

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

November 8, 2018

Re: Animal Welfare Assurance A3230-01 [OLAW Case 4R)

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

Dear Ms. Caudill,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 6, 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 report on October 10, 2018. According to the information provided, OLAW understands that a rat died following surgery due to dehiscence of an abdominal incision which had been closed with a single layer simple continuous suture pattern. The protocol and institutional policy state that two layers must be closed after entry into a body cavity.

The corrective actions consisted of counseling the Principal Investigator and surgeons on performing procedures as described in the approved protocol and the rodent surgery policy. The surgeons were retrained on surgical technique by the veterinarian.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

Yale Office of Research Administration

November 6, 2018

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

Dear Dr. Morse:

PAMELA S. CAUDILL Senior Associate Provost for Research Administration

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

courier 25 Science Park, Suite 322 New Haven CT 06511

On September 06, 2018, a laboratory performed an arteriovenous fistula surgery on a rat. A senior lab member was demonstrating how to perform this procedure to a new surgeon. As part of the training activity, the new surgeon sutured the abdominal incision with a simple continuous pattern with only one layer. Later that same day, a Yale Animal Resources Center (YARC) technician reported finding the same rat deceased with an abdominal dehiscence. This incident was self-reported to OLAW on October 10, 2018.

The associated IACUC approved protocol describes the incision closure to be in two layers, the muscle and the skin. The IACUC's rodent surgery policy also requires closure of a body cavity to be by at least two layers. The Office of Animal Research Support post-approval monitoring staff reinforced, with the surgeons and the principal investigator, the importance of performing procedures as approved by the IACUC, and reviewed the rodent surgery policy with the surgeons. Also, at the next scheduled surgery (October 03), a YARC veterinarian conducted a training session with the surgeons on proper suture technique for rats.

The IACUC reviewed the details of the incident and follow-up at its regularly scheduled meeting on October 10, 2018.

This incident has been reported to the sponsoring institute/center.

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, Animal Research Support, Yale University

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Morse, Brent (NIH/OD) [E]

From:

Morse, Brent (NIH/OD) [E]

Sent:

Thursday, October 11, 2018 3:50 PM

To:

'Hallman, Troy'

Subject:

RE: Self-report

Thank you for this preliminary report Troy. Yes, this will be case -4R. We'll open a file and await the final report.

Best regards, Brent Morse

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: Wednesday, October 10, 2018 11:23 AM

To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>

Subject: Self-report

Brent,

I would like to report a serious adverse event regarding an incisional dehiscence in a rat model, related to not fully adhering the protocol nor the IACUC approved rodent surgery policy. Retraining was performed straightaway (before the next procedure). We will be able to finalize this case shortly. This will be 4R, correct?

Troy

Troy Hallman, MS, VMD, DACLAM Director, Office of Animal Research Support



Yale University
25 Science Park – 3rd floor
New Haven, CT 06520
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OARS Suggestion Box