



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 21, 2021

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

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

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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 11, 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, at the USDA's routine site visit on July 20-21, 2021, the VMO identified a discrepancy for a NHP where the record concerning the animal's water restriction and consumption for the month of July did not adhere to what the IACUC had approved in the protocol (i.e. the animal got less water than it was supposed to get daily). While the animal's health and well-being did not appear to be affected in any way as noted in their Inspection Report, the USDA did cite UCB under 2.31(c)(7) Institutional Animal Care and Use Committee (IACUC) - for the PI not submitting this significant change to the IACUC for review and approval.

A subsequent thorough investigation by the ACUC determined that it was a serious noncompliance with PHS Policy on Humane Care and Use of Laboratory Animals. On July 21 when ACUC notified the PI, lab personnel immediately followed the protocol as it was written and the PI submitted an amendment to ACUC to correct/clarify the protocol and ensure compliance in all future experiments. The ACUC accepted this plan, and approved the amendment.

The PI has informed the ACUC that the activities were performed under any 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]

A3084-3E

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 13, 2021 7:12 AM
To: Rebecca D. ARMSTRONG PhD
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Report - UCB

Thank you for this preliminary report, Dr. Armstrong. We will open a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Rebecca D. ARMSTRONG PhD <rda@berkeley.edu>
Sent: Wednesday, August 11, 2021 2:38 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; VC Research <vcr@berkeley.edu>;
(b) (6)
Subject: Preliminary Report - UCB

To Whom It May Concern:
On behalf of the IO at UCB, I am submitting this preliminary report.

At the USDA's routine site visit on July 20-21, 2021, the VMO identified a discrepancy for a NHP where the record concerning the animal's water restriction and consumption for the month of July did not adhere to what the IACUC had approved in the protocol (i.e. the animal got less water than it was supposed to get daily). While the animal's health and well-being did not appear to be affected in any way as noted in their Inspection Report, the USDA did cite us under 2.31(c)(7) Institutional Animal Care and Use Committee (IACUC) - for the PI not submitting this significant change to the IACUC for review and approval. This study is funded by NIH, R01MH117763 - Frontostriatal Rhythms Underlying Reinforcement Learning.

The ACUC will be reviewing the USDA citation and the PI's response/corrective actions at their meeting later this month. A final report will be sent after this is fully resolved.
If you have any questions, please let me know.

Sincerely,
Dr. Becky Armstrong

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