



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

September 15, 2021

Re: Animal Welfare Assurance
A3084-01 [OLAW Case 3F]

Dr. Randy Katz
Vice Chancellor for Research
University of California, Berkeley
(b) (4) California Hall, MC 1500
Berkeley, CA 94720-1500

Dear Dr. Katz,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 14, 2021 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 report on August 25, 2021. According to the information provided, OLAW understands that on three separate occasions an expired analgesic was given to a nonhuman primate. No adverse effects were noted due to use of the expired drug.

The corrective action consisted of discarding the expired agent and obtaining new stock. The veterinary staff was retrained, the tracking and identification of expiration dates was refined, and all pharmacy locations are checked monthly for expired substances, which are removed.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
Robert Gibbens, D.V.M., USDA-APHIS-AC

A3084

UNIVERSITY OF CALIFORNIA, BERKELEY

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

BERKELEY, CALIFORNIA 94720-1500

September 14, 2021

Axel V. Wolff, M.S., D.V.M.
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
WolffA@OD.NIH.GOV
OLAWDCP@OD.NIH.GOV

Dear Dr. Wolff:

RE: Animal Welfare Assurance # **D16-00050**

This is to follow up on the preliminary report you received via email on August 20, 2021 from Dr. Rebecca Armstrong, Director, Office for Animal Care and Use (OACU) on behalf of the Animal Care and Use Committee (ACUC) regarding a USDA citation for a NHP that occurred at our institution.

As previously noted in the preliminary report, on 8/16/21, a NHP underwent explantation per protocol and standard multimodal analgesic regimen was initiated. Then on, 8/17/21, 8/18/21 and 8/19/21, OLAC veterinary staff (AHT) administered oral meloxicam that had expired on July 31, 2021. There were no apparent negative clinical effects; the NHP recovered as expected and no increase in any of the analgesics was necessary as a result of this action. The issue was corrected the morning, 8/20/21, with a new properly dated bottle of meloxicam prior to any further administration.

A subsequent thorough investigation by the ACUC determined that this was a serious noncompliance with PHS Policy on Humane Care and Use of Laboratory Animals. The OLAC veterinary staff conducted staff refresher training; reviewed and refined the tracking and identification system for monitoring product expiration dates; and, reviewed the monthly task of checking for and removing expired substances from all pharmacy locations. The ACUC accepted this plan and no further action was deemed necessary.

The PI has informed the ACUC that the animal procedures were performed under Public Health Service funding, by NIH, R01MH117763 - Frontostriatal Rhythms Underlying Reinforcement Learning.

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,

(b) (6)

Randy H. Katz, Vice Chancellor for Research
Institutional Official

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Wednesday, September 15, 2021 9:34 AM
To: Randy Howard Katz
Subject: RE: Animal Welfare Report Follow Up - UC Berkeley #D16-00050

Thank you for these reports, Dr. Katz. We will send responses soon. For future reference, please send all final noncompliance reports to olawdco@od.nih.gov. This allows prompt processing if I am not available.
Axel Wolff

From: Randy Howard Katz <vcr@berkeley.edu>
Sent: Wednesday, September 15, 2021 9:26 AM
To: OLAWDCP@od.nih.gov; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Subject: Animal Welfare Report Follow Up - UC Berkeley #D16-00050

Dear Dr. Wolff:

Attached please find two final report letters following up on preliminary animal welfare incident reports sent to you via email on August 11, 2021 and August 20, 2021. If you have any questions or need additional information please do not hesitate to contact me.

Thank you, and best regards,
Randy

--
Randy Howard Katz
Vice Chancellor for Research and
United Microelectronics Corporation Distinguished Professor in
Electrical Engineering and Computer Sciences
University of California, Berkeley
(b) (6)
vcr@berkeley.edu

(b) (6)

Wolff, Axel (NIH/OD) [E]

A3084-3F

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 27, 2021 6:58 AM
To: Rebecca D. ARMSTRONG PhD
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary report of NHP incident

Thank you for this preliminary report, Dr. Armstrong. We will open a new case file.

Axel Wolff

From: Rebecca D. ARMSTRONG PhD <rda@berkeley.edu>
Sent: Wednesday, August 25, 2021 12:09 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: VC Research <vcr@berkeley.edu>; (b) (6)
(b) (6) Acuc Departmental <acuc@berkeley.edu>
Subject: Preliminary report of NHP incident

To Whom It May Concern:

On behalf of UC Berkeley's IO, this is a preliminary report on an incident that was identified and corrected on 8/20/2021. UCB has self-reported this to the USDA already. The incident and corrective actions will be reviewed at the next IACUC meeting and the IO will submit a final report when the situation is fully resolved.

On 8/16/21, a NHP underwent explantation per protocol and standard multimodal analgesic regimen was initiated.

On 8/17/21, 8/18/21 and 8/19/21, OLAC veterinary staff (AHT) administered oral meloxicam that expired on the last day of July 2021.

There were no apparent negative clinical effects; the NHP recovered as expected and no increase in any of the analgesics was necessary as a result of this action.

The issue was corrected the morning, 8/20/21, prior to any administration. The expired bottle was removed and replaced with a new, unexpired bottle.

Refresher training and refinement of processes to track pharmacy item expiration have already begun for OLAC veterinary staff and should be completed this week.

This study is funded by NIH, R01MH117763 - Frontostriatal Rhythms Underlying Reinforcement Learning.

If you have any questions, please let me know. A final report will be forthcoming.

Sincerely,
Dr. Becky Armstrong

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Rebecca D. Armstrong, DVM, PhD
Director, Research Subject Protection
Office for Protection of Human Subjects (OPHS)
Office for Animal Care and Use (OACU)

Office for Stem Cell Research Oversight (SCRO)
UC Berkeley

"If you're going to live life, you've got to be all in."
Marian Cleeves Diamond
UCB Alumna and Emeritus Professor

