

## 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
<u>Telephone</u>: (301) 496-7163
<u>Facsimile</u>: (301) 402-7065

November 4, 2019

Re: Animal Welfare Assurance A3177-01 [OLAW Case 1L]

Dr. Martha Farrell
General Counsel and Vice President of Human Resources
Institutional Official
Schepens Eye Research Institute
20 Stanford Street
Boston, MA 02114-2500

Dear Dr. Farrell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 22, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Massachusetts Eye and Ear Infirmary- Schepens Eye Research Institute. According to the information provided, OLAW understands that on a Saturday morning, Animal Care Staff discovered that one cage of recently weaned mice had water available but not food since Thursday afternoon after these animals were weaned. Two animals appeared emaciated and dehydrated therefore supplementary food and water was provided, subcutaneous fluids administered, and the cage was maintained on a heating pad until the animals were full recovered. By midday Saturday, both mice were active, eating and drinking and full recovered.

Corrective actions comprised of retraining the principal investigator (PI) and laboratory personnel including in-person demonstrations of cage weaning and requiring a PI- appointed senior laboratory member to be present for all future weaning sessions to ensure all newly weaned cages have food and water.

The Animal Care Facility Technicians received retraining and several key recommendations including pulling out all cages from the two top and two bottom rows, paying special attention to newly weaned cages and flipping up cage card holders to visually identify checked cages. Additionally, training was provided to ensure that personnel understand the consequences of animals not receiving food and/or water and resulting clinical signs.

OLAW appreciates the prompt consideration of this matter by Massachusetts Eye and Ear Infirmary-Schepens Eye Research Institute which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC contact

October 22, 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 September 5, 2019 at 1pm, a quorum of the Schepens Institutional Animal Care and Use Committee (IACUC) found, by a unanimous vote, that a laboratory at Schepens conducted a reportable violation of our Institute's PHS Assurance #D16-00112 and established Schepens IACUC Policies.

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

• Failure to replace food following weaning: On a Saturday morning the Animal Care Staff discovered one cage of recently weaned mice that had water but no food. Upon further investigation it was found that the animals had been without food since Thursday afternoon when they were weaned by laboratory personnel. Two of the mice appeared emaciated and dehydrated, therefore the Animal Care Staff provided food and Hydrogel packs on the bottom of the cage, administered subcutaneous fluids and kept the cage on a heat pad until the mice were fully recovered. By midday Saturday (the day they were found by the staff) the 2 mice were fully recovered and were observed to be active, eating and drinking.

The issue of non-compliance was performed on a NIH funded protocol (grant number: RO1EY017653-A1).

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

The Director, Animal Care contacted the PI and lab staff immediately upon notification of the incident. She met with the PI and lab personnel where re-training was provided regarding the appropriate process for weaning mice. Following the re-training there was also a round of weaning performed by the lab personnel alongside members of the Animal Care Staff to ensure proper procedures were followed when weaning the mice. The Animal Care Staff suggested to the lab that as a last step, one person in the lab should be in charge of going back and checking that each newly weaned cage has food and water.

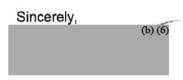
The Committee reviewed the issue of non-compliance at a convened meeting and voted unanimously on the following actions:

• The Committee decided that one representative from the lab must oversee all weaning and following each weaning session, this representative will be responsible for ensuring that all newly weaned cages have both water and food. The Committee requested that the PI submit a written response that will identify the senior lab member who will oversee the weaning process and inform the IACUC of any additional procedures that have been put in place to ensure such an incident does not occur in the future.



• The Committee also noted that the newly weaned mice were without food for two days and the Animal Care Facility Technicians should have discovered the lack of food on the first day during their daily health checks. The IACUC notified the Animal Care Facilities Manager and he met with the Animal Care Technicians to discuss the incident and methods to ensure this does not happen again. Key recommendations that were made during the retraining included: (i) Fully pulling out all cages from the top 2 and bottom 2 rows when performing daily health checks, as these rows are harder to see inside, (ii) paying special attention to newly weaned cages and pulling them out to ensure the animals have all of their needs met, (iii) flipping up cage card holders to help identify the cages that have already been checked, (iv) being familiar with the consequences of animals not receiving food and/or water and the signs to look for.

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



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

cc: Meredith Gregory-Ksander, Ph.D., IACUC Chair
Patricia D'Amore, Ph.D., Director of Research and Animal Care Facility Faculty Head
Marie Ortega, BA, CPIA, RLATG, Director, Animal Care
AAALAC

## Morse, Brent (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Tuesday, October 29, 2019 1:40 PM
To: Cc:	(b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject:	Farrell, Martha Pyle; Gregory, Meredith; Ortega, Marie; D'Amore, Patricia RE: Schepens Eye Research Institute (D16-00112) Report (Case NN)
Subject.	NE. Schepens Eye Research Institute (D16-00112) Report (Case NN)
Thank you for providing this repo	rt (b) (6) We will send an official response soon.
Best regards, Brent Morse	
	are d any of its attachments are intended for the named recipient(s) only and may contain sed information that should not be distributed to unauthorized individuals. If you have
From:	(b) (6)
Sent: Tuesday, October 29, 2019	11:32 AM
	Oversight (NIH/OD) <olawdco@od.nih.gov></olawdco@od.nih.gov>
Cc: Farrell, Martha Pyle <martha_farrell@meei.harvard.edu>; Gregory, Meredith</martha_farrell@meei.harvard.edu>	
<pre><meredith_gregory@meei.harvard.edu>; Ortega, Marie <marie_ortega@meei.harvard.edu>; D'Amore, Patricia <patricia_damore@meei.harvard.edu></patricia_damore@meei.harvard.edu></marie_ortega@meei.harvard.edu></meredith_gregory@meei.harvard.edu></pre>	
Subject: Schepens Eye Research Institute (D16-00112) Report (Case NN)	
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Dr. Morse,	
Attached places find a latter for	one and Institutional Official Months Puls Foundly and discount for the first form
Attached please find a letter from our Institutional Official, Martha Pyle Farrell, reporting an issue of non-compliance (Case NN) that occurred at Schepens Eye Research Institute (Assurance Number: D16-00112).	
compliance (Case 1414) that occ	uned at Schepens Eye Research histitute (Assurance Number: D10-00112).
Please feel free to contact me si	hould you have any questions or require additional information.
Thanks,	(b) (6)
	(7,6)

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