



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

October 23, 2019

Re: Animal Welfare Assurance
#A3213-01 (OLAW Case 2C)

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

Dear Dr. Moler,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 5, 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 July 9, 2019. According to the information provided, OLAW understands that ten mice died after having been inadvertently left in a transport vehicle overnight with external temperature outside of the acceptable parameters.

The corrective actions consisted of counseling all animal transport drivers, developing a standard operating procedure and checklist addressing animal transportation, and training staff on these procedures.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to 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



STANFORD UNIVERSITY

KATHRYN A. MOLER
VICE PROVOST
DEAN OF RESEARCH

Confidential

October 5, 2019

Brent Morse, DVM, DACLAM
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 as defined in PHS Policy IV.F.3.

IACUC determination	Serious noncompliance
Funding	National Institutes of Health

Description:

At a convened meeting, the IACUC discussed an allegation of noncompliance involving rodents. During a routine transfer of animals, several mouse cages were left in a closed vehicle and may have been exposed to environmental conditions outside of recommended limits. Ten mice died. The APLAC determined that this incident met the definition of 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 animals.

These animals were purchased under an approved protocol that included NIH funding, however, the animals were experimentally naïve and all costs associated with these animals have been refunded.

A preliminary report of this incident was provided to OLAW on July 9th, 2019, via a telephone call from the Associate Director of the Institutional Animal Care and Use Program, Research Compliance Office. The discussion confirmed that this was a husbandry event and did not involve the research investigator.

IACUC Determination:

An IACUC subcommittee met to review these concerns and the corrective actions that had been taken. Based on its review, 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".

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Tel (650) 723-0977 • Fax (650) 725-1653 • kmoler@stanford.edu

Dr. Brent Morse
October 5, 2019

At the convened meeting, the IACUC discussed the subcommittee's recommendation. A motion to accept this finding was made, seconded and approved. A determination memo from the IACUC Chair has been sent to the Associate Director (AD) of the Veterinary Service Center (VSC).

Corrective Actions and Follow up:

The AD reported that the following had been done proactively:

- They met with all approved transport drivers in the employ of the VSC to discuss this issue and briefed them on the importance of following all relevant guidelines.

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

- Institute a new SOP and checklist regarding animal transportation and that the APLAC review these documents prior to implementation.
- Train all relevant personnel on the SOP and checklist, and submit documentation of this training to the APLAC for confirmation. A roster of attendees will be provided to the IACUC.

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 VSC members have received appropriate training, and the AD and VSC 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)

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

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

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, October 23, 2019 8:41 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Notification for PHS Assured Institution #A3213-01

Thank you for providing this final report. 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: (b) (6)
Sent: Tuesday, October 22, 2019 1:02 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: OLAW Notification for PHS Assured Institution #A3213-01

Dear Dr. Morse -

On behalf of Stanford University's Institutional Official, I am writing to notify OLAW of a serious noncompliance. Please see the attached document.

Feel free to contact me if you have any questions or concerns.

Best,
(b) (6)

(b) (6)

As part of an on-going effort to improve our services, we invite you to complete a post-approval survey regarding your APLAC experience.

Please use this link: https://stanforduniversity.qualtrics.com/jfe/form/SV_e5694IPKNqUvDM1



Initial Report of Noncompliance

By: aw

Date: 7/9/19

Time: 11:30

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #: (b) (6)

Email: (b) (6)

Name of Institution: Stanford U

Assurance number: A3213

Did incident involve PHS funded activity? yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Mice left in van overnight, vet services did the transport
Naïve animals. 4 cages ok, 10 mice overheated + died

Species involved: Mice

Personnel involved: _____

Dates and times: _____

Animal deaths: 10

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

Discipline driver

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY

Case # _____