

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

April 28, 2006

REC'D
MAY 5, '06

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

Dear Dr. Wolff:

I am writing to provide you with a report of continued noncompliance involving animals housed in a UCLA investigator's laboratory. This lab receives funding from various Federal sources, including NIH #1P20CA32737,17-94J, and U.S. Department of Defense #BC 0344798.

The Chancellor's Animal Research Committee (ARC) was notified January 31, 2006 of continued incidents of noncompliance involving failure to treat or euthanize animals¹. Specifically, in March 2005, a veterinarian from the Division of Laboratory Animal Medicine (DLAM) contacted the lab staff regarding several mice with tumors exceeding the size limit permitted by the ARC and specified in the approved research protocol. At that time, the veterinarian provided suggestions for enhanced record keeping and monitoring of tumor-bearing mice.

On September 15, 2005 the veterinarian contact the Principal Investigator (PI) for the lab regarding mice observed during the months of May, June and September with tumors exceeding the size limits set in the ARC approved protocol. At that time, the

¹ In accordance with ARC Policy on Notification of Investigators with Sick or Injured Animals, DLAM veterinary staff contact researchers immediately to order treatment or euthanasia of animals found to be moribund or in a state of undue pain or distress. If the investigator cannot be reached, the animal may be euthanized in accordance with the ARC Policy on Authority of the Attending Veterinarian. Continued failure of research personnel to carry out veterinary orders is considered a serious violation reportable to the NIH Office of Laboratory Animal Welfare. Further, ARC Policy clarifies that "it is unacceptable to simply fail to respond to such notification and expect DLAM staff to treat or euthanize the animal."

veterinarian requested that the PI provide a "summary of what other efforts will be taken by [his] laboratory to prevent any further reports of mice bearing tumors that are too large." She also cautioned the PI that "any future reports must be taken to the ARC."

On January 31, 2006, the veterinarian observed additional mice in the lab with tumors exceeding the size limits, and notified the ARC of the continued noncompliance. The veterinarian also noted that as of the date of her report to the ARC, the PI had not replied to her request for a summary of actions to prevent future occurrences of such incidents.

In accordance with the ARC Policy, Investigating Allegations of Mistreatment or Other Noncompliance Issues², the investigator was provided an opportunity to comment on the incident.

The investigator replied promptly to apologize for the oversight. In response to the noncompliance, educational meetings were scheduled between the PI, DLAM veterinary staff, the ARC Chair, the Associate Director-Animal Subjects Research, and the PI's lab staff to discuss improved monitoring of tumor-bearing animals. Other topics discussed included applicable animal care and use regulations, consequences of continued noncompliance, and improved communication between the lab, DLAM and the ARC staff.

The ARC reviewed the matter at a convened meeting of April 10, 2006 and found the investigator's corrective actions to be acceptable.

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

² "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."



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

May 17, 2006

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

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 April 28, 2006 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California, Los Angeles. According to the information provided, OLAW understands that on numerous separate occasions mice had been identified with tumors which exceeded the allowable size limits. The Principal Investigator had been unresponsive to the veterinarian's requests to take action to address tumor size in mice.

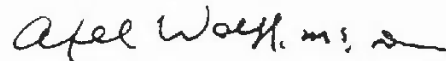
The investigative team was counseled and retrained. Improved monitoring of tumor-bearing mice was implemented.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance although a more immediate response would have been preferable. In cases where noncompliance is found to be ongoing for almost one year, it is necessary to take more immediate and decisive action. Since the noncompliance consisted of a failure to adhere to an Institutional Animal Care and Use Committee-approved protocol, the initial incident constituted a reportable event to OLAW and it

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was not necessary for a chronic condition to develop in order to report an event of continuing noncompliance. OLAW also recommends that periodic checks be made of the mice to ensure that ongoing compliance with the tumor size guidelines is now being maintained. 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
Judith Brookshire, Director, OPRS
Kathy Wadsworth, Associate Director, Animal Subjects Research