



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

February 28, 2022

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

Dr. Kathryn A. Moler
Vice Provost and Dean of Research
Stanford University
(b) (4) Panama Mall
Stanford, CA 94305-2061

Dear Dr. Moler,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 14, 2022 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Stanford University, following up on an initial telephone report on October 1, 2021. According to the information provided, OLAW understands that a rat died while being transported across campus as a result of having been left inside the vehicle for several hours exposed to high temperature.

The corrective actions consisted of counseling all of the animal transport drivers, updating the relevant standard operating procedures (SOP) on transportation and transport training, retraining all drivers and staff involved with animal transport on the updated SOP, and implementing an electronic confirmation of successful animal delivery.

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 on Humane Care and Use of Laboratory Animals. 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

Kathryn A. Moler, Ph.D.

Vice Provost and Dean of Research

Marvin Chodorow Professor

Professor of Applied Physics and of Physics

e-mail: kmoler@stanford.edu

phone: (b) (6)

Confidential

February 14, 2022

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 one rodent. During a routine transfer, this rat expired after being left in a closed vehicle for several hours and potentially being exposed to environmental conditions outside of recommended limits. 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 an animal.

This animal was purchased under an approved IACUC protocol that included NIH funding; however, the animal was experimentally naïve and all costs associated with this animal have been refunded.

A preliminary report of this incident was provided to OLAW on October 1st, 2021, 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

Dr. Brent Morse
February 14, 2022

noncompliance as it constituted a failure to adhere to the PHS "Policy on Humane Care and Use of Laboratory Animals".

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:

- All approved transport drivers in the employ of the VSC met to discuss this issue and were briefed by the AD on the importance of following all relevant guidelines.

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

- Refine the transportation training and VSC Standard Operating Procedures (SOP) to list all vehicles that may be used for animal transport and discuss past failures. Additionally, the IACUC will review the updated VSC SOP prior to implementation.
- Retrain all designated drivers, husbandry supervisors or other personnel that may transport animals on the IACUC Guideline and updated VSC SOP. A roster of attendees will be provided to the IACUC.
- Will work with relevant IT groups on a technical solution to ensure that inter-campus animal transfers have been successfully completed. This solution will be reviewed by the IACUC prior to implementation.

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)

Electronically signed by:
Kathryn A Moler
Reason: I have reviewed and
am approving this document.
Date: Feb 14, 2022 11:53
AMT

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

cc:

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, February 25, 2022 7:30 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Notification for PHS Assured Institution #A3213-01

Thank you for this report, (b) (6) We will send a response soon.

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

From: (b) (6)
Sent: Thursday, February 24, 2022 4:00 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] OLAW Notification for PHS Assured Institution #A3213-01

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

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)

The Research Compliance Office (IRB, SCRO, APLAC) is operating with a full staff and conducting protocol review business as usual. Incoming questions, help tickets or other support services are also being maintained.

******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: (b) (6)

Date: 10/1/21

Time: 10:30

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: STANFORD UAssurance number: A3213Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

*Rat transported across campus + left in vehicle. Probably heat stress.
There was food + water in vehicle.*

Species involved: *Rat*Personnel involved: *Animal care supervisor*

Dates and times:

Animal deaths: *1 rat*

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

Investigate, necropsy. Retrain.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____