



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

July 13, 2022

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

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 July 6, 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 May 12, 2022. According to the information provided, OLAW understands that one mouse was moribund and one died after not receiving water following the conclusion of an approved water restriction procedure.

The corrective action consisted of retraining the individual responsible, placing the individual under enhanced oversight, counseling the laboratory staff, and implementing use of cage cards that describe the procedures and monitoring underway during water restriction. The Institutional Animal Care and Use Committee (IACUC) directed laboratory staff to review the details of the protocol, to confirm on the cage card that a water bottle has been returned to the cage following water restriction, and to ensure that the details of the water restriction are clearly outlined in the protocol.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to reduce the likelihood of a recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

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

cc: IACUC Chair

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Wednesday, July 13, 2022 9:03 AM
To: [REDACTED] (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD); [REDACTED] (b) (6)
Subject: OLAW Case A3213-2J
Attachments: OLAW Case A3213-2J.pdf

Good morning Dr. Moler,

Attached please find Dr. Wolff's final response to OLAW Case A3213-2J. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

Stanford | RESEARCH

Vice Provost and Dean of Research

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

(b) (6)

Confidential

July 6, 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	Multiple National Institutes of Health Grants

Description:

At a convened meeting on May 26th, 2022, the IACUC discussed an allegation of noncompliance that involved an approved water restriction model. At the conclusion of the water restriction, two mice that should have been provided with ad-lib water, were not. This resulted in one morbidity and one mortality. The IACUC 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.

A preliminary report of this incident was provided to OLAW on May 12th, 2022, via a telephone call from the Associate Director of the Institutional Animal Care and Use Program, Research Compliance Office.

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".

Dr. Brent Morse
July 6th, 2022

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 Protocol Director (PD).

Corrective Actions and Follow up:

The PD reported that the following had been done proactively:

- The individual involved in the incident in question has undergone specific retraining regarding water restriction and will undergo additional oversight and monitoring.
- All laboratory staff under the PD's direction using water restriction were contacted to reiterate the importance of monitoring during water restrictions and all have confirmed that they are monitoring and providing water to their animals according to the approved protocol.
- The PD has agreed to place cage-side monitoring cards on the cages of all animals undergoing water restriction. This will allow husbandry staff, veterinary technicians, veterinarians, etc. to clearly understand what is happening to the mice at the cage level.

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

- Have all laboratory staff who use water restriction re-review the relevant parts of the APLAC protocol. Documentation of this training will be reviewed by the IACUC.
- Further customize the cage-side monitoring card to include a check-box indicating the end of water restriction and document that a water bottle has been placed in the cage.
- Ensure that the duration of water restriction/number of sessions that will be utilized are clearly outlined within the procedure section of the APLAC protocol

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 parties have received appropriate training, and the PD is 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:

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, July 13, 2022 6:54 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: Monday, July 11, 2022 6:15 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] 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)



Initial Report of Noncompliance

By: (b) (6)

Date: 5/12/22

Time: 1135

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

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?

2 mice had stereotaxic injection then on water restriction.
1 mouse died because investigator forgot to give water.
Human Error.

Species involved: Mice

Personnel involved: _____

Dates and times: _____

Animal deaths: 1

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

Retrain

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

OFFICE USE ONLY

Case # _____