



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

December 23, 2019

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

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 December 20, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at UConn Health, following up on an initial report on December 4, 2019. According to the information provided, OLAW understands that an approved bone defect surgery was conducted on a rabbit but the radius was inadvertently impacted rather than the ulna as stated in the protocol.

The corrective actions consisted of the Attending Veterinarian counseling the research staff and having the Principal Investigator amend the protocol to allow use of either bone. The rabbit was able to be used for the study and recovered without any signs of pain or distress.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and 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 Contact
Robert Gibbens, D.V.M., USDA-APHIS-AC

UConn 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 20892-7962

December 20, 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 December 4, 2019.

On November 21, 2019, a rabbit surgery was performed under an approved IACUC protocol. The surgeon operated on a rabbit limb to create a segmental defect on the rabbit ulna approaching medially. In the middle of the surgery, the Attending Veterinarian was called in to clarify the positioning/approach of the defect. It was clear based on radiological evidence that the defect was created in the radius instead of the ulna.

The Attending Veterinarian discussed the issue with the research staff; it was felt that the research was still viable as other regeneration studies in rabbits have tested and used both the radius and ulna due to their similar size and anatomy. He suggested that the researchers modify the protocol to include both bones as an option.

The Committee representative spoke with the surgeon who performed this surgery to determine what might have happened to allow the incorrect bone being used in the segmental defect surgery. The surgeon stated that typically the animal is positioned in a way that allows for a medial access to the ulna; however, the animal had been draped and she did not realize that the rabbit was in a different position that led to the wrong bone being used.

The IACUC discussed this incident during its December IACUC meeting. The IACUC determined that this was an unfortunate error that did not result in the euthanasia of the animal as the defect could still be used in research. The modified protocol has been submitted to the IACUC but it is not approved. The Committee determined that the rabbit did not show any signs of pain or distress related to the error that required any veterinary intervention; in this case, the Committee determined that no further action was required by the researchers.

Institutional Animal Care and Use Committee
263 FARMINGTON AVENUE, MC 1523
FARMINGTON, CT 06030-1523
PHONE 860.679.3429
FAX 860.679.1005
osacc@uconn.edu
research@uconn.edu

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Retrieved from Animal Research Laboratory Overview (ARLO)

No federal funds were used in this research.

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

Sincerely,

(b) (6)

Wesley G. Byerly, Pharm.D.
Associate Vice President, Research Integrity and Regulatory Affairs

cc:

(b) (6)
Dr. Kathryn Bayne, AAALAC
Dr. Paula Gladue, USDA-APHIS

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, December 23, 2019 8:16 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Gladue, Paula S - APHIS
Subject: RE: Final report of non-compliance, PHS A3471-01/D16-00295

Thank you for providing this final report (b) (6) We will send an official response soon.

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: Friday, December 20, 2019 2:48 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: AAALAC International <accredit@AAALAC.org>; (b) (6) Gladue, Paula S - APHIS <paula.s.gladue@usda.gov>
Subject: Final report of non-compliance, PHS A3471-01/D16-00295

Hi-

Attached is a final report regarding an instance of non-compliance at UConn Health. Please let me know if you have any questions.

Thank you and have a wonderful holiday.

(b) (6)

A large rectangular area of the document is completely redacted with a solid grey fill. The text "(b) (6)" is visible in the top right corner of this redacted area.

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 04, 2019 10:03 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Initial report of protocol non-compliance

Thank you for this preliminary report (b) (6) We will open a case 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: (b) (6)
Sent: Wednesday, December 04, 2019 9:28 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Initial report of protocol non-compliance

Good morning-

I'm writing on behalf of our Institutional Official to inform you of a non-compliance event that occurred at UConn Health, A3471-01/D16-00295.

On 11/21/19, a rabbit surgery was performed under an approved IACUC protocol. The surgeon operated on a rabbit limb to create segmental defect on ulna approaching medially. In the middle of the surgery, the attending veterinarian was called in to clarify the positioning/approach about the defect. It was clear based on the radiograph that the defect was created in the radius instead of ulna.

The attending veterinarian recommended to them to modify the protocol as rabbit ulnar/radial non-union bone regeneration with composite microspheres scaffold rather than just an ulnar-non-union model. Regeneration studies in rabbits have tested/used both radius and ulna, due to their similar size/anatomy. The researchers have since submitted an modification of the approved protocol to do this but it has not, as yet, been approved.

We will be discussing this during our December IACUC meeting (12/19/19) and I will send you a final report of this non-compliance after that date.

Thank you and I hope all have a wonderful Holiday Season!

(b) (6)

(b) (6)