

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

September 10, 2019

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Eacsimile</u>: (301) 402-7065

Re: Animal Welfare Assurance #A3471-01 [OLAW Case 3H]

Dr. Wesley Byerly Associate Vice President, Research Integrity and Regulatory Affairs University of Connecticut Health Center 263 Farmington Ave., ASB Farmington, CT 06030-1920

Dear Dr. Byerly,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 29, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at UCONN Health. Your letter supplements the prompt email report made to this office on July 29, 2019. According to the information supplied OLAW understands that on July 29, 2019 it was determined that breeding of mice was being conducted on an approved protocol that did not include breeding as an approved activity. The PI was counseled and instructed to cease the breeding activity and to separate the breeding pair. The PI was also instructed to submit a protocol amendment adding the breeding activity. The amendment was approved on August 20, 2019. This was not a PHS-supported activity.

The consideration of this matter by UCONN Health was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We find no cause for further action by this office.

	Sincerely,
(b) (6)	
	Brent C. Morse, DVM
	Director
	Division of Compliance Oversight
	Office of Laboratory Animal Welfare

cc: IACUC Contact

HEALTH

Dr. Brent Morse Director, Division of Compliance Oversight Office of Laboratory Animal Welfare Rockledge One, Suite 360 6705 Rockledge Drive – MSC 7962 Bethesda, MD 20892-7982

August 29, 2019

RE: PHS Assurance D16-00295 (A3471-01) UConn Health

Dear Dr. Morse-

I am writing to you to provide a final report of an incident of non-compliance at UConn Health. Our IACUC Administrator provided an initial report via email on July 29, 2019.

On July 29, 2019, while performing a post-approval monitoring meeting, it was discovered that a PI was breeding mice and a breeding procedure was not described on the approved animal care and use protocol. The PI had one cage of breeders that had produced one litter of 3 mice. The PI was informed that they must cease breeding and separate the breeding pair. The PI complied with this request on July 29, 2019. The PI was informed that they need to modify the approved protocol, add the breeding, and submit the modification to the IACUC for approval. The PI submitted a modified protocol on August 6, 2019 which was approved on August 20, 2019.

The PI was informed that this was a reportable non-compliance to OLAW. The PI was reminded that all procedures being performed on animals, and this included breeding, must be described in the animal care and use protocol and approved by the IACUC. This incident was brought to the August IACUC meeting for discussion. There are no federal funds supporting this IACUC protocol.

While all efforts were made to deal with this matter in a timely and meaningful manner, I realize there may be questions that arise following your review of this material. Please feel free to contact me at <u>byerly@uchc.edu</u> or at $^{(b)}$ (6)

Sincerely,	
(b) (6)	
Wesley G. Byerly, Phalm.D.	п р .

Associate Vice President, Research Integrity and Regulatory Affairs

(b) (6) cc:

Institutional Animal Care and Use Committee 263 FARMING FON AVENUE, MC 1523 FARMING TON CT 06030-1525 PHONE 860,679:3429 FAX 860,679 1005 Poecc@uchc edu research.uchc.edu

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Obtained by Rise for Animals. Uploaded 08/11/2020

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Na, Jane (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)	
Sent:	Friday, September 6, 2019 2:35 PM	
To:	(b) (6)	
Cc:	(b) (6) OLAW Division of Compliance Oversight (NIH/C)D
Subject:	RE: Final report of non-compliance, A3471-01 (D16-00295)	

Dear^{(b) (6)}

Thank you for this final report. We will send an official response soon.

Jane

Jane Na, DVM, CPIA Veterinary Medical Officer Office of Laboratory Animal Welfare National Institutes of Health Phone (301) 402-1922 E-fax (301) 451-5609

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From: ^{(b) (6)}

 Sent: Friday, September 6, 2019 7:32 AM

 To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

 Cc:^{(b) (6)}
 \AALAC International <accredit@AAALAC.org>

 Subject: Final report of non-compliance, A3471-01 (D16-00295)

Hi,

Attached please find a final report of an issue of non-compliance at UConn Health, PHS A3471-01 (D16-00295) I'm sending on behalf of our Institutional Official.

Please let me know if you have any questions.

Thank you and have a great day.

(b) (6)

Morse, Brent (NIH/OD) [E]

A3471-3H

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Monday, July 29, 2019 4:24 PM
To:	(b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: Initial report of non-compliance, PHS assurance A3471-01/D16-00295

Thank you for this prompt preliminary report (b) (6) We will open a case file and await further information.

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: (b) (6)

Sent: Monday, July 29, 2019 3:00 PM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Subject: Initial report of non-compliance, PHS assurance A3471-01/D16-00295

Good afternoon-

I am writing on behalf of my Institutional Official to inform you of a reportable non-compliance discovered today at our institution. While doing a post-approval monitoring visit, it was discovered that a PI is breeding animals and the protocol does not have approval for this procedure in the protocol. The PI was informed that this is non-compliance, that breeding has to cease until the protocol is modified to include breeding and this modification is approved by the IACUC.

A final report will be sent after the UConn Health IACUC reviews and discusses this non-compliant activity.

Thank you and have a wonderful afternoon.

(b) (6)