



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

June 6, 2022

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

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 May 24, 2022 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 28, 2022. According to the information provided, OLAW understands that twelve mice failed to receive post-operative analgesia as stipulated in the approved protocol.

The corrective actions consisted of requiring the surgeons to undertake retraining, having surgical records reviewed by the laboratory animal care office, and ensuring that the surgical team review the relevant rodent survival surgery guidelines and protocol. The laboratory was placed under enhanced post-approval monitoring.

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

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

May 24, 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 awards RO1NS100180, R01AG070839

Description:

At a convened meeting, the IACUC discussed an allegation of noncompliance involving mice. After undergoing a surgical procedure, 12 mice were not provided post-operative analgesia as described in the approved IACUC protocol. 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 January 28th, 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
May 24, 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:

- A post-approval monitoring visit overseen by a veterinarian took place to establish compliance with the approved protocol.

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

- Have all survival surgeons listed on the protocol retake the hands-on rodent survival surgery course offered by the Veterinary Service Center.
- Ensure that the surgeon who performed the surgeries in question submit their next 5 survival surgical records to the APLAC office for review.
- Have anyone performing survival surgery review the [IACUC Rodent Survival Surgery Guideline](#) and the relevant APLAC protocol. Documentation of this training will be reviewed by 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 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)

Electronically signed by:
Kathryn A. Moler
Reason: I have reviewed and
am approving this document.
Date: May 24, 2022 14:22
PDT

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, June 1, 2022 7:37 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, May 26, 2022 3:27 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)

A3213-2I



Initial Report of Noncompliance

By: (b) (6)

Date: 1/28/22

Time: 3:00

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?

12 mice on stroke model didn't get required analgesia
Mice survived 4 hrs after procedure

Species involved: mouse

Personnel involved: _____

Dates and times: _____

Animal deaths: _____

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

Monitor next procedure to see if analgesics can
be used

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

OFFICE USE ONLY

Case # _____