



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

April 20, 2022

Re: Animal Welfare Assurance
A3230-01 [OLAW Case 5W]

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 April 7, 2022 letter reporting an incident of noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at Yale University. According to the information provided, OLAW understands that on February 3, 2022, your program discovered sixteen mice that underwent toe clipping for genotyping purposes. Although the procedure was done under anesthesia, all the mice at the time of the procedure were older than 12 days, exceeding Yale's Rodent Identification & Genotyping policy age threshold of 12 days. The mice underwent veterinary examination the same day, and analgesia was administered immediately. It was subsequently determined that one of the two researchers that were involved in the procedure had not completed the required training and was not approved to be working under the PI's protocol at the time of the procedure.

Corrective and preventive measures were as follows: the untrained researcher completed all required trainings and was added to the protocol. The other researcher retook the genotyping training course. The PI and the lab were counseled regarding the age limit and other conditions for toe clipping from the IACUC's genotyping policy. This incident will be reported to the appropriate NIH Institute/Center.

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 - Digitally signed by Brent C.
Morse -S
Date: 2022.04.20 10:05:08
-04'00'

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

cc: IACUC contact

(b) (6)

Yale Office of Research Administration

A3230-5W

April 7, 2022

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

PAMELA S. CAUDILL
Senior Associate Provost
for Research Administration

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New Haven CT 06520-8327
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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 a protocol-related incident, identified by the Yale Animal Resource Center (YARC).

On February 3, 2022, YARC husbandry staff identified sixteen mice that underwent toe clipping for genotyping purposes. Although the procedure was done under anesthesia, all the mice at the time of the procedure were older than 12 days, exceeding Yale's Rodent Identification & Genotyping policy age threshold of 12 days. YARC's Veterinary Clinical Services examined the mice the same day, and analgesia was administered immediately.

During the Office of Animal Research Support (OARS) fact-finding activity, it was found that one of the two researchers that were involved in the procedure had not completed the required training and was not approved to be working under the PI's protocol at the time of the procedure. OARS ensured that the untrained researcher completed all required trainings and was added to the protocol. The other researcher retook the genotyping training course. The OARS Director emphasized the age limit and other conditions for toe clipping from the IACUC's genotyping policy to the PI and the lab.

The IACUC reviewed the details of the incident at its monthly meeting on March 9, 2022. They accepted the remediation actions taken and without further recommendations.

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 (b) (6) via email

Sincerely,

Pamela Caudill

Digitally signed by Pamela
Caudill
Date: 2022.04.07 15:03:26 -04'00'

Pamela S. Caudill
Institutional Official
Senior Associate Provost for Research Administration

Cc:

Adam Wisniewski, IACUC Chair, Yale University
James Macy, Attending Veterinarian, Yale University

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 8, 2022 7:19 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: A Final Report from Pamela Caudill of Yale University dated April 7, 2022

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

-----Original Message-----

From: (b) (6)
Sent: Thursday, April 7, 2022 3:16 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Macy, James <james.macy@yale.edu>; (b) (6) Caudill, Pamela <pamela.caudill@yale.edu>; accredit@AAALAC.org; Wisnewski, Adam <adam.wisnewski@yale.edu>
Subject: [EXTERNAL] A Final Report from Pamela Caudill of Yale University dated April 7, 2022

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Morse,

I've attached a final report from Pamela Caudill of Yale dated April 7, 2022.

Regards,

(b) (6)