

DEPARTMENT OF HEALTH & HUMAN SERVICES

FOR US POSTAL SER VICE DELIVERY: Office of Laboratory Animal Welfare Rockledge One, Suite 360 6705 Rockledge Drive – MSC 7982 Bethesda, Maryland 20892-7982 Home Page; http://grants.nih.gov/grants/olaw/olaw.htm PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

> FOR EXPRESS MAIL: Office of Laboratory Animal Welfare Rockledge One, Suite 360 6705 Rockledge Drive Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 402-7065

May 9, 2017

Re: Animal Welfare Assurance A3426-01 [OLAW Case U]

Ms. Grace Fisher-Adams Director, Research Compliance California Institute of Technology 1200 E. California Boulevard, MC 104-31 Pasadena, CA 91125-3100

Dear Dr. Fisher-Adams,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter, received in this office on April 27, 2017, reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the California Institute of Technology. Your letter supplements information in the prompt initial telephone report by Dr. Baer on March 9, 2017. According to the information provided, OLAW understands that on March 7, 2017 an HVAC temperature controller malfunctioned in a facility housing mice on a behavior study. The ambient temperature of the room rose to 94 degrees during the day. Although maintenance personnel responded to an alarm, they inadvertently responded to an HVAC issue in a different room. Due to the nature of the study the room is only checked once daily in the early morning. The following morning it was determined that eighteen mice had died and another 100 mice were rendered unusable for experimentation. It was stated that this animal activity was funded by the PHS.

Corrective actions included replacing the faulty system controller and adding an independent, redundant sensor in the exhaust vent. A campus-wide, thorough review of the animal facility HVAC systems was initiated and redundant sensors will be installed as needed. The surviving mice will be used by the investigator on pilot studies or for breeding recovery and then euthanized. NIH funding components will be notified and grants will not be charged for the direct costs associated with the affected mice.

OLAW appreciates the prompt consideration of this matter by the California Institute of Technology, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate the incident and to prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

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Brent C. Morse, DVM Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact

Bient A3426-11



Office of Research Compliance

Grace Fisher-Adams, PhD, JD Director, Institutional Official 1200 E. California Blvd., MC B110-31 Pasadena, CA 91125 (626) 395-2907 gracefa@caltech.edu

Axel Wolff, DVM Director, Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health Rockledge 1, Suite 360 6705 Rockledge Drive Bethesda, MD 20892

Dear Dr. Wolff:

The California Institute of Technology, in accordance with Assurance D16-00266 and PHS Policy IV.F.3., provides this report of a serious deviation from the Guide, specifically an HVAC mechanical failure resulting in conditions that jeopardized the health or well-being of animals and resulted in actual harm or death to animals. This incident was first reported to Dr. Brent Morse, OLAW, on March 9, 2017, via a telephone call by Janet Baer, DVM, Director of Caltech's Office of Laboratory Animal Resources.

On Wednesday, March 8, 2017, the Office of Research Compliance received information from the Attending Veterinarian that the HVAC system had failed in a mouse housing facility, causing the temperature to rise to approximately 94°F. The room temperature was within desired range when the animal care staff performed daily animal health observations early Tuesday, March 7, 2017, at around 6 a.m. Forensic review of the faulty temperature controller data showed that the HVAC controller malfunctioned and had been offline since Tuesday, March 7, 2017, at around 7 a.m. The malfunctioning controller triggered an alarm, but maintenance personnel responding to that alarm inadvertently addressed an HVAC issue in a different room. No further maintenance follow up occurred on March 7. Because these are behavioral suites, animal care staff only enter the room once daily to minimize disturbances to the mice, so no additional animal care staff entered the room on March 7. Finally, there was no backup temperature probe/alarm present in the exhaust ducting to alarm. The combination of these factors resulted in the high temperature condition being overlooked until the animal care staff entered the room to perform daily health observations early Wednesday, March 8 in the morning. When the animal care staff entered the room early Wednesday morning and determined that the temperature was outside of the desired range, they took immediate action to remove the animals from the room and to provide emergency treatment.

Eighteen mice died because of the high temperature and approximately one hundred more were exposed to the elevated room temperature, rendering them unusable for continued experimentation. It was determined that the researchers would use the surviving mice for pilot experiments and/or breeding recovery and then euthanize them. The IACUC discussed the incident and requested corrective actions be provided by Caltech Facilities Administration.

Caltech Office of Research Compliance

A review of billing records showed that a portion of the direct costs associated with the procurement, care, and use of the affected mice were scheduled to be charged to federal grants, including grants from NIH. These costs have been reallocated, invoiced to, and paid from nonfederal sources. NIH funding components affected will be notified of the situation.

To address the situation, corrective actions were taken including initiating a campuswide, thorough review of the animal facility HVAC systems. The faulty system controller was replaced in the room where the failure was detected and an independent temperature sensor, connected to the building management system, was placed in the exhaust vent. The building management system is monitored 24/7 by Facilities personnel. The new sensor was wired to an independent controller to ensure redundancy. Caltech Facilities will install redundant independent temperature sensors, as needed, in all animal housing facilities.

Caltech Facilities has assured the IACUC that measures are being taken to prevent a similar incident from occurring in the future. At their meeting on April 11, 2017, the IACUC also reviewed and accepted the corrective actions as submitted by Caltech Facilities.

The IACUC determined that this was a systematic failure. However, the IACUC agreed that the corrective action plan provided, the implementation of system changes, and major program revisions in progress would adequately address the situation and guard against future failures.

Caltech is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Richard Andersen, PhD, IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

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Grace Fisher-Adams, PhD, JD Director of Research Compliance Institutional Official Page 2

Morse, Brent (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Friday, April 28, 2017 7:24 AM
То:	IACUC; OLAW Division of Compliance Oversight (NIH/OD)
Cc:	Fisher-Adams, Grace C.
Subject:	RE: Caltech Follow-up Report of Incident Reported on March 9, 2017

Thank you for the report ndary Indii We will send an official response soon.

Regards, Brent Morse

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

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From: ondary Individ [mailto lary In@caltech.edu] On Behalf Of IACUC Sent: Thursday, April 27, 2017 7:33 PM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Cc: Fisher-Adams, Grace C. <Grace.Fisher-Adams@caltech.edu> Subject: Caltech Follow-up Report of Incident Reported on March 9, 2017

To Whom It May Concern:

Attached is a copy of the follow-up report of an animal welfare incident that took place at Caltech on Wednesday, March 8, 2017. The incident was initially reported to Dr. Brent Morse, OLAW, by Dr. Janet Baer on March 9, 2017. If there are any questions or concerns regarding the attached follow-up report, please let me know.

Thank you, ondary indivi

ondary Indivi 1200 E. California Boulevard, Pasadena, CA 91125 Tel: Phone Number Fax: Phone Number Email: <u>iacuc@caltech.edu</u>

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office of Laboratory Animal Welling Office of Laboratory Animal Welling OLANY Ini	tial Report of Noncompliance		
Date: 3/9/17	Time: Voice-		
Name of Person reporting: Telephone #: Fax #: Email:			
Name of Institution: Assurance number: <u>A3426</u>			
Did incident involve PHS funded activity? Funding component: Was funding component contacted (if necessary):			
What happened? HVAC problem. 18 mice died due to A temp. Others are O.K. due to intervetion.			
Species involved: Personnel involved: Dates and times: Animal deaths: Yes, 18 mice.			

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY Case #_____