



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

February 23, 2022

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

Ms. Pamela S. Caudill
Senior Associate Provost
for Research Administration
Yale University – New Haven
25 Science Park, (b) (4)
New Haven, CT 06520

Dear Ms. Caudill,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 7, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Yale University. According to the information provided, OLAW understands that rats on an approved protocol exhibited significant, unexpected weight loss. The investigator was directed by a veterinarian to submit a protocol amendment to account for the weight loss but this was not done. The adverse event thus progressed to an unapproved significant change to a protocol.

The corrective actions consisted of retraining the investigators involved on identifying and documenting clinical endpoints and on addressing adverse events.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and to reduce the likelihood of a recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. Unless informed to the contrary, OLAW assumes that the protocol was subsequently amended to include the weight loss and applicable humane endpoints addressing euthanasia or removal from study as necessary. Thank you for informing OLAW about this matter.

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

A3230-54

PAMELA S. CAUDILL
Senior Associate Provost
for Research Administration

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courier
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New Haven CT 06511

February 7, 2022

Brent Morse, DVM, DACLAM
Office of Laboratory Animal Welfare
National Institutes 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 an animal welfare-related incident identified by the Yale Animal Resource Center (YARC).

On January 4, 2021, YARC's Veterinary Clinical Services (VCS) notified Office of Animal Research Support (OARS) of an adverse event in an experiment that caused significant weight loss in rats. Although the experiment was approved in the protocol, the weight loss was not expected. The Veterinarian in charge of the case advised the researcher to submit a modification to the protocol to include the weight loss, however the researcher continued the study without acquiring approval by the IACUC. The researcher started the modification process but did not submit the protocol amendment to the IACUC. The liaison along with OARS leadership retrained the Principal Investigator (PI) and the responsible researcher in identifying and documenting clinical endpoints and how to properly address adverse events.

At the August 11, 2021, IACUC meeting, the Committee determined that the adverse event is considered as unapproved research because of the delay in getting the modification approved in a timely fashion.

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 at (b) (6)

Sincerely,

**Pamela
Caudill**

Pamela S. Caudill
Institutional Official

Senior Associate Provost for Research Administration

Digitally signed by Pamela
Caudill

Date: 2022.02.09 08:39:14
-05'00'

Cc:

(b) (6)
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, February 11, 2022 7:30 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: A Second Final Report from Pamela Caudill of Yale University dated February 7, 2022 (Unapproved research)

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: Wednesday, February 9, 2022 1:54 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 Second Final Report from Pamela Caudill of Yale University dated February 7, 2022 (Unapproved research)

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Dear Dr. Morse,

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

Regards,

(b) (6)