



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) 402-7065

January 14, 2020

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

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 January 14, 2020 letter responding to my January 6, 2020 request for additional information regarding a reported instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California- Berkeley. According to the information provided, OLAW understands the following about the facts surrounding the provision of expired analgesic to a nonhuman primate:

- 1) To prevent use of expired substances in animals, the laboratory will log controlled drug expiration dates in the laboratory calendar and in the surgery checklist. The dates will be checked in advance of conducting surgery.
- 2) Outdated substances are identified during the Institutional Animal Care and Use Committee (IACUC) semiannual inspection.
- 3) No pain or distress was noted by the veterinary staff in the monkey that had received the expired drug.
- 4) The matter had been reported to the USDA. An unannounced inspection was conducted and no problems were identified.

Based on its assessment of this additional information, OLAW has a better understanding of the matter and concurs with the actions taken by the IACUC. We recommend that, if not already in place, the responsibility for ensuring use of in-date substances in animals be placed on the laboratory rather than relying only on the biannual facility inspections. Other institutions have policies in place for regular monitoring of drugs and supplies and may use color coded labels, calendars, checklists, and designated staff monitors. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Director, Research Subject Protection
Robert Gibbens, D.V.M., USDA-APHIS-AC

UNIVERSITY OF CALIFORNIA, BERKELEY

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO

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



SANTA BARBARA • SANTA CRUZ

BERKELEY, CA 94720-1500

January 14, 2020

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

Dear Dr. Wolff:

Here is our response to your request of January 6, 2020 for more information about OLAW Case A3084-2Y that was originally reported to OLAW on November 27, 2019.

- 1) Pertaining to the corrective action plan accepted by the ACUC the Principal Investigator stated:
"We [the lab] will log [controlled drug] expiration dates in the lab calendar and update our surgery preparation checklists to double check expiration dates a week in advance."
- 2) UCB's ACUC conducts semi-annual inspections of all facilities and lab spaces on a regular basis. Two ACUC inspectors visited this PI's facilities and lab space on June 18, 2019 (with no findings) and again on December 10, 2019 (one tube of Neosporin was found to be expired and was thrown out immediately).
- 3) And, as documented to the ACUC in an email from one of the Office of Laboratory Animal Care (OLAC) veterinarians on November 7, 2019: "At no time before or after this administration [of Buprenorphine, expiration date 9/19] was the macaque assessed to be in pain by veterinary staff, and recovery was routine."

In addition, as you will note in the attached letter from the ACUC Chair to the Principal Investigator, UCB's AV did promptly report this incident to our USDA-APHIS VMO who noted that she would review the situation at her next visit. Subsequently, on December 18 & 19, 2019, we had an unannounced site visit by our VMO and no citations or findings were made at that visit.

If you have any additional questions, please let us know. 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,

(b) (6)

Randy Howard Katz, Vice Chancellor for Research
Institutional Official

Cc: ACUC Chair
Robert Gibbens, D.V. M., USDA-APHIS-AC



14 November 2019

Professor XXXXXXX
Department of YYYYYYYY
UC Berkeley

Dear Professor XXXXXXX,

I am writing to follow up on an incident in your lab in which a macaque was inadvertently injected with an expired drug. This incident was discussed by the ACUC at its November meeting, which took place yesterday.

The ACUC would like to commend you for your rapid self-reporting of this incident. Because this event involved a non-human primate and NIH funding, it will need to be reported to OLAW. In addition, on behalf of UCB and the ACUC, Dr. Lawson has self-reported this incident to the USDA also. However, the ACUC is satisfied that you have taken appropriate and sufficient corrective action to prevent a re-occurrence of this type of incident and that conclusion will be conveyed to both regulatory agencies.

Again, thank you for your attention to this matter.

Sincerely,

(b) (6)

Eileen A. Lacey
Chair, Animal Care and Use Committee
UC Berkeley

Cc: Greg Lawson, AV
ACUC

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Wednesday, January 15, 2020 6:51 AM
To: Randy Howard Katz
Subject: RE: OLAW Case A3084-2Y

Thank you for this prompt response, Dr. Katz. I will send a response soon.

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

From: Randy Howard Katz <vcr@berkeley.edu>
Sent: Tuesday, January 14, 2020 6:01 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: acuc@berkeley.edu; Walker, Keri (NIH/OD) [C] <keri.walker@nih.gov>; Robert.m.gibbens@usda.gov; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Re: OLAW Case A3084-2Y

Dear Dr. Wolff:

Attached please find our response to your request for more information about OLAW Case A3084-2Y. If you have any questions or need additional information please do not hesitate to contact me.

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
Executive Assistant: Joel Moldenhauer <joelmold@berkeley.edu>

On Tue, Jan 7, 2020 at 7:21 AM Walker, Keri (NIH/OD) [C] <keri.walker@nih.gov> wrote:

Dear Dr. Katz,

Attached please find Dr. Wolff's initial response to OLAW Case A3084-2Y.

If you have any questions, feel free to contact us by phone or by e-mail.

Best Regards,

Keri

Keri Walker

Program Specialist (Contractor)

Office of Laboratory Animal Welfare

National Institutes of Health

6700B Rockledge Dr., Suite 2500

Bethesda, MD 20892

301-435-2390

keri.walker@nih.gov



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) 402-7065

January 6, 2020

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

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 November 27, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California- Berkeley. According to the information provided, OLAW understands that a non-human primate received a dose of recently expired analgesic following a minor procedure.

The corrective action consisted of the Principal Investigator implementing a corrective action plan.

In order for OLAW to have a complete understanding of the corrective actions, please provide the following additional information:

- 1) Provide a copy or summary of the corrective action plan accepted by the Institutional Animal Care and Use Committee.
- 2) Provide information on the program wide procedures for ensuring that in date drugs and supplies are used in animals.
- 3) Indicate whether the macaque showed any adverse signs from use of the expired agent.

Please provide the requested information by **January 15, 2019**.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Director, Research Subject Protection
Robert Gibbens, D.V.M., USDA-APHIS-AC

UNIVERSITY OF CALIFORNIA, BERKELEY

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO



SANTA BARBARA • SANTA CRUZ

OFFICE OF THE VICE CHANCELLOR FOR RESEARCH
119 CALIFORNIA HALL #1500
BERKELEY, CALIFORNIA 94720

November 27, 2019

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
morseb@mail.nih.gov

RE: Animal Welfare Assurance # D16-00050

Dear Dr. Morse:

This is to inform you regarding an animal welfare incident with one macaque that occurred at our institution.

On Tuesday November 5, 2019 a non-human primate investigator performed a minor procedure (dura scrape). At the time of the procedure Office of Laboratory Care (OLAC) staff gave Buprenorphine from the OLAC drug inventory. On the evening of November 5, the PI's staff followed up with the second dose of Buprenorphine injection (doses to be given every 12 hours) taken from the lab's drug inventory, but the PI's staff later realized the bottle they used was dated 9/2019 and thus had expired. The PI reported the incident to the OLAC veterinarians the morning of November 6 at which time the veterinarian suggested that the PI also self-report this incident to the IACUC which was done. The investigator took further action by immediately setting in place safeguards to prevent this from recurring.

This incident was discussed at the IACUC meeting held November 14, 2019 and it was determined that this was a serious noncompliance with PHS Policy on Humane Care and Use of Laboratory Animals. The PI presented a detailed plan for ensuring compliance and animal welfare in all future experiments and the IACUC accepted this plan.

The PI has informed the ACUC that the activities *were* performed with Public Health Service/NIH funding: 1R01MH117763-01.

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,

(b) (6)

Randy Howard Katz
Institutional Official
Vice Chancellor for Research

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Thursday, December 19, 2019 7:48 AM
To: Rebecca D. ARMSTRONG PhD
Cc: OLAW Division of Compliance Oversight (NIH/OD); Acuc Departmental
Subject: RE: Report of Incident and Resolution

Thank you for providing this report Dr. Armstrong. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Rebecca D. ARMSTRONG PhD [mailto:rda@berkeley.edu]
Sent: Thursday, December 19, 2019 12:26 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Acuc Departmental <acuc@berkeley.edu>
Subject: Report of Incident and Resolution

Dear Dr. Morse:

On behalf of UC Berkeley's IO, I am sending you a letter about an incident involving a macaque that occurred at our institution. While the IO was informed and responded with the letter in a timely manner, I take responsibility for the delay in forwarding it on to OLAW as it unfortunately got buried in the end of the semester workload crunch.

If you have any questions, please don't hesitate to contact me.

Happy Holidays!

Sincerely,

Dr. Becky Armstrong

Rebecca D. Armstrong, DVM, PhD
Director, Research Subject Protection
Office for Protection of Human Subjects
Office for Animal Care and Use
UC Berkeley

****Please note I telecommute on Monday and Thursday so please email me for a quicker response!**