



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

October 1, 2021

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

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 September 23, 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 email report on July 22, 2021. According to the information provided, OLAW understands that on June 24, 2021, it was determined that tail biopsies had just been performed without anesthesia or post-procedure analgesia in 13 mice, all of which were over 21 days of age. The Veterinary Clinical Services (VCS) staff examined the animals and recommended to the PI that all mice either be euthanized, or their wounds treated. The lab, after consulting with the PI, chose to immediately euthanize the animals. The associated activity was PHS funded. This incident will be reported to the appropriate NIH Institute/Center.

During the Office of Animal Research Support (OARS) fact-finding activity, the assigned OARS Research Liaison reinforced the genotyping policy, emphasizing the age limit for tail biopsies with the lab staff member responsible for conducting the procedure.

The IACUC also mandated that all personnel who are currently associated with any rodent protocol involving genotyping must complete a recently made available, and enhanced, rodent identification and genotyping training.

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: 2021.10.01 09:17:11 -04'00'

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

cc: IACUC contact

(b) (6)



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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

PAMELA S. CAUDILL
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for Research Administration

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25 Science Park, Suite 322
New Haven CT 06511

September 23, 2021

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

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 June 24, 2021, a routine health monitoring detected tail biopsies performed without anesthesia or post-procedure analgesia in 13 mice all of which were over 21 days of age. The monitoring activity occurred immediately after a tail biopsy procedure was performed. The Veterinary Clinical Services (VCS) staff examined the animals and recommended to the PI that all mice either be euthanized, or their wounds treated. The lab, after consulting with the PI, chose to immediately euthanize the animals.

During the Office of Animal Research Support (OARS) fact-finding activity, the lab staff member confirmed that the animals were not anesthetized before the procedure nor were they treated with analgesics after the procedure. In addition, the lab staff member acknowledged that he did not recall the age threshold requirement described in the genotyping policy. The assigned OARS Research Liaison reinforced the genotyping policy, emphasizing the age limit for tail biopsies with the lab staff member responsible for conducting the procedure.

The IACUC reviewed the details of the incident at its monthly meeting held on July 14, 2021. The IACUC accepted the remediation actions taken for this event and also mandated that all personnel who are currently associated with any rodent protocol involving genotyping must complete a recently made available and enhanced rodent identification and genotyping training.

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 [REDACTED] (b) (6)

Sincerely,

[REDACTED] (b) (6)

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

Cc:

[REDACTED] (b) (6)

Gary Cline, IACUC Chair, Yale University
James Macy, Attending Veterinarian, Yale University

[REDACTED] (b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, September 27, 2021 7:45 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: A Final Report from Pamela Caudill of Yale University dated September 23, 2021

Thank you for this report. We will send a response soon.

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

From: (b) (6)
Sent: Friday, September 24, 2021 11:09 AM
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; Cline, Gary <gary.cline@yale.edu>
Subject: A Final Report from Pamela Caudill of Yale University dated September 23, 2021

Dear Dr. Morse,

I've attached a final report from Pamela Caudill of Yale dated September 23, 2021.

Regards,

(b) (6)

Walker, Keri (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Friday, July 23, 2021 12:26 PM
To: Walker, Keri (NIH/OD) [E]
Subject: FW: Self report A3270 A3230

Follow Up Flag: Follow up
Flag Status: Flagged

Keri,

Please use this email to open a new case file and assign it to me. Thanks. Brent

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

From: Morse, Brent (NIH/OD) [E]
Sent: Friday, July 23, 2021 12:25 PM
To: (b) (6)
Cc: (b) (6)
Subject: RE: Self report

Thank you for this preliminary report, (b) (6). We'll open a case file and await the final report. I hope your training efforts are fruitful.

Brent

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

From: (b) (6)
Sent: Thursday, July 22, 2021 7:46 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: (b) (6)
Subject: Self report

Hi Brent,

The IACUC decided last week that we would self-report an incident of non-compliance—another case of tail snipping after the IACUC-approved age limit. Since the last case a few months ago, we created an online training course for ID'ing and genotyping, since we seem to be have more of these cases in the last year or so. We'll explain more in the letter.

(b) (6)

(b) (6)