



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

December 27, 2018

Re: Animal Welfare Assurance
#A3213-01 (OLAW Case 1Y)

Dr. Kathryn A. Moler
Vice Provost and Dean of Research
Stanford University
Panama Mall
Stanford, CA 94305-2061

Dear Dr. Moler,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 11, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Stanford University, following up on an initial telephone report on January 23, 2019. According to the information provided, OLAW understands that a sentinel mouse, housed in an investigator maintained colony, developed extensive skin lesions but the veterinary staff was not notified. The laboratory's standard operating procedure stated that veterinary staff would be contacted for all animal health concerns.

The corrective actions consisted of euthanizing the mouse, counseling the laboratory staff, and having the Veterinary Service Center take over responsibility for care of most of the rodent colony. The Institutional Animal Care and Use Committee (IACUC) directed the laboratory to implement and document mandatory training for all current and future staff.

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 IACUC 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



STANFORD UNIVERSITY

KATHRYN A. MOLER
VICE PROVOST
DEAN OF RESEARCH

Confidential

February 11, 2019

Brent Morse, DVM, DACLAM
Acting Director of Compliance Oversight
Office of Laboratory Animal Welfare
Division of Compliance Oversight
National Institutes of Health
6705 Rockledge Drive
RKL 1, Suite 360 MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Morse:

As Stanford University's authorized institutional official under its PHS Assurance (Animal Welfare Assurance #A3213-01), I am writing to notify OLAW of a reportable incident that resulted in conditions that jeopardized the health or well-being of animals including actual harm to animals.

| | |
|---------------------|--|
| IACUC determination | Serious noncompliance |
| Funding | NIH grants # 2R01DC00415414, 2R01NS07240606, 1R21EY026152-01 |

Description:

At the convened meeting on December 13th, 2018, the IACUC discussed an allegation of noncompliance involving the sentinel mouse in a PI managed colony. When this mouse developed extensive skin lesions, the lab did not contact the Veterinary Service Center (VSC) in order to obtain veterinary care as was outlined in their approved SOP. The veterinary staff discovered the situation, assessed the lesions, and decided to euthanize the mouse.

A preliminary report of this incident was provided to OLAW on January 23rd, 2019, via a telephone call from (b) (6) Research Compliance Office.

IACUC Determination:

An IACUC subcommittee met on November 5th, to investigate these concerns and the corrective actions that had been taken. The subcommittee recommended that this incident be classified as serious noncompliance as it constituted a failure to adhere to the PHS "Policy on Humane Care and Use of Laboratory Animals" and resulted in actual harm to an animal.

At its convened meeting on December 13th, the IACUC discussed this recommendation. A motion to accept this finding of serious noncompliance was made, seconded and approved. A determination memo from the IACUC Chair was sent to the Protocol Director (PD) on January 17th, 2019.

408 Panama Mall • Stanford, California 94305-2061
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Dr. Brent Morse
February 11, 2019

Corrective Actions and Follow up:

The PD reported that they had proactively:

- Met with all animal users in the laboratory to discuss this issue and briefed them on the importance of following all relevant guidelines for animal use at Stanford.
- Returned the care of most of the animals in this colony (including the sentinel animal) to the VSC.

The IACUC requested that in addition to this corrective action that:

- The lab institute and document mandatory training for existing and future lab staff (specifically for protocol and guideline adherence). All applicable lab staff listed on this protocol must be trained within 30 days from the date the PD received the IACUC's determination memo. A roster of attendees will be provided to the IACUC. All future staff joining the lab after that date will receive the same training.

Concluding Remarks:

The IACUC has carefully reviewed this incident with all parties involved. Stanford believes that a recurrence of an incident of this nature is unlikely as all lab members have received appropriate training, and the PD and laboratory staff are committed to preventing a future occurrence. Please contact me or (b) (6) if you have any questions or need additional information.

Sincerely,

(b) (6)

Electronically signed by: Kathryn Ann Moler
Date: 2019-02-18 08:32:35-08:00

Kathryn A. Moler, PhD
Vice Provost and Dean of Research

cc: Kathryn Bayne, MS, PhD, DVM, DACLAM, DACAW, CAAB, Global Director AAALAC International

(b) (6)

(b) (6)

(b) (6)

(b) (6)

A3213-1Y



Initial Report of Noncompliance

By: aw

Date: 1/23/19

Time: 11:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Stanford U

Assurance number: A 3213

Did incident involve PHS funded activity? Yes, room was PHS

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Sentinel mouse w/ lesions not reported to IACUC.
IN PI Rm Room.

Species involved: mouse

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

Euthanize mouse. PI no longer managing room.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____