

## 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

March 7, 2019

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

Dr. Martha Farrell General Counsel and Vice President of Human Resources 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 March 6, 2019 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Schepens Eye Research Institute. According to the information provided, OLAW understands that ongoing low humidity levels in eight rodent rooms led to the development of ringtail in a litter of five mouse pups. A malfunction in the humidity control system led to this situation.

The corrective actions consisted of repairing the humidity control system and monitoring the pups which were developing normally. Following the repairs, the humidity continued to be monitored and was found to be within acceptable parameters although a few low readings were still recorded. The institution will continue to work with the vendor to permanently fix the problem. No additional cases of ringtail have occurred.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and reduce the likelihood of a recurrence of the problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Should additional related health or physical plant issues recur, please promptly report them to this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair

A3177-1K



March 6, 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.

Re: Ringtail: Schepens Eye Research Institute (Assurance #D16-00112)

Dear Dr. Morse.

At the convened February 6, 2019 IACUC meeting Ms. Ortega, Director, Animal Care reported that on January 23, 2019 a case of ringtail was discovered in a single cage containing a litter of 5 pups in (b) (4) While the adults were normal in appearance, the 5 pups had distinct annular rings (minimal constriction however, visibly apparent) on their tails. The 5 pups continue to be monitored and remain otherwise healthy, gaining weight as expected and are showing normal behavior. Ms. Ortega reminded the committee that (b) (4) was one of the 8 rooms where low humidity readings were first detected in November 2018 and reported to the IACUC during the convened December 6<sup>th</sup> and January 9<sup>th</sup> meetings. However, at the time of the previous meetings there were no health related issues with the animals and the Facilities Department was actively working to fix the humidity issue.

Upon the discovery of ringtail, Ms. Ortega immediately notified Facilities and requested a new update in regards to the corrective/preventive actions that were taking place to fix the humidity issue. In summary, Facilities reported the following: After the first report of low humidity readings in November 2018, Facilities personnel went through each room to measure the humidity levels with a handheld instrument to confirm the low humidity readings were accurate and to determine if the humidistats were functioning properly. With low humidity readings still being reported in December 2018, an outside contractor was called in to inspect the piping and duct work and identified leaks in the steam coil that were fixed in early February. In addition, (b) (4) was called in to inspect the humidity control system and they replaced the controller in the animal facility and ordered a new humidistat for (b) (4) As of the February 6th meeting, the new humidistat had (b) (4) was also scheduled to return on February been ordered but had not yet arrived. 15<sup>th</sup> to review and/or re-write the control programs for monitoring humidity in the animal housing rooms. It is expected that once the new humidistat is in place and the automated control programs are confirmed to be working properly, the humidity set point should be properly maintained.

While the humidity issue was being addressed, the Committee unanimously voted for the IACUC Office to contact OLAW to confirm whether the appearance of ringtail due to low humidity is a reportable situation. The IACUC Manager contacted OLAW and received confirmation that the issue was reportable and this report was prepared for submission to OLAW. However, with several corrective actions being taken in the two weeks following the February IACUC meeting, the IACUC office wanted to first confirm whether the planned corrective actions were able to fix the humidity issue before sending this report to OLAW.



On Wednesday February 13 <sup>th</sup> , Facilities reported that following the installation of the new humidity and replacement of the inside of the humidity actuator, the humidity in to review and update humidity set point.  (b) (4) was on site on Friday February 15 <sup>th</sup> to review and update control programs for monitoring humidity and Facilities continued to closely monitor the umidity. In a follow up meeting on Wednesday February 27 <sup>th</sup> , Facilities reported that following the pairs, the majority of humidity readings in (b) (4) were above the desired 30% value. However were still sporadic readings below 30%. Facilities are continuing to work with (b) (4) to determine the cause of the humidity issues. All of the animals in (b) (4) and proughout the facility continue to be closely monitored and no new cases of ringtall have been deported.	te
you have any further comments or questions, please contact me tha farrell@meei.harvard.edu or by phone at (b) (6)	at
cerely,	
(b) (6)	
tha Pyle Farrell	
eral Counsel & Vice President of Human Resources tutlonal Official	

cc: Meredith Gregory-Ksander, Ph.D., IACUC Chair
(b) (6)

Patricia D'Amore, Ph.D., Director of Research and Animal Care Facility Faculty Head Marie Ortega, BA, CPIA, RLATG, CMAR Director, Animal Care AAALAC

## Wolff, Axel (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Thursday, March 7, 2019 6:58 AM

To:

(b) (

Cc:

OLAW Division of Compliance Oversight (NIH/OD)

Subject:

RE: Schepens Eye Research Institute (D16-00112) Report (Case MM)

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: Wednesday, March 6, 2019 5:07 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Farrell, Martha Pyle <Martha\_Farrell@MEEI.HARVARD.EDU>; Gregory, Meredith

<Meredith\_Gregory@MEEI.HARVARD.EDU>; D'Amore, Patricia <patricia\_damore@meei.harvard.edu>; Ortega, Marie

<Marie\_Ortega@MEEI.HARVARD.EDU>

Subject: Schepens Eye Research Institute (D16-00112) Report (Case MM)

Dr. Morse.

Attached please find a letter from our Institutional Official, Martha Pyle Farrell, reporting an issue regarding ringtail in mice (Case MM) that occurred at Schepens Eye Research Institute (Assurance Number: D16-00112).

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



Mass. Eye and Ear Confidentiality Notice: This e-mail and any files transmitted with it are confidential and are intended solely for the use of the individual(s) addressed in the message above. This communication may contain sensitive or confidential information. If you are not an intended recipient, dissemination, forwarding, printing, or copying of this e-mail is strictly prohibited. If you believe you have received this e-mail in error and the email contains patient information, please contact the Mass. Eye and Ear Compliance Line at (800) 856-1983. If the e-mail was sent to you in error but does not contain patient information, please contact the sender and delete the e-mail.