

DEPARTMENT OF HEALTH & HUMAN SERVICES

<u>FOR US POSTAL SER VICE DELIVERY</u>. Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, Maryland 20892-6910 <u>Home Page:</u> http://grants.nih.gov/grants/olaw/olaw.htm

April 10, 2019

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FUR EXPRESS MAIL: • ffice of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Faesimile</u>: (301) 402-7065

Re: Animal Welfare Assurance #A3213-01 (OLAW Case 1Z)

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 (OLA W) acknowledges receipt of your March 21, 2019 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 February 25, 2019. According to the information provided, OLAW understands that a tank was severely overcrowded with fish awaiting euthanasia. The fish were in the tank for 15 hours which resulted in low oxygen and several deaths. This incident occurred in a room managed by the Principal Investigator (PI) and was investigated by the Institutional Animal Care and Use Committee.

The corrective actions consisted of counseling the laboratory staff on the requirement to follow all animal use guidelines, having the PI ensure that all current and future staff are adequately trained, having the PI develop a euthanasia standard operating procedure and train staff on it, and having the PI amend the protocol to justify continuation of the PI managed facility.

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.

Sincerely,

(b) (6)

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

cc: IACUC Chair

A3213-2A



STANFORD UNIVERSITY

KATHRYN A. MOLER VICE PROVOST DEAN OF RESEARCH

Confidential

March 21, 2019

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 # 1R01AG063418-01, 1R01AG057334-01, 1DP1AG044848- 01, K99AG057807-01A1

Description:

At the convened meeting on February 28th, 2019 the IACUC discussed an allegation of noncompliance involving killifish in a PI managed colony. During a routine walk through, it was noted that a static tank held several times the approved density of adult killifish. An investigation determined that these animals were held in this tank for approximately 15 hours while awaiting euthanasia. During this time, several fish died and the rest experienced low oxygen conditions.

A oreliminary reoortof this incident was provided to OLAW on February 21, 2019, via a telephone call from (b) (6)

IACUC Determination:

An IACUC subcommittee met on February 19th, 2019, 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 an animal.

At its convened meeting on February 28th, 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 March 11th, 2019.

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

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Dr. Brent Morse March 21, 2019

Corrective Actions and Follow up:

The PD reported that they had proactively:

• Met with all animal users in the laboratory to discuss this issue and briefed them on the importance of following all relevant guidelines for animal use at Stanford.

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

- The lab institute and document mandatory training for existing and future lab staff (specifically for
 protocol and guideline adherence). All applicable lab staff listed on this protocol must be trained
 within 30 days from the date the PD received the IACUC's determination memo. A roster of attendees
 will be provided to the IACUC. All future staff joining the lab after that date will receive the same
 training.
- The lab provide the IACUC with a euthanasia SOP and that this SOP be reviewed by a Stanford veterinarian. Once finalized, all applicable lab staff listed on this protocol must be trained on this SOP. A roster of attendees will be provided to the IACUC. All future staff joining the lab after that date will receive the same training.
- The lab submit a revision to the approved IACUC protocol that provides a stronger scientific justification to continue with PI managed care of this colony. This revision will be reviewed by the IACUC at a convened meeting.

Concluding Remarks:

Sincerely,

Electronically signed by: Kalbryn Ann Molei Dale: 2019-03-23 14:02:04-07:00 Kathryn Ann Moler

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

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

Morse, Brent (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Thursday, March 28, 2019 9:13 AM
To:	(b) (DOLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: OLAW Notification for PHS Assured Institution #A3213-01

Thank you for providing this final report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM Director Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: (b) (6) Sent: Wednesday, March 27, 2019 2:01 PM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Subject: 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)

(b) (6)

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, _v_e5694IPKNqUvDM1

