



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

March 21, 2022

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

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 March 7, 2022 letter reporting an incident of noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at Yale University. According to the information provided, OLAW understands that your program discovered several mice with large tumors at the IACUC policy size limit. The responsible researchers in this laboratory were notified and promptly euthanized the mice and collected tissues in each case. It was subsequently discovered that on July 24, 2021, a tumor in one mouse had exceeded the policy limit and the endpoint criteria approved on the protocol. There was an additional case reported on September 13th and confirmed that 4 mice had exceeded the policy limit and the endpoint criteria.

The PI and several lab members were counseled to reinforce the tumor policy, emphasizing the size limit and endpoint criteria approved under the protocol. It was agreed that the PI would be notified of any tumor-related sick animal cases identified by VCS. Although there were two additional incidents in the ~4 weeks following this meeting, for which the two researchers were again counseled, during the enhanced monitoring period from October 2021 to the present, there has not been any additional cases of tumors exceeding endpoints.

In accordance with university procedure, these incidents will be reported to the appropriate NIH Institute/Center.

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: 2022.03.21 08:10:28 -04'00'

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

cc: IACUC contact

(b) (6)

# Yale Office of Research Administration

March 07, 2022

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

PAMELA S. CAUDILL  
Senior Associate Provost  
for Research Administration

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

courier  
25 Science Park, Suite 322  
New Haven CT 06511

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).

Through its routine health monitoring program, YARC identified and reported several mice with large tumors at the IACUC policy limit of 1 cm<sup>3</sup>. The responsible researchers in this laboratory were notified and promptly euthanized the mice and collected tissues in each case.

During the Office of Animal Research Support's (OARS) fact-finding activity and a review of the PI's sick animal cases, it was discovered that on July 24, 2021, a tumor in one mouse had exceeded the policy limit and the endpoint criteria approved on their protocol. There was an additional case reported on September 13<sup>th</sup> and confirmed that 4 mice had exceeded the policy limit and the endpoint criteria. On September 14, representatives from the IACUC, OARS, YARC, and Veterinary Clinical Services (VCS) met with the PI and several lab members to reinforce the tumor policy, emphasizing the size limit and endpoint criteria approved under the protocol. The PI had not appreciated the number of "sick animal" cases reported and made it clear that large tumors were not needed for the research model. It was agreed that the PI would be notified of any tumor-related sick animal cases identified by VCS and contact information would be updated and clearly communicated with YARC and VCS by the lab.

In the ~4 weeks following this meeting, there were two additional incidents of with 6 mice that had again exceeded the policy limit and the endpoint criteria. The PI further counseled the two responsible researchers. The IACUC reviewed the details of the incidents at its monthly meeting held on September 8 and October 13, 2021, and accepted the remediation actions taken for this event. During the enhanced

monitoring period from October 2021 to the present, there has not been any additional cases of tumors exceeding endpoints.

In accordance with university procedure, these incidents will be reported to the appropriate NIH Institute/Center. If you have questions regarding this report, please contact (b) (6)

Sincerely,

(b) (6)

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

Cc:

(b) (6)

Adam Wisnewski, IACUC Chair, Yale University  
James Macy, Attending Veterinarian, Yale University

(b) (6)

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, March 9, 2022 9:28 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: A Final Report from Pamela Caudill of Yale University dated March 7, 2022

Thank you for this report, (b) (6) We will send a response soon.

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

-----Original Message-----

**From:** (b) (6)  
**Sent:** Wednesday, March 9, 2022 9:06 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; Wisnewski, Adam <adam.wisnewski@yale.edu>  
**Subject:** [EXTERNAL] A Final Report from Pamela Caudill of Yale University dated March 7, 2022

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Morse,

I've attached a final report from Pamela Caudill of Yale dated Regards,

(b) (6)

-----Original Message-----

**From:** (b) (6)  
**Sent:** Wednesday, March 9, 2022 8:55 AM  
**To:** (b) (6)  
**Subject:** FW: Message from "YU-SCIPK25-3-RESORA-322A-MFP-6"

Regards,

(b) (6)

-----Original Message-----

From: Caudill, Pamela <pamela.caudill@yale.edu>

Sent: Tuesday, March 8, 2022 3:22 PM

To: (b) (6)

Subject: FW: Message from "YU-SCIPK25-3-RESORA-322A-MFP-6"

-----Original Message-----

From: GCAscan@yale.edu <GCAscan@yale.edu>

Sent: Tuesday, March 8, 2022 3:18 PM

To: Caudill, Pamela <pamela.caudill@yale.edu>

Subject: Message from "YU-SCIPK25-3-RESORA-322A-MFP-6"

This E-mail was sent from "YU-SCIPK25-3-RESORA-322A-MFP-6" (MP C4503).

Scan Date: 03.08.2022 15:17:46 (-0500)

Queries to: GCAscan@yale.edu

A3230 Prelim.

Assign to Brent

**Morse, Brent (NIH/OD) [E]**

**From:** [REDACTED] (b) (6)  
**Sent:** Tuesday, November 9, 2021 11:52 AM  
**To:** Morse, Brent (NIH/OD) [E]  
**Cc:** [REDACTED] (b) (6)  
**Subject:** Re: Self report

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

[REDACTED] (b) (6)

Yes, mice.

Troy

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**From:** Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>  
**Sent:** Tuesday, November 9, 2021 7:46:13 AM  
**To:** Hallman, Troy <troy.hallman@yale.edu>  
**Cc:** [REDACTED] (b) (6)  
**Subject:** RE: Self report

Thank you for this preliminary report, Troy. [REDACTED] (b) (6)  
[REDACTED] (b) (6)

I assume that mice were the involved species in your report?

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:** [REDACTED] (b) (6)  
**Sent:** Monday, November 8, 2021 4:39 PM  
**To:** Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>  
**Cc:** [REDACTED] (b) (6)  
**Subject:** Self report

Hi Brent,

I hope all is well. [REDACTED] (b) (6)

We are self-reporting an incident where a laboratory exceeded tumor size end points. We'll follow-up with more details in the coming weeks.

Troy

(b) (6)