



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 1X)

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 December 11, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Stanford University. According to the information provided, OLAW understands that rodents undergoing surgery were not in a surgical plane of anesthesia and post-operative analgesics were not given.

The corrective actions consisted of counseling the laboratory on adhering to the protocol, retraining the laboratory staff, and placing the surgeon and laboratory under enhanced post approval monitoring.

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 institution to comply with the PHS Policy. Please remember to specify the species involved and indicate the final status of the animal (i.e., euthanasia, successful recover). Thank you for informing OLAW about this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair

A3213-1X



STANFORD UNIVERSITY

KATHRYN A. MOLER
VICE PROVOST
DEAN OF RESEARCH

Confidential

December 11, 2018

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 # 5R37MH052804-14; 1P50MH086403-01; 2R01MH052804 - 17; 1K99AG05340901; 1K99MH113764-01; 1K01NS105155-01; K99AG054616; P50AG047366

Description:

At the convened meeting on October 25th, 2018, the IACUC discussed an allegation of noncompliance in which rodent surgery was conducted without maintaining a surgical plane of anesthesia and post-operative analgesia was not administered as described in the approved protocol surgical plan.

A preliminary report of this incident was provided to OLAW on September 26, 2018, via a telephone call from (b) (6) Research Compliance Office.

IACUC Determination:

An IACUC subcommittee met on October 23rd, 2018, 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 animals.

At its convened meeting on October 25th, 2018, 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 November 20th, 2018.

408 Panama Mall • Stanford, California 94305-2061
Tel (650) 723-0977 • Fax (650) 725-1653 • kmoler@stanford.edu

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Initial Report of Noncompliance

By: Jane Na

Date: 9/26/18

Time: 1:10 PM

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #: (b) (6)

Email: (b) (6)

Name of Institution: Stanford University

Assurance number: D16-00134 (A3213-01)

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

During routine facility walkthrough, it was noted that no analgesia was provided after a surgical procedure per protocol.

Species involved: Mouse

Personnel involved: Lab

Dates and times: 9/21/18

Animal deaths: No adverse animal welfare effects were noted.

Projected plan and schedule for correction/prevention (if known): **Plan for correction to be reviewed by IACUC shortly.**

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____

Ward, Joan (NIH/OD) [E]

From: Na, Jane (NIH/OD) [E]
Sent: Wednesday, September 26, 2018 1:47 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Question regarding preliminary reports - Please start one case.
Attachments: Stanford - incident 1.doc; Stanford - incident 2.doc

Hello Joan,

I spoke with (b) (6) and took in the preliminary reports and answered her questions. The preliminary reports are attached. Please start one case at this time. If the final reports are submitted at the same time, Brent may decide that combining these two cases may be optimal given the nature of each incident is nearly identical. I anticipate that the final report from at least incident one, potentially both, will be sent shortly.

Thank you!

Jane Na, DVM
NIH OLAW Veterinary Medical Officer
Assurance Officer, Division of Assurances
(301) 402-1922

From: Na, Jane (NIH/OD) [E]
Sent: Wednesday, September 26, 2018 12:52 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Question regarding preliminary reports

Hello Joan,

I can call her. Thank you.

Jane Na, DVM
NIH OLAW Veterinary Medical Officer
Assurance Officer, Division of Assurances
(301) 402-1922

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, September 26, 2018 12:51 PM
To: Na, Jane (NIH/OD) [E] <jane.na@nih.gov>
Subject: FW: Question regarding preliminary reports

Jane,
Would you like to speak to (b) (6) or should I ask her to put the reports by e-mail?

From: (b) (6)
Sent: Wednesday, September 26, 2018 12:23 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Question regarding preliminary reports

Hello,

I have two separate preliminary noncompliance issues to report to OLAW and see that both Dr. Morse and Dr. Wolff are out of office. Would you please direct me to the appropriate person with whom I should speak? Thank you in advance!

Regards,

[Redacted]

[Redacted] (b) (6)

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