procedures, pending ARC review of the events. It was also suggested that the Principal Investigator provide a corrective action plan to ensure appropriate training and oversight of new research staff.

The investigator replied promptly, stating that he had spoken to the surgeon at length about the need to follow all required perioperative procedures. The PI further clarified that the surgeon had performed kidney transplants in rats, but that mouse transplantation surgeries are new for him. He reminded the ARC that mouse heart transplants are very demanding procedures even for the most experienced microsurgeons. However, the Principal Investigator assured the Committee that the new surgeon is capable of performing the procedure appropriately. In the meantime, the surgeon will observe mouse procedures performed by the principal microsurgeon until he is able to demonstrate proficiency. Also, all staff will be reminded to follow all required procedures, including antibiotic administration.

The ARC reviewed the investigator's response during the convened meeting of April 28, 2008 and found his explanation and corrective actions to be acceptable. The ARC stipulated that the surgeon must observe a minimum of five (5) surgeries before being provided the opportunity to demonstrate his skill in performing the procedure. Additionally, the Committee requested that the new surgeon increase post-operative monitoring following all surgeries to ensure that any complications are promptly identified and treated.

In accordance with PHS Policy IV.F.3, the ARC requested that this incident be reported to the NIH Office of Laboratory Animal Welfare (OLAW) as a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals*.

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: Dr. William McBride, Chair, ARC
Judith L. Brookshire, Director, OPRS
Kathy Wadsworth, Associate Director, Animal Subjects Research

