

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 17, 2021

Re: Animal Welfare Assurance A3230-01 [OLAW Case 5N)

Ms. Pamela S. Caudill
Senior Associate Provost
for Research Administration
Yale University – New Haven
25 Science Park,

(b) (4)
New Haven, Connecticut 06520

Dear Ms. Caudill,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 14, 2021 letter reporting an incident of noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at Yale University. Your letter supplements the information in the preliminary phone report on April 21, 2021. According to the information provided, OLAW understands that on March 18, 2021, Veterinary Clinical Services (VCS) identified a mouse deemed a humane concern and instructed the responsible researcher to euthanize the mouse no later than 11:00 am. The researcher requested that the mouse not be euthanized until 3:00 pm in order to harvest a tissue sample but the veterinarian re-confirmed VCS's initial prognosis, indicating that the mouse would not be likely to survive until 3:00 pm. The researcher delayed euthanizing the mouse as originally instructed and it was found deceased by VCS before the researcher could euthanize it. The associated activity was PHS funded. This incident will be reported to the appropriate NIH Institute/Center.

Corrective and preventive actions included counseling of the researcher of the importance of following veterinary orders and addressing humane concerns within the allotted time period and if unable to do so, the expectation is to authorize VCS to perform the euthanasia on their behalf. The IACUC also requested an explanation from the PI, as to why VCS orders were not followed and an assurance that the lab will comply with future VCS's instructions of a similar nature. The IACUC was satisfied with the PI's response.

OLAW believes that the corrective and preventive measures put in place by Yale University are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of this matter and find no cause for further action by this office at this time.

Sincerely,

Brent C. Morse -S Digitally signed by Brent C. Morse -S Date: 2021.06.18 12:13:08 -04'00'

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

cc: IACUC contact

(b)(6)

Yale Office of Research Administration

A3230

June 14, 2021

Brent Morse, DVM, DACLAM
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, MD 20892

PAMELA S. CAUDILL Senior Associate Provost for Research Administration

PO Box 208327 New Haven CT 06520-8327 T 203 785-3012 F 203 785-3510 pamela.caudill@yale.edu

courier 25 Science Park, Suite 322 New Haven CT 06511

Dear Dr. Morse:

In accordance with the Public Health Service Policy and Yale University's Animal Welfare Assurance (#D16-00146), I am writing to report the fact-finding results of an animal welfare-related incident identified by the Yale Animal Resource Center (YARC).

On March 18, 2021, YARC's Veterinary Clinical Services (VCS) identified a mouse deemed a humane concern and instructed the responsible researcher to euthanize the mouse no later than 11:00 am. The researcher requested that the mouse not be euthanized until 3:00 pm in order to harvest a tissue sample but the veterinarian reconfirmed VCS's initial prognosis, indicating that the mouse would not be likely to survive until 3:00 pm. The researcher delayed euthanizing the mouse as originally instructed and it was found deceased by VCS before the researcher could euthanize it.

During the Office of Animal Research Support (OARS) fact-finding activity, the researcher stated that they hoped to collect valuable tissue samples from this animal. The researcher was involved in another experiment and was unable to go to the animal room before the 3:00pm. The OARS Research Liaison emphasized the importance of following veterinary orders and addressing humane concerns within the allotted time period and if unable to do so, the expectation is to authorize VCS to perform the euthanasia on their behalf.

The IACUC reviewed the details of the incident at its April 14, 2021 meeting. In addition to retraining of the researcher in promptly addressing veterinary and humane concerns, the IACUC requested a detailed explanation, in writing directly from the PI, as to why VCS orders were not followed and an assurance that the lab will comply with future VCS's instructions of a similar nature. OARS received the PI's written explanation on April 23rd and the IACUC discussed it at its May 12th meeting. The IACUC was satisfied with the response.

In accordance with University procedure, this incident will be reported to the appropriate NIH Institute/Center. If you have questions regarding this report, please contact Dr. Troy Hallman via email at troy.hallman@yale.edu.

Sincerely,

Pamela

Digitally signed by Pamela Caudill

Caudill

Date: 2021.06.14 09:37:33

-04'00

Pamela S. Caudill Institutional Official

Senior Associate Provost for Research Administration

Cc: Kathryn Bayne, Chief Executive Officer, AAALAC International
Gary Cline, IACUC Chair, Yale University
James Macy, Attending Veterinarian, Yale University
Troy Hallman, Director, Office of Animal Research Support, Yale University

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD) Wednesday, June 16, 2021 7:26 AM Sent: (b) (6) To: Cc: OLAW Division of Compliance Oversight (NIH/OD) RE: A Final Report from Pamela Caudill of Yale University dated June 14, 2021 Subject: (b) (6) We will send a response soon. Thank you for this report, Axel Wolff, M.S., D.V.M. Deputy Director, OLAW (b) (6) From: Sent: Monday, June 14, 2021 10:46 AM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Cc: Macy, James <james.macy@yale.edu>; Hallman, Troy <troy.hallman@yale.edu>; Caudill, Pamela <pamela.caudill@yale.edu>; accredit@AAALAC.org; Cline, Gary <gary.cline@yale.edu> Subject: A Final Report from Pamela Caudill of Yale University dated June 14, 2021 Dear Dr. Morse, I've attached a final report from Pamela Caudill of Yale dated June 14, 2021. Regards, (b) (6)



Initial Report of Noncompliance

By: BCM

Date: 4/2	1/2021	Time: 7:25 PM
Name of Pers Telep Fax # Email	-	
Name of Insti Assurance no	itution:Yale Univ umber:A3230	
Did incident involve PHS funded activity?? Funding component: Was funding component contacted (if necessary):		
	ed? died without the benefit of euthanasia because timeline for euthanasia.	the lab didn't abide by the
Projected plan and schedule for correction/prevention (if known):		
Full retraining of all labs doing genotyping		
Projected submission to OLAW of final report from Institutional Official:		
Starting inves	stigation	
OFFICE USE Case #	EONLY	