



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

January 23, 2019

Re: Animal Welfare Assurance
A3306-01 [OLAW Case 2P]

Dr. Terence Flotte
Dean, Provost and Executive Deputy Chancellor
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655

Dear Dr. Flotte,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 3, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Massachusetts Medical School, following up on an initial report on December 5, 2018. According to the information provided, OLAW understands that three pigs failed to receive the second post-operative analgesic described in the protocol.

The immediate action taken upon discovery consisted of notifying the veterinarian who determined the animals did not exhibit signs of pain or distress. The veterinarian determined that one dose of analgesic plus a local analgesic at the incision site was adequate and the protocol was amended accordingly. The laboratory staff was counseled on the requirement for following the protocol.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



University of
Massachusetts
Medical School

Institutional Animal Care and Use Committee (IACUC)
Office of Research
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655-0002 USA
508.856.5416 (office) 508.856.5004 (fax)

January 3, 2019

Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge I, Suite 260
6705 Rockledge Drive
Bethesda, MD 20892

Dear members of the Division of Compliance Oversight,

RE: Assurance #D16-00196 (A3306-01); Protocol #1909-18

On behalf of the University of Massachusetts Medical School, I am submitting a final report for your consideration. A preliminary report was submitted on December 5, 2018.

Survival surgery was performed on 3 pigs (2 on October 29, 2018 and one on October 30, 2018) which involved exposing the femoral artery via a cut-down for device implantation. All pigs were administered a pre-operative dose of buprenorphine and bupivacaine. A second dose of buprenorphine scheduled to be administered 8-12 hours later was inadvertently withheld. A veterinarian was notified and after evaluation determined that the animals showed no signs of pain or distress. The PI self-reported this incident to the IACUC on November 20, 2018.

In consultation with a Department of Animal Medicine veterinarian, it was determined that a single dose of buprenorphine and bupivacaine would be sufficient to manage pain associated with this procedure, therefore the PI amended the protocol to reflect this change. The PI also met with the laboratory to discuss the incident and importance of protocol adherence.

The IACUC discussed the incident on December 17th, 2018 and determined the corrective actions to be sufficient. NIH funds were not used to support the animal activities involved in this incident.

Sincerely,

(b) (6)

Terence Flotte, M.D.
Institutional Official
Dean, Provost and Executive Deputy Chancellor
University of Massachusetts Medical School

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, January 15, 2019 12:31 PM
To: Moran, Casey; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Assurance D16-00196 (A330601)

Thank you for providing these two reports. We will send official responses 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: Moran, Casey [mailto:Casey.Moran@umassmed.edu]
Sent: Tuesday, January 15, 2019 10:19 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Assurance D16-00196 (A3306-01)

Dear members of the Division of Compliance Oversight,

On behalf of the University of Massachusetts Medical School Institutional Official, Dean Flotte, I am sending two attached reports for your consideration:

1. A report related to an incident for which a specific protocol was unable to be identified.
2. A report linked to IACUC protocol A-1909-18. A preliminary report was submitted on 12/5/2018.

Please contact me with questions or concerns.

Thank you,
Casey

Casey Moran
Director, IACUC/IBC Office
Tel: (b) (6)
<http://inside.umassmed.edu/iacuc/>
<http://inside.umassmed.edu/IBC/>



Office of Research

55 Lake Avenue North, Suite 51-859
Worcester MA 01655-0002

Confidentiality Notice:

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, December 06, 2018 9:30 AM
To: Moran, Casey; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Assurance D16-00196 (A3306-01) Preliminary Report

Thank you for submitting this prompt preliminary report. We will open a case file and await further information as noted in your email below.

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: Moran, Casey [mailto:Casey.Moran@umassmed.edu]
Sent: Wednesday, December 05, 2018 4:49 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Assurance D16-00196 (A3306-01) Preliminary Report

To whom it may concern,

I am submitting a preliminary report on behalf of the University of Massachusetts Medical School Institutional Official, Dean Flotte, assurance # D16-00196 (A3306-01), IACUC protocol A-1909-18.

Survival surgery (femoral artery cutdown for device implant) was performed on 3 pigs (2 on 10/29 and 1 on 10/30). For pain management, the IACUC protocol is approved for a pre-operative dose of buprenorphine, a second dose of buprenorphine administered 8-12 hours post first injection and a local anesthetic of bupivacaine at the incision site. The first dose of buprenorphine and bupivacaine were administered, however the second dose of buprenorphine was inadvertently withheld from the 3 pigs. This incident was reported to the IACUC by the PI on 11/20/2018. The IACUC is investigating the incident and will discuss corrective actions on December 17, 2018. A final report will be submitted thereafter. Should there be any questions in the meantime, please contact me.

Thank you,
Casey

Casey Moran
Director, IACUC/IBC Office
Tel: (b) (6)
<http://inside.umassmed.edu/iacuc/>
<http://inside.umassmed.edu/IBC/>



Office of Research

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