



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) 402-7065

February 13, 2017

Re: Animal Welfare Assurance
A3084-01 [OLAW Case 2S]

Dr. Paul Alivisatos
Vice Chancellor for Research
University of California, Berkeley
119 California Hall, MC 1500
Berkeley, CA 94720-1500

Dear Dr. Alivisatos,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 2, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California- Berkeley, following up on an initial telephone report on April 7, 2016. According to the information provided, OLAW understands that several guinea pigs were given a lower dose of anesthetic than described in the approved protocol, record keeping for controlled drugs was inadequate, and expired analgesics and euthanasia drugs were used.

The corrective actions consisted of stopping the imaging procedure for which the anesthetics were used, retraining the Principal Investigator (PI) and staff on appropriate handling of controlled drugs and on maintaining animal health and research records, using color codes on drugs and checking inventory monthly, and counseling the PI and staff on record keeping and following the protocol. The PI was directed by the Animal Care and Use Committee to improve management of the laboratory and the laboratory was placed under enhanced oversight by the veterinarians and the Office of Animal Care and Use. The protocol was amended to include the lower dose of anesthetic and the animal activity resumed.

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: IACUC Chair

Secondary Individual Director, Research Subject Protection

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OFFICE OF THE VICE CHANCELLOR FOR RESEARCH
119 CALIFORNIA HALL #1500

BERKELEY, CALIFORNIA 94720-1500

February 2, 2017

Axel V. Wolff, M.S., D.V.M., Director
DIVISION OF COMPLIANCE OVERSIGHT
Office of Laboratory Animal Welfare, National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
OLAWDCO@MAIL.NIH.GOV

Dear Dr. Wolff:

RE: Animal Welfare Assurance #A3084-01

This is to follow up on the preliminary report that you received via a phone call on April 7, 2016 from **Secondary Individual** Director of the Office for Animal Care and Use (OACU). The call was made on behalf of the Animal Care and Use Committee (ACUC) and pertained to an animal welfare incident involving guinea pigs. The incident was discovered during a routine USDA visit (inspection).

The incident encompassed several issues:

- Use of lower doses of an anesthetic agent combination (ketamine and xylazine) to reduce animal recovery time for a non invasive imaging procedure than what was approved in the protocol. Although researchers consulted with OLAC veterinarians who indicated the lower anesthetic dose was appropriate for the procedure the PI neglected to submit an amendment to revise her protocol.
- Continued use of the unapproved dose of the anesthetic agent combination between 3/24/2016 and 4/5/2016 for 11 guinea pigs by lab personnel despite the PI's statement that such activity had ceased.
- Inadequate record keeping for the controlled drug, specifically inadequate documentation of use per animal and expired controlled substances were not separated from unexpired controlled drugs.
- Sedative/analgesic (xylazine) and euthanasia agents used beyond their expiration date.

Subsequent investigation by the ACUC determined that collectively, these issues comprised a serious noncompliance with PHS Policy on the Humane Care and Use of Laboratory Animals. Based on the ACUC investigation, the following steps have been taken to address this incident:

1. The PI voluntarily ceased the specific imaging procedure that required use of the anesthetic agents in question.
2. The PI and her lab personnel underwent retraining by the EH&S Controlled Substances Used in Research program Leader. This retraining covered use, record keeping, storage and disposal of expired controlled drugs.

3. The PI implemented an SOP that employs a color-coded system to track drug inventory. As part of this SOP, a senior staff member is responsible for verifying inventory each month.
4. An OLAC veterinarian worked with the PI and lab personnel to ensure that health and research records for each guinea pig are appropriate and accurately record all drug doseages and procedures performed on each animal.
5. The AV met with the PI and her lab to reinforce the importance of appropriate record keeping and the need to follow the ACUC-approved protocol, meaning that changes to drug doseages and/or procedures cannot be made without appropriate review and approval by ACUC.
6. OLAC veterinarians and OACU staff have made multiple follow-up visits to the PI's lab to ensure that all of the above corrective measures have been and are continuing to be implemented as directed.
7. The PI attended an ACUC meeting to discuss direct methods for improving the management of her lab so as to ensure that these issues do not reoccur in the future.
8. As requested by ACUC, OACU staff continue to monitor this lab closely by performing announced and unannounced post-approval monitoring visits.

The ACUC approved the corrective actions outlined above and plans to continue to monitor this PI's activities closely. A protocol amendment containing a lower dose of the anesthetic agent combination was subsequently submitted to and approved by the ACUC. The PI then re-initiated the imaging procedure that necessitated anesthesia.

The PI has informed the ACUC that the activities were performed under NIH/NEI EY12392 funding.

As Institutional Official, I am satisfied that the campus has spared no resources in resolving this unfortunate incident and thereby has fulfilled its commitment to maintaining the highest standards of animal welfare, as described in our Animal Welfare Assurance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'A. Paul Alivisatos', followed by a long horizontal line and a small vertical tick mark at the end.

A. Paul Alivisatos, Vice Chancellor for Research
Institutional Official

cc: Bill Sha, ACUC Chair
ACUC

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, February 13, 2017 7:41 AM
To: Secondary Individual
Subject: RE: UCB Final Report

Thank you for this report, Secondary Individual I will respond soon.
Axel Wolff

From: Secondary individual [mailto:Secondary Individual@berkeley.edu]
Sent: Friday, February 10, 2017 5:35 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Acuc Departmental <acuc@berkeley.edu>; Secondary Individual <glawson@berkeley.edu>
Subject: UCB Final Report

Dear Dr. Wolff:
Attached is the final report from our IO regarding the incident with guinea pigs that was initially reported to OLAW on 4/7/2016. If you have any questions, please do not hesitate to contact us.

Sincerely,

Secondary Individual

Secondary Individual

Director, Research Subject Protection
Office for Protection of Human Subjects
Office for Animal Care and Use
UC Berkeley

****Please note I telecommute on Mondays so please email me for a quick response!****



Initial Report of Noncompliance

By: *aw*

Date: *4/7/16*

Time: *1500*

Name of Person reporting: *Secondary Individual*
Telephone #: *Phone Number*
Fax #:
Email:

Name of Institution: *U of California - Berkeley*
Assurance number: *A 3084*

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

What happened?
Out date controlled dump on guinea pigs; not on protocol
Expired euthanasia solution

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

Projected plan and schedule for correction/prevention (if known): _____
PI stopped, use, restrain

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case # _____