



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

September 17, 2020

Re: Animal Welfare Assurance

A3230-01 [OLAW Case 5D]

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 August 31, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Yale University. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the Yale University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol and institutional policy. The final report states on July 8, 2020 the Yale Animal Resource Center (YARC) found 18 mice that underwent tail clipping for genotyping purposes. The animals were older than 21d which exceeds Yale's 21-day threshold policy for tail clipping. The Office of Animal Research Support (OARS) determined that tail clipping was not approved on the protocol. No tail bleeding was found during examination of the mice, and analgesia was administered within 1h post-procedure and continued for 48h. The following corrective actions were implemented:

- The OARS Post-Approval Monitoring Specialist discussed the genotyping policy with the responsible individual and the requirement to have IACUC approval for all procedures before they are conducted.
- Tail biopsy for genotyping was added to the investigator's protocol and the amended protocol was approved by the IACUC on August 8, 2020.

The IACUC reviewed the incident at its regularly scheduled meeting on August 12, 2020 and accepted the corrective actions with no additional recommendations.

It is understood that this research is supported by PHS funds and will be reported to the appropriate NIH Institute/Center in accordance with university procedure. Based on its assessment of this explanation, OLAW understands that the Yale University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T. Tubbs - Digitally signed by Jacquelyn T.
Tubbs -S
S Date: 2020.09.17 08:07:16 -0400

Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

Yale Office of Research Administration

A3230-5D

PAMELA S. CAUDILL
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for Research Administration

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courier
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August 31, 2020

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 write to report the results of fact-finding activities related to an incident identified by the Yale Animal Resource Center (YARC).

On July 8, 2020, YARC identified eighteen mice that underwent a tail-clipping procedure for genotyping purposes. The mice were older than 21 days exceeding Yale's 21-day age threshold policy for tail clipping. When conducting the fact-finding process, the Office of Animal Research Support (OARS) determined that tail clipping was not approved in the IACUC approved protocol.

YARC's Veterinary Clinical Services examined the mice and found no tail bleeding. Analgesia was administered within one-hour post-procedure and continued for 48 hrs. The OARS Post-Approval Monitoring Specialist reviewed the genotyping policy with the responsible researcher making special note of the age requirement and the need to have prior IACUC approval for all procedures being performed. Tail biopsy for genotyping procedure was added to the Investigator's protocol via a protocol modification and the amended protocol was approved by the IACUC on August 8, 2020.

The IACUC reviewed the details of the incident at its regularly scheduled meeting on August 12, 2020 and accepted the remediation actions taken, without further recommendations.

This incident will be reported to the appropriate NIH Institute/Center in accordance with University procedure. Please contact Dr. Troy Hallman (troy.hallman@yale.edu) directly if you require additional information.

Sincerely,

(b) (6)

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)
Sent: Tuesday, September 1, 2020 10:15 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: A Final Report from Pamela Caudill of Yale University dated August 31, 2020

Thank you for this report, (b) (6) We will respond soon.

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

From: (b) (6)
Sent: Monday, August 31, 2020 4:16 PM
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 August 31, 2020

Dear Dr. Morse,

I've attached a final report from Pamela Caudill of Yale dated August 31, 2020.

Regards,

(b) (6)

(b) (6)