



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

June 10, 2019

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

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 May 24, 2019 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 32 mice were subjected to injections of experimental agents prior to approval by the Institutional Animal Care and Use Committee (IACUC).

The corrective actions consisted of the Principal Investigator suspending the animal use privileges of the research fellow responsible and informing the IACUC that animal protocol oversight would be increased. The IACUC conducted post-approval monitoring of the laboratory's protocols and required retraining of the PI and all laboratory staff. Upon completion of the required retraining, the fellow's animal use privileges will be reinstated.

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 IACUC to comply with the PHS Policy. Please ensure that the NIH grant is not charged for any unauthorized animal activities. Thank you for informing OLAW about this matter.

Sincerely,

(b) (6)

For

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

cc: IACUC Chair



MASSACHUSETTS
EYE AND EAR

A3332-X

May 24, 2019

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 May 15, 2019 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 Fellow committed the following violation:

Failure to adhere to an IACUC-approved protocol: During a convened IACUC meeting, the Committee reviewed a procedural amendment to perform IP injections of Nicotinamide mononucleotide (NMN) in mice for an NIH funded protocol (grant number: R01EY025362). In the process of reviewing the submitted amendment, it came to our attention that some of these injections had previously been performed. NMN was administered to 21 mice and PBS was administered to 11 control mice by IP injection. The injections were administered daily until euthanasia within a week after the first injection. After thorough review of all of the PI's approved protocols and amendments, it was determined that these injections were not yet IACUC approved.

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

- The PI informed the IACUC that the Fellow had been suspended from all animal work until the issue was discussed with the Committee and a final Committee decision had been made. The PI also noted that they would double their oversight to ensure that this issue will not occur again in the future.
- The IACUC Office performed Post Approval Monitoring (PAM) on the approved protocols and amendments.

The Committee reviewed the issue of non-compliance at a convened meeting and voted unanimously on the following actions:

- The Committee requests that the PI provide a response specifying how they will ensure that double oversight will be provided and maintained over all of their approved animal protocols to ensure that no further procedures will be performed without prior IACUC approval.
- The laboratory is required to attend a mandatory training session that will be scheduled for all approved animal users in the laboratory, including the PI and the Laboratory Manager. This training will be conducted by the IACUC Office as well as the Animal Care Facility Staff. In addition, all of their approved animal users will be required to complete specific



Harvard Medical School Affiliate

AALAS Learning Library online training modules. The Committee is aware that the Fellow that performed the unapproved procedures has not worked with animals since the IACUC was made aware of the issue. Once the Fellow completes the mandatory lab training and all required online training modules, the Fellow will be granted access to the Animal Care Facility by the IACUC to continue with their animal work.

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

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: John Rosowski, Ph. D. IACUC Chair
Marie Ortega, CPIA, CMAR, Director, Animal Care

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, May 29, 2019 6:48 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 J)

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Tuesday, May 28, 2019 2:52 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Farrell, Martha Pyle <Martha_Farrell@MEEI.HARVARD.EDU>; Rosowski, John <John_Rosowski@meei.harvard.edu>; Ortega, Marie <Marie_Ortega@MEEI.HARVARD.EDU>
Subject: Massachusetts Eye and Ear (D16-00215) Report of Non-Compliance (Case J)

Dr. Morse,

Attached please find a letter from our Institutional Official, Martha Pyle Farrell, reporting an issue of non-compliance (Case J) 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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