



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

May 1, 2019

Re: Animal Welfare Assurance
#A4752-01 (OLAW Case 1Q)

Ms. Allison P. Moriarty
Vice President, Research Administration
and Compliance
Brigham and Women's Hospital
75 Francis Street
Boston, MA 02115

Dear Ms. Moriarty,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 24, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Brigham and Women's Hospital. According to the information provided, OLAW understands that three sheep had not received one of the two protocol-required pre-operative antibiotics. Additionally, a follow-up dose of one of the protocol-required analgesics was missed in one sheep. The veterinary and research teams did not report signs of pain in this animal. It was stated that the sheep were assigned to an activity receiving PHS funding.

Preventive and corrective actions included the research team creating a safety checklist listing required drugs, surgical supplies, and actions and assigned responsible parties to ensure that the actions are completed as described in the protocol. Surgery and monitoring forms have been modified to be less redundant and to better display the information. The protocol and roles and responsibilities of everyone involved have been clarified. The research team now understands that both antibiotics are required and moving forward will administer all drugs as described in the protocol.

The consideration of this matter by Brigham and Women's Hospital was consistent with the philosophy of institutional self-identification and self-regulation. Similarly, the actions taken to correct and resolve the issue were appropriate and would be expected to prevent a recurrence of this incident. We appreciate being informed of this matter and find no cause for further action by this office at this time.

Sincerely,

(b) (6)

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

cc: IACUC Chair

A4752-1Q



BRIGHAM AND WOMEN'S HOSPITAL

Institutional Animal Care and Use Committee

Brent Morse, D.V.M., DACLAM
Acting Director, Division of Compliance Oversight Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

April 24, 2019

FINAL REPORT

Non-Compliance Report: Assurance **A4752-01**

Sponsors: **5R01EB017722-04**

Brigham and Women's Hospital IACUC

Dear Dr. Morse,

This letter serves as a final report of a resolved issue of non-compliance that has been reviewed by the Brigham and Women's Hospital Institutional Animal Care and Use Committee. During veterinary rounds, three sheep had not received one of the two pre-operative antibiotics that had recently been amended to the protocol. The research team had misunderstood that both antibiotics listed on the protocol must be provided. Additionally, a follow up dose of one of the analgesics approved in the protocol was missed in one sheep; the veterinary and research teams did not report signs of pain in this animal. The research team now understands that both antibiotics are required and moving forward will administer all drugs as described in the protocol.

The research team has been very engaged and met on several occasions with both the veterinary team and IACUC administration to clarify the protocol and review the roles and responsibilities of everyone involved. The research team has created a safety checklist listing required drugs, surgical supplies, and actions and assigned responsible parties to ensure that the actions are completed as described in the research protocol. The veterinary and research team have jointly worked to modify surgery and monitoring forms so that they less redundant and better display the information. Due to these actions, the BWH IACUC was satisfied with the corrective actions employed by this group.

Thank you for your review of these incidents. Please let us know if any further action is required at this time.

Sincerely,

(b) (6)

Allison Moriarty

Vice President, Research Operations
Institutional Official for the BWH IACUC

CC: **Amber Hoggatt, DVM, DACLAM**

Attending Veterinarian & Director, Center for Comparative Medicine, Brigham & Women's Hospital

Srinivasan Mukundan, Jr., Ph.D., M.D.

Chairman, Brigham & Women's Hospital Institutional Animal Care and Use Committee

(b) (6)

Kathryn Holthaus, MS, MA

Director of Research Subjects Protection and Laboratory Safety Compliance

A Teaching Affiliate

of Harvard Medical School

A FOUNDING MEMBER OF



Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, April 25, 2019 7:40 AM
To: Holthaus, Kathryn; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Moriarty, Allison P.; Mukundan, Srinivasan, Jr., M.D., Ph.D.; Hoggatt, Amber
Subject: RE: Noncompliance Reports A4752-01

Thank you for this report Ms. Holthaus. 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: Holthaus, Kathryn [mailto:kholthaus@bwh.harvard.edu]
Sent: Wednesday, April 24, 2019 5:08 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: 'accredit@aaalac.org' <accredit@aaalac.org>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; (b) (6) Moriarty, Allison P. <AMORIARTY@BWH.HARVARD.EDU>; Mukundan, Srinivasan, Jr., M.D., Ph.D. <smukundan@bwh.harvard.edu>; Hoggatt, Amber <ahoggatt1@bwh.harvard.edu>
Subject: Noncompliance Reports A4752-01

Dear Dr. Morse,

Please find attached to this email, a final report of noncompliance that was reviewed and discussed at a recent IACUC meeting at Brigham and Women's Hospital, AWA# # D16-00941 (A4752-01). This has also been reported to the USDA. Thank you in advance for your review of this incident and please let us know if any further action is required at this time.

Best regards,
Kathryn

Kathryn A. Holthaus, M.S., M.A.

*Director of Research Subjects Protection and Laboratory Safety Compliance
Research Administration and Compliance*
Office: (b) (6)
kholthaus@bwh.harvard.edu
brighamandwomens.org



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