



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
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June 6, 2007

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

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 an animal activity was conducted after the Institutional Animal Care and Use Committee (IACUC) approved protocol had expired. Specifically, mice were subjected to surgery although the protocol was no longer active. A similar incident had previously occurred in the same laboratory.

The corrective actions consisted of having the investigator periodically review protocol status with staff, notifying staff of pending protocol expirations, having copies of the protocol available for staff, including laboratory staff in key communications, and having the investigative staff undergo retraining. The investigator was counseled about his responsibility for animal care and use issues.

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 reported incident was not PHS-funded but recommends that the enclosed guidance is shared with investigators to stress the consequences of conducting work without IACUC approval. 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
Enclosure

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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 report of an incident of noncompliance involving a non USDA-covered species (mice) used in a study conducted by a UCLA investigator. The study receives funding from various sources, including National Institutes of Health (NIH) grant #HL075826.

The Chancellor's Animal Research Committee (ARC) was notified on April 6, 2007 that mice used in the above referenced study may have undergone a procedure that was not approved by the ARC (administration of sub-lethal irradiation).

In accordance with the ARC Policy, Investigating Allegations of Mistreatment or Other Noncompliance Issues¹, the Principal Investigator was contacted on April 6, 2007 and provided an opportunity to comment on the incident. She was also instructed to immediately cease all non-approved animal research activities.

The investigator replied promptly, stating that she took full responsibility for the error and explained that she was "under the impression from [her] staff that radiation was included in the ARC protocol." As such, she submitted a protocol amendment to the

¹ "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."

ARC to include sublethal irradiation in her approved protocol and provided her assurance that she would stop using radiation immediately until the amendment has been approved.”

To avoid future noncompliance, the investigator stated that she will review all amendment and renewal applications with her staff. The investigator also scheduled an ARC/DLAM Educational meeting for May 9, 2007 between herself, her lab staff, a clinical veterinarian, and Associate Director Kathy Wadsworth, to discuss ARC policies and DLAM procedures concerning the research.

The Animal Research Committee (ARC) reviewed the investigator’s response during the convened meeting of May 7, 2007, and found her corrective action plan to be acceptable. The Committee also required that she provide her staff with copies of all approved protocols, and ensure that current copies of all approved protocols are kept in a location accessible to all research staff.

The Committee reminded the investigator that as Principal Investigator, she is responsible for upholding the federal, State and local policies and regulations governing the humane care and use of laboratory animals. Furthermore, as Principal Investigator, she is also accountable for ensuring that all personnel listed under her approved protocol 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 her animal research.

As this incident constitutes a serious violation of PHS Policy IV.C and UCLA’s Animal Welfare Assurance on file with the NIH Office of Laboratory Animal Welfare (OLAW), the ARC, through the Institutional Official, is required to report this violation to NIH/OLAW.

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



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:	AAALAC Status:	1
	Effective: 07/11/2006	PHS Grant / Contract #:	
	Expiration: 07/31/2010	Last Modified: 5/9/2007	By: sm
	AR Reporting Cycle: 01/2008		

Chairman:	William H. McBride, Ph.D.	Degree:	Ph.D.
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