



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

November 18, 2022

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

Dr. Kathryn Moler
Vice Provost and Dean of Research
Stanford University
1705 El Camino Real, MC 5579
Palo Alto, CA 94306

Dear Dr. Moler,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 11, 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 July 28, 2022. According to the information provided, OLAW understands that mice on a tumor study were not being monitored at the appropriate intervals resulting in nine animals exceeding the humane endpoints.

The corrective actions consisted of counseling the laboratory staff on the monitoring and humane endpoint guidelines. The individual responsible has left the institution, the individuals on the protocol were retrained on monitoring and surgery, the protocol director developed a form on specific responsibilities for users on the protocol, and the laboratory will maintain documentation of training and proficiencies. The Institutional Animal Care and Use Committee (IACUC) placed the laboratory on enhanced post-approval monitoring and will assess tumor monitoring records.

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 IACUC 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

phone: (b) (6)

Confidential

November 11, 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 1U54CA209971-01, 1R01CA222969-01A1, 1R01CA222969-01A1, 1P01 CA244114-01A1, 1R01CA262361-01, 4K00CA234946

Description:

At a convened meeting in September 2022, the IACUC discussed an allegation of noncompliance involving mice. During an approved tumor study, animals were not monitored at the appropriate time intervals as described in the IACUC protocol, and at least nine mice were allowed to exceed the humane endpoints. 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 July 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

Dr. Brent Morse
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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 Protocol Director (PD).

Corrective Actions and Follow up:

The PD reported that the following had been done proactively:

- The PD met with all members of the lab to ensure they understood the IACUC approved and required experimental monitoring and humane endpoints.

The IACUC requested that in addition to this action that:

- The Responsible Person (RP) involved in this matter be required to take the Mouse Handling and Basic Techniques Workshop offered by the VSC; however, this individual has left the university.
- All animal users on the protocol retake the online Stanford Animal Care and Use Training Program.
- In order to ensure that all animal users in this laboratory understand their monitoring responsibilities, they will be required to review the IACUC Guidelines for Animal Care and Monitoring (Including Weekends and Holidays) and their relevant IACUC protocol(s). Documentation of this training will be reviewed by the IACUC.
- Anyone performing rodent survival surgery must review the IACUC Rodent Survival Surgery Guideline and the relevant IACUC protocol. Documentation of this training will be reviewed by the IACUC.
- The PD develop an *Experimental Responsibility Questionnaire* to be filled out by all animal users and that this questionnaire will include details regarding monitoring requirements for specific procedures and what to do when the Responsible Person is away from the lab. The IACUC will review this document.
- The lab mentorship program within the lab will include documentation of training and competencies regarding relevant approved animal procedures under which they will be working. The IACUC will review these documents.
- Tumor monitoring records will be submitted to the IACUC office for review for the next 6 months.

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,

Kathryn A Moler

Electronically signed by: Kathryn A Moler
Reason: I have reviewed and am approving this document.
Date: Nov 11, 2022 14:56 PST

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

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

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, November 16, 2022 8:10 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: CORRECTED: OLAW Notification for PHS Assured Institution #A3213-01

Good morning (b) (6)

Thank you for sending us this final report and we will send a response soon.

Best,
Devora

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

From: (b) (6)
Sent: Tuesday, November 15, 2022 4:54 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] CORRECTED: OLAW Notification for PHS Assured Institution #A3213-01

Dear Dr. Morse -

Please disregard the previous letter, this is the correct version, apologies.

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: BCM

Date: 7/28/2022

Time: 2:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Stanford Univ.

Assurance number: A3213-2K

Did incident involve PHS funded activity? yes

Funding component: ?

Was funding component contacted (if necessary):

Morbidity reports submitted to Veterinarian indicated inadequate monitoring of mice and humane endpoints not adhered to.

Species involved: mouse

Personnel involved: researcher

Dates and times: 7/5/22

Animal deaths: No, but three mice euthanized, so far.

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

IACUC investigating

Projected submission to OLAW of final report from Institutional Official:

< 60 days

OFFICE USE ONLY

Case #