



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
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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
Facsimile: (301) 402-2803

June 6, 2007

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

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 May 25, 2007 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 post-operative analgesia was not given to two pigs, contrary to the approved protocol. The technician responsible had not given analgesia due to the animals not exhibiting signs of pain and not receiving adequate instruction from the Principal Investigator (PI). A similar incident involving five pigs had previously occurred.

The PI was counseled on his animal care and use responsibilities and for assuring that staff understands the content of the protocol. A check list was developed which lists all medications to be given to the pigs peri-operatively.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. 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

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May 25, 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: 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 a USDA-covered species (swine) in a study conducted by a UCLA investigator. The report is provided to you in accordance with UCLA's Assurance Of Compliance With Public Health Service Policy On Humane Care And Use Of Laboratory Animals¹. The study is not supported by federal funds.

The incident involved failure to provide post-surgical analgesia to two pigs, as required by the Animal Research Committee (ARC) Policy on Post-operative Analgesia², and as described in the investigator's approved protocol. Specifically, on April 18, 2007, the ARC was notified that a veterinarian from the Division of Laboratory Animal Medicine (DLAM) observed that the surgical report for that day did not indicate the use of post operative analgesia. When asked, the surgical technician confirmed that the animals were not given post-operative analgesia, but had not exhibited any sign of pain following the procedure.

¹ UCLA Assurance of Compliance, dated July 2006. "Verified violations and subsequent actions are reported to the Institutional Official, OLAW and USDA if applicable."

² ARC Policy on Post-operative Analgesia. "Analgesics must be provided to all animals following survival surgery unless scientific justification for withholding post-operative analgesics is provided by the investigator and approved by the ARC, or if a veterinarian examines the animal and determines that analgesic administration is no longer necessary."

In accordance with the ARC Policy, Investigating Allegations of Mistreatment or Other Noncompliance Issues³, the Principal Investigator was contacted on April 20, 2007 and provided an opportunity to comment on the incident.

The investigator replied promptly, stating that the error was completely his fault. He explained that previous animals had developed fevers post-operatively, and as such, "the majority of [their] attention was focused on [the pigs] receiving proper antibiotics." When the Principal Investigator questioned the surgical technicians about the omission, the technicians discovered that he had not sufficiently communicated to them that analgesia was to be administered to all animals, rather than only to animals that appeared to be experiencing discomfort. To prevent future incidents of this sort, the investigator developed a check sheet to be used for each animal undergoing surgical manipulations, listing all medications required before, during and after surgery.

The Animal Research Committee (ARC) reviewed the investigator's response during the convened meeting of May 7, 2007 and found his explanation and corrective actions to be acceptable. However, at the time of the meeting, the Campus Veterinarian recounted another recent incident occurring on March 12, 2007, in which five (5) pigs also were not provided post-operative analgesia. Of those five pigs, one had apparently exhibited signs of pain. The ARC was informed by the attending veterinarian that he had discussed the event with the investigator at that time, and that he provided his assurance that he would "make sure that this does not happen again." As the investigator did not have a history of noncompliance, he accepted his assurance without further action. In retrospect, the veterinarian noted that he should have notified the ARC of the incident, and will do so for any future incidents.

The Committee expressed concern that the problem had not been resolved when the veterinarian discussed this matter with the Principal Investigator in March. As such, the investigator was reminded that the University, investigators and the ARC share a collective responsibility for the ethical conduct of research at UCLA. Additionally, the Committee reminded the investigator that he is also 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. Finally, the investigator was informed that future incidents of noncompliance may result in suspension of his animal research.

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*.

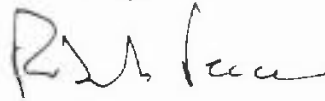
³ "In every investigation, the person(s) against whom the complaint has been raised shall be given notice of the concern and provided an opportunity to address the allegations in writing."

Axel V. Wolff, M.S., D.V.M.
May 25, 2007

Page 3

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Roberto Peccei', written in a cursive style.

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

