

Na, Jane (NIH/OD) [E]

From: Na, Jane (NIH/OD) [E]
Sent: Tuesday, October 02, 2018 11:15 AM
To: 'nunned@mail.nih.gov'
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: FW: Puria: 2R01DC007910-10, 2300184 OLAW Notification
Attachments: MEEI 3332-W.pdf

Good morning Mr. Nunn,

Thank you for the email. This matter has been resolved with OLAW. Attached are the communications that OLAW sent to the Massachusetts Eye and Ear Infirmary (MEEI). I apologize for not cc'ing you as I had intended. Please let me know if you require any further information.

Jane

Jane Na, DVM
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health
Phone (301) 402-1922
E-fax (301) 451-5609

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From: Nunn, Eric (NIH/NIDCD) [E]
Sent: Tuesday, October 02, 2018 9:07 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: Puria: 2R01DC007910-10, 2300184 OLAW Notification

Good Morning Dr. Morse,

Please find the attachments.

NIDCD was notified last week by Massachusetts Eye and Ear Infirmary (MEEI) that OLAW found the IACUC for the above-referenced grant award to be in noncompliance. However, NIDCD does not have any documentation from OLAW to indicate what action NIDCD should take.

Has this matter been resolved with OLAW? If this matter has not been resolved, should NIDCD restrict the award to limit vertebrate animal costs to maintenance only? If the matter has been resolved, can we get a copy of the letter OLAW sent to MEEI for our grant file?

Question(s) are welcome.

Thank you. Have a good day.

Best,

Eric Nunn

Grants Management Branch

The National Institute on Deafness and Other Communication Disorders (NIDCD)

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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

September 28, 2018

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

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 letter dated September 20, 2018 that was provided in response to our August 20, 2018 correspondence requesting updates and additional information concerning the reported noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals at Massachusetts Eye and Ear. The noncompliance, initially reported in your August 7, 2018 letter, was discovered by the attending veterinarian during animal disposition records review and involved the unexpected deaths of seven gerbils during terminal surgeries as a result of inadequate understanding of the procedure by the laboratory personnel and an unclear description of the surgery within the IACUC protocol. Although the date(s) of when the incident was discovered was not included, we appreciate being provided with the dates of the animal procedures to clarify that the deaths occurred on six different dates from January 22, 2018 to May 16, 2018 with three procedures occurring in April.

Your response indicated that the IACUC protocol was revised to clarify the surgical procedure and that the protocol will undergo review at the September IACUC meeting. Once approved, the remainder of the previously described corrective actions will be completed which includes lab personnel undergoing training(s) on the surgery followed by assessment of training adequacy and continued monitoring by the facility veterinary staff until three successful procedure outcomes have occurred. To prevent future similar incidents, all principal investigators (PIs), laboratory managers, and IACUC members will complete mandatory training to review PI oversight of approved IACUC protocols and regulatory compliance oversight prior to December 1, 2018. All other animal users will be welcome to attend. In addition to emphasizing that personnel are to be appropriately qualified and trained in procedures, OLAW expects that the responsibility for timely communication of abnormalities or animal health concerns to the veterinary staff will be included in this mandatory training. Lastly, the letter indicated that animal charges incurred on the NIH grant during the period of noncompliance have been transferred to non-NIH funds.

We appreciate the submission of the additional information to update and further address the incident. OLAW accepts the corrective actions to reduce the likelihood of recurrence of this noncompliance and finds no cause for further action at this time.

Page 2 – Ms. Farrell
September 28, 2018
OLAW Case A3332-W

Sincerely,

(b) (6)

Jane Na, DVM
Veterinary Medical Officer
Office of Laboratory Animal Welfare

cc: IACUC Chair
Dr. Robert M. Gibbens, USDA, APHIS, AC



**Massachusetts
Eye and Ear**

September 20, 2018

Jane Na, D.V.M.
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
Bethesda, MD 20892-7982.

Dear Dr. Na,

The Massachusetts Eye and Ear received a response from your office on August 20, 2018 regarding a self-reported incident of non-compliance that occurred at our Institution (PHS Assurance #D16-00215) concerning terminal surgical experiments in gerbils.

Upon review of the disposition records for gerbils, the Attending Veterinarian noted that there were 7 unexpected deaths (prior to the experimental endpoint) that occurred during repeated terminal surgical procedures to access the apical cochlea. The mortality dates were as follows:

1/22/18, 3/21/18, 4/13/18, 4/16/18, 4/19/18, 5/16/18 (2 animals)

Following a meeting regarding the incident with the PI, laboratory personnel, IACUC Office, Attending Veterinarian and Director, Animal Care, the laboratory (in consultation with the Attending Veterinarian) submitted a procedural amendment to the IACUC Office that further describes and clarifies the surgical procedure to access the apical cochlea. The amendment will be reviewed by the Full Committee at the next convened IACUC meeting to be held on September 19, 2018.

Once final IACUC approval for the amendment has been granted, the respective laboratory personnel will contact the IACUC-recommended experienced animal user to schedule training sessions for the apical surgical approach. This process will then move forward following the guidelines stated in the original letter to OLAW:

- Members of the Animal Care Facility Veterinary Staff will be present for these training sessions with the laboratory and the experienced animal user.
- Once the trainer and the Animal Care Facility Veterinary Staff have observed and documented that lab members have been adequately trained on the procedure, the lab will notify the Animal Care Facility Veterinary Staff in advance of performing any future terminal surgeries. Animal Care Facility Veterinary Staff will discontinue monitoring these activities until three successful outcomes for this procedure.



Harvard Medical School Affiliate

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August 20, 2018

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

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 letter dated August 7, 2018 regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at Massachusetts Eye and Ear. According to the information supplied, OLAW understands that the Attending Veterinarian (AV) was performing document review and noted that there were seven unexpected deaths of gerbils during terminal surgeries. Upon investigation, the approved IACUC protocol did not include a clear description of the surgery and it was determined that the laboratory personnel needed a better understanding of the procedure and required additional hands-on training. The involved animal activity was supported by NIH grant 2R01DC007910.

Corrective actions that were reviewed by the IACUC that must be completed by the lab before further animal purchasing or before performing any additional surgical procedures include the following. A protocol amendment to clarify the surgical procedure must be submitted and approved by the IACUC. All lab personnel that will perform this surgical procedure must be trained by an IACUC-recommended experienced animal user with members of the facility veterinary staff present for the trainings until the trainer and veterinary staff observe and document that lab members have been adequately trained. Prior to any future surgical procedures, the lab is to notify the veterinary staff who will monitor the surgeries until at least three successful outcomes of the procedure.

Please note that reports of noncompliance to OLAW should include dates of occurrence when describing the incident. Please include this information in future submissions. OLAW commends the AV in identifying the potential issue regarding the unexpected deaths during review of the gerbil disposition records. We concur with the corrective measures that were described in your letter but are concerned with the absence of additional corrective actions to prevent future similar incidences. The Guide for the Care and Use of Laboratory Animals states that the IACUC and AV are responsible "for determining that personnel performing surgical procedures are appropriately qualified and trained in the procedures" (pg. 116) and that everyone involved in animal care and use is responsible for communicating abnormalities or animal health concerns (pg. 115), such as unexpected animal deaths, to the veterinary staff.

We request further information as well as any updates regarding the progress or schedule for corrective actions already described. Please indicate any additional corrective measures that have been or that will be instituted to prevent similar occurrences of this incident. Additionally, please provide information

Page 2 -- Ms. Farrell
August 20, 2018
OLAW Case A3332-W

regarding compliance with terms and conditions of the grant award or any actions taken with respect to the funding component. For further information regarding this request, please refer to the last bullet point under Final Report on the OLAW Reporting Noncompliance website <https://olaw.nih.gov/guidance/reporting-noncompliance.htm>. Please submit this information to OLAW **no later than September 21, 2018** by email to jane.na@nih.gov. We appreciate being informed of these matters and look forward to your response.

Sincerely,

(b) (6)

 Jane Na, DVM
Veterinary Medical Officer
Office of Laboratory Animal Welfare

cc: IACUC Chair



**Massachusetts
Eye and Ear**

A3332-W

August 7, 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 June 20, 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:

Upon review of the disposition records for gerbils, the Attending Veterinarian noted that there were 7 unexpected deaths (prior to the experimental endpoint) that resulted from a terminal apical surgical approach for accessing the cochlear. After further discussions with the laboratory personnel, it was noted that the description of the surgical approach in the protocol was not clear. It was determined that the personnel performing the procedure needed a better understanding of the procedure and also needed further hands-on training for the specific technique.

This is an NIDCD-funded protocol (grant number: 2R01DC007910).

The Committee reviewed the issue of non-compliance at a convened meeting and noted that the following actions would be taken before any more animals can be purchased and any new surgical procedures can be performed:

- An amendment that further describes and clarifies the surgical procedures performed for accessing the cochlea needs to be submitted and approved by the IACUC.
- Training for all lab personnel that will perform this surgical procedure has to be scheduled with an experienced animal user named by the Committee, who has agreed to train the staff in performing the apical exposure of the cochlea. Members of the Animal Care Facility Veterinary Staff must be present for these training sessions.
- Once the trainer and the Animal Care Facility Veterinary Staff have observed and documented that lab members have been adequately trained on the procedure, the lab will need to notify the Animal Care Facility Veterinary Staff in advance of performing any future terminal surgeries. Animal Care Facility Veterinary Staff will discontinue their monitoring activities after at least three successful outcomes for this procedure.



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: John Rosowski, Ph.D. IACUC Chair

(b) (6)

Marie Ortega, CPIA, CMAR, Director, Animal Care

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, August 09, 2018 8:05 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Farrell, Martha Pyle; Rosowski, John; Ortega, Marie
Subject: RE: Massachusetts Eye and Ear (D16-00215) Report of Non-Compliance (Case I)

Thank you for providing this 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: Wednesday, August 08, 2018 8:14 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 I)

Dr. Morse,

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