



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

September 9, 2019

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

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 July 12, 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. Your letter supplements information in the prompt email report received on March 14, 2019. According to the information provided, OLAW understands that on March 12, 2019 unapproved cranial surgeries were performed on mice with subsequent inappropriate and inadequate post-operative care of three mice that necessitated their euthanasia. The AV immediately suspended all mouse surgery by the PI and the lab. On March 13, 2019 the ACUC suspended the PI's protocol. It was determined that the animal activities were not funded by awards from the PHS.

Corrective actions in addition to the suspension consisted of a corrective action plan that included retraining all lab members regarding the specific surgical procedures involved in this incident and adherence to the procedures described in the PI's approved animal protocol. The protocol was reinstated by the ACUC on April 10, 2019.

The prompt consideration of this matter by the University of California, Berkeley was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. We support and commend the immediate action of the AV to protect animal welfare and your involvement in the corrective actions. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this matter and find no cause for further action by this office at this time.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



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

BERKELEY, CALIFORNIA 94720-1500

July 12, 2019

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
By email: olawdco@mail.nih.gov

RE: Animal Welfare Assurance D16-00050

Dear Dr. Wolff:

This letter is to report a protocol suspension action taken by the Animal Care and Use Committee (ACUC) at UC Berkeley in response to an animal welfare incident involving cranial surgeries on mice that occurred at our institution on March 12, 2019. The incident in question involved inappropriate and inadequate post-operative care of three mice that necessitated their euthanasia. The incident was serious enough that when it was discovered by the AV, he immediately suspended all mouse surgery by the PI and her lab.

Subsequent investigation by the ACUC determined that the specific incident in question was a serious noncompliance with PHS Policy on Humane Care and Use of Laboratory Animals. As a result and with the agreement of the IO, the ACUC suspended the PI's protocol on March 13, 2019, thereby halting all animal research in her lab, to enable the PI to develop comprehensive and permanent solutions to both the incident of immediate concern and other, ongoing issues within the lab documented as part of semi-annual inspections dating back several years. As IO, I met with the PI, the Chair of the ACUC, the AV, and the Director of OACU to impress upon the PI the significance of this suspension and the underlying need for full compliance with animal welfare regulations. The PI has proposed a detailed plan for ensuring future compliance with her protocol and with animal welfare regulations. One component of this plan was to require that all lab members undergo re-training regarding the specific surgical procedures involved in this incident and, more generally, adherence to the procedures described in the PI's approved animal protocol. The ACUC has accepted this plan and voted to reinstate the protocol on April 10, 2019.

The PI has informed the ACUC that the activities *were not* performed under any Public Health Service funding.

As Institutional Official, I am satisfied that the campus has spared no resources in resolving this 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 Howard Katz
Vice Chancellor for Research and Institutional Official

Cc: ACUC

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, July 15, 2019 12:48 PM
To: Rebecca ARMSTRONG; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Acuc Departmental
Subject: RE: UC Berkeley Suspension Report

Thank you for 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 ARMSTRONG [mailto:rda@berkeley.edu]
Sent: Friday, July 12, 2019 5:03 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Acuc Departmental <acuc@berkeley.edu>
Subject: UC Berkeley Suspension Report

Dear Dr. Wolff,
On behalf of UC Berkeley's IO, I am sending to you our report of a suspension action taken by our IACUC. If you have any questions, please let us know.
Sincerely,
Dr. Becky Armstrong

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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!**

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 15, 2019 6:50 AM
To: Rebecca ARMSTRONG
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Animal incident report

Thank you for this preliminary report, Dr. Armstrong. We will start 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 ARMSTRONG <rda@berkeley.edu>
Sent: Thursday, March 14, 2019 2:58 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Vcr Departmental <vcr@berkeley.edu>; (b) (6)
(b) (6)
Subject: Animal incident report

To Whom It May Concern at OLAW:

On behalf of UC Berkeley's IO, this is a quick preliminary report of a protocol suspension action taken by our IACUC (aka ACUC) at their regular meeting yesterday afternoon (3/13/2019). A formal letter will be forthcoming from our IO in regards to this incident.

The ACUC suspended a PI's protocol for animal welfare and noncompliance issues discovered on 3/12/2019. The species involved is mice bred for research. Two of three mice that underwent surgery on 3/11/2019 have been euthanized at this point. No NIH funds supported this specific research surgery procedure.

ACUC is continuing to investigate and will deliberate the next steps and/or further actions at their next meeting in April. 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
Office for Animal Care and Use
UC Berkeley

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