



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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February 6, 2018

Re: Animal Welfare Assurance
A3332-01 [OLAW Case U]

Ms. Martha Farrell
General Counsel and Vice President of HR
Massachusetts Eye and Ear Infirmary
243 Charles Street
Boston, MA 02114

Dear Ms. Farrell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 31, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Massachusetts Eye and Ear. According to the information provided, OLAW understands that two guinea pigs failed to receive the complete required analgesic regimen following surgery. The animals were reportedly not exhibiting signs of pain or distress the day after surgery.

The corrective actions consisted of the Attending Veterinarian (AV) counseling the Principal Investigator on the requirement for following the approved analgesic regimen and maintaining medical records. A Protocol Summary Statement form was developed which lists all procedures and treatments to ensure that all activities have been performed as approved. The form will be signed by the animal users and reviewed by the AV.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Robert Gibbens, D.V.M., USDA-APHIS-AC



**Massachusetts
Eye and Ear**

A3332-4

January 31, 2018

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

Dear Dr. Morse,

On January 17, 2018 a quorum of the Mass Eye and Ear Institutional Animal Care and Use Committee (IACUC) found, by a unanimous vote, that a laboratory conducted a reportable violation of our Institute's PHS Assurance #D16-00215.

The committee voted unanimously that a PI committed the following violation:

- **Failure to administer analgesia:** The PI on the project failed to administer to two guinea pigs the approved doses of Meloxicam on both the day following survival surgery and the subsequent day. The animals underwent a craniotomy as well as a nerve bundle (olliocochlear neurons) cut. The surgeries were performed on December 19 & 20, 2017. The animals did not appear to be in pain or distress the day after surgery.

This procedure was conducted on an NIH-funded protocol (grant number: 2R01 DC 001089-23A1).

Upon discovery of the violation, the following steps were taken:

- Dr. Mike Kaplan, the Attending Veterinarian (AV), met with the PI to review post-operative care and treatment procedures. During the meeting, the importance of strictly following and carefully documenting the IACUC-approved analgesic treatment regimen was emphasized regarding animal welfare as well as medical record compliance. The PI was contrite, receptive and understanding during the discussion and the AV reported to the Committee that he has no doubt that the PI has learned a valuable lesson from the experience.
- A newly developed Protocol Summary Statement for regulated species has been developed to help animal users with the various treatments performed. The Summary Statement, completed by the animal users and reviewed for accuracy by the AV, contains a chart that identifies both surgical and non-surgical procedures and their associated treatments. The completed chart will help to ensure that the appropriate drugs, dosages and treatment frequencies of administration are being used. This chart will be especially useful in protocols describing more than one procedure and/or having multiple animal users. The animal user as well as the PI are required to sign the end of the Protocol Summary Statement.

The Committee reviewed the issue of non-compliance at a convened meeting and voted unanimously that the actions taken after the violation were sufficient.



Harvard Medical School Affiliate

If you have any further comments or questions, please contact me at Martha farrell@meei.harvard.edu or by phone at (b) (6)

Sincerely,

(b) (6)

Martha Pyle Farrell
General Counsel & Vice President of Human Resources
Institutional Official

cc: James Chodosh, MD, IACUC Chair

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, February 06, 2018 7:40 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Massachusetts Eye and Ear (D16-00215) Report of Non-Compliance (Case G)

Thank you for this report, (b) (6) We will respond soon.

Axel Wolff

From: (b) (6)@MEEI.HARVARD.EDU]
Sent: Monday, February 05, 2018 5:35 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Farrell, Martha Pyle <Martha_Farrell@MEEI.HARVARD.EDU>; Chodosh, James
<James_Chodosh@MEEI.HARVARD.EDU>; (b) (6)@meei.harvard.edu>; (b) (6)
(b) (6)@MEEI.HARVARD.EDU>
Subject: Massachusetts Eye and Ear (D16-00215) Report of Non-Compliance (Case G)

Dr. Morse,

Attached please find a letter from our Institutional Official, Martha Pyle Farrell, reporting an issue of non-compliance (Case G) that occurred at Massachusetts Eye and Ear (Assurance Number: D16-00215).

Please feel free to contact me should you have any questions or require additional information.

Thanks,

(b) (6)

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