



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) 402-7065

August 15, 2018

Re: Animal Welfare Assurance
A3230-01 [OLAW Case 4N]

Ms. Pamela S. Caudill
Senior Associate Vice Provost
for Research Administration
Yale University – New Haven
25 Science Park, [REDACTED]
New Haven, CT 06520

Dear Ms. Caudill,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 13, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Yale University, following up on an initial June 13, 2018 email notification. According to the information provided, OLAW understands that a laboratory performed unauthorized tail biopsies for genotyping on eight ten-week old anesthetized mice with no provision of analgesia, contrary to the approved protocol and institutional policy. The animals were examined by Veterinary Clinical Services and determined to be bright, alert and responsive with no signs of hemorrhage.

The corrective action consisted of counseling the investigator on the provision of appropriate post-procedural care and ensuring protocol and policy compliance.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

[REDACTED] (b) (6)

For

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair

Yale Office of Research Administration

August 13, 2018

Neera Gopal, DVM, PhD, DACLAM, DABT
Office of Laboratory Animal Research
National Institutes of Health
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PAMELA S. CAUDILL
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for Research Administration

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courier
25 Science Park, Suite 322
New Haven CT 06511

Dear Dr. Gopal:

On April 20, 2018, the Yale Animal Resource Center (YARC) observed eight 10-week old mice, in their home cages, with active bleeding from the tail tip. Veterinary Clinical Services was immediately notified and examined the, noting that they were bright, alert, and responsive and the bleeding had stopped.

In reviewing this incident, it was determined that on April 19, 2018, the laboratory biopsied the tail tips of the eight 10-week old mice in order to collect tissue for genotyping. The mice were anesthetized with isoflurane and no post-procedure analgesia was administered. According to Yale's IACUC genotyping policy, tail biopsies on mice > 21 days of age requires anesthesia and analgesia and must be justified and approved by the IACUC. IACUC approval was not requested by the PI. This incident was self-reported to OLAW on June 13, 2018.

The investigator was counseled regarding the importance of adhering to an approved protocol, to the IACUC policy, and for providing appropriate post-procedure care. The investigator confirmed that the laboratory would not perform tail biopsies on mice over 21 days of age.

The IACUC reviewed the details of the incident and follow-up reports at its regularly scheduled meetings on May 9 and June 13, 2018.

The reporting of the incident to the sponsoring institute/center will be sent under a separate correspondence, as appropriate.

Sincerely,

(b) (6)

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

CC: Kathryn Bayne, Chief Executive Officer, AAALAC International
Elizabeth Eynon, IACUC Chair, Yale University
James Macy, Attending Veterinarian, Yale University
Troy Hallman, Director, Animal Research Support, Yale University

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Gopee, Neera (NIH/OD) [E]

A3230-4N

From: Gopee, Neera (NIH/OD) [E]
Sent: Wednesday, June 13, 2018 3:45 PM
To: 'Hallman, Troy'
Cc: OLAW Division of Compliance Oversight (NIH/OD); Morse, Brent (NIH/OD) [E]
Subject: RE: Self-reports

Troy,

Thank you for these 4 preliminary reports. We will start 4 new case files and look forward to receiving the final reports from the IO after the IACUC has completed its investigation. You are correct in that case 4N is next in queue to be assigned but it depends on how they are assigned during processing.

Best Regards,
Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Hallman, Troy [mailto:troy.hallman@yale.edu]
Sent: Wednesday, June 13, 2018 3:34 PM
To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Subject: FW: Self-reports

Hi Neera,

I received Brent's away message, so I figured that I'd forward this to you, rather than wait for Brent's return. We just discussed these at this morning's IACUC meeting and the Committee decided to report each one.

Troy

From: "Hallman, Troy" <troy.hallman@yale.edu>
Date: Wednesday, June 13, 2018 at 3:30 PM
To: "Morse, Brent (NIH/OD) [E]" <morseb@mail.nih.gov>
Subject: Self-reports

Brent,

I'd like to take this opportunity to self-report a few unrelated issues.

- Eight 7-8 week old anesthetized mice were tail clipped for genotyping and were not provided analgesia. Because of the age of the mice (likely having full growth of the caudal vertebrae) there is a reasonable likelihood that these mice may have experienced post-procedure pain.
- Through regular maintenance in a zebrafish facility, the outflow baffle was not replaced on one tank. As a consequence, 10 fish were found dead on the spillway filter.
- A primary enclosure of mice was returned to the housing rack without replacing the food and water. As a consequence, 4 mice were found dead during routine husbandry care.
- A primary enclosure of mice was returned to the housing rack without checking the functionality of the lixit. During routine husbandry care, the lixit was found in the enclosure, unattached to the water supply. As a consequence, 2 mice were found dead.

These cases will be 4N, 4O, 4P, and 4Q, right?

Troy

Troy Hallman, MS, VMD, DACLAM
 Director, Office of Animal Research Support
 Yale University
 25 Science Park - 3rd floor
 New Haven, CT 06520
 (b) (6) office)

OARS Suggestion Box

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Tuesday, August 14, 2018 8:05 AM
To: 'Hallman, Troy'
Subject: RE: Self report

Thank you for this report Troy. We will open a case file and await further information. I'll get back to you concerning the case number.

Best regards, Brent

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

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From: Hallman, Troy [mailto:troy.hallman@yale.edu]
Sent: Monday, August 13, 2018 4:38 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: Self report

Hi Brent,

We recently identified a cage of mice that did not have a functioning lixit. One mouse was found dead and 2 others were treated for dehydration.

Will this be 4Q? In June, I reported 4 cases to Neera (you were away) and the 4th one was 4Q, but I soon withdrew it because it actually was not associated with PHS/NSF funds.

Troy

Troy Hallman, MS, VMD, DACLAM
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OARS Suggestion Box