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

August 6, 2018

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

Ms. Martha Farrell
General Counsel and
Vice President of Human Resources
Schepens Eye Research Institute
243 Charles Street
Boston, MA 02114-2500

Dear Ms. Farrell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 31, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Schepens Eye Research Institute. According to the information provided, OLAW understands that on July 11, 2018 it was determined that three mice that had undergone craniotomies had not been given the required second post-operative dose of buprenorphine. Upon notification, the PI administered the proper treatment to the mice. Subsequently it was determined that the Fellow responsible for the mice was home sick and no other lab member knew the status of the mice. These activities were funded by the PHS.

Corrective actions included the IACUC requiring modifications to the post-procedural checklist. These changes included that, among other additions, the PI must sign and date that they have been notified of the study that is being performed.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3177-15

Schepens Eye
Research Institute
Massachusetts Eye and Ear

July 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 July 12, 2018 at 12pm, 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 #A3177-01 and established Schepens IACUC Policies.

The committee voted unanimously that a Fellow committed the following violations:

- **Failure to administer proper post-procedure care:** On the morning of July 11, 2018, one cage of mice (3 mice) were found to have missed a dose of Buprenorphine one day post a craniotomy procedure. The mice received their initial dose of Buprenorphine at the time of the procedure at 3pm on July 10, 2018. However, the mice had not yet received the second dose that was required to be administered every 8-12 hours for 48 hours post surgery as approved in the protocol. When found, the mice were fully recovered from the surgical procedure and showed no signs of pain and distress and the veterinary staff immediately notified the PI of the laboratory. Upon notification the PI confirmed that the second analgesic dose had been missed; a dose of Buprenorphine was administered upon notification.

  This procedure was conducted on an NIH-funded protocol (Grant # 2R01 EY019703).

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

- Immediately upon finding that the mice had not received the second dose of Buprenorphine, the Veterinary Technologist contacted the lab. The PI of laboratory discovered that the Fellow who had performed the surgery was home sick and confirmed that the second dose had not yet been administered. The PI immediately went down to the animal facility and administered the second dose of Buprenorphine. Following this incident, the IACUC Chair met with the PI to discuss why the post-procedure checklists that were implemented following a missed dose of Buprenorphine in 2017 did not work in this situation. During the discussion it was determined that the Fellow who had performed the procedure had completed a post-procedure checklist, however had become ill and could not come in the next morning to administer the second dose of analgesic. Unfortunately, the Fellow failed to notify anyone in the lab about these mice, thus no one knew that these mice required a second dose of analgesic.

- This incident was discussed at the July 12th IACUC meeting and the Committee voted unanimously for the following modifications to be made to the post-procedure checklist for all procedures that require multiple doses of analgesics (currently only craniotomy):

- The Post-procedure checklist must include the name of the person performing the surgical procedure.

- The post-procedure checklist must be modified to include a spot for the PI to sign and date that they have been notified of the study that is being performed.

- The post-procedure checklist must include the exact dates and times that each dose of Buprenorphine (every 8-12 hours for 48 hours following craniotomy) will be administered and the person administering the analgesia must sign and include the time after each dose is administered.

- These checklists will be stored in a binder within the lab and will always be available for review by the PI and during semiannual lab inspections.

The IACUC believes the implementation of these revisions to the post-procedure checklist will help ensure that the PI is (i) notified when surgical procedures that require multiple administrations of post-procedure analgesia begin and (ii) able to follow up and confirm that all doses of analgesia are administered as required. This revised checklist must be submitted to the IACUC for review and approval at next convened IACUC meeting.

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: 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

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

**From:** OLAW Division of Compliance Oversight (NIH/OD)
**Sent:** Monday, August 06, 2018 7:43 AM
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
**Cc:** Farrell, Martha Pyle
**Subject:** RE: Schepens Eye Research Institute (D16-00112) Report of Non-Compliance (Case LL)

Thank you for submitting 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



**From:** (b) (6)
**Sent:** Friday, August 03, 2018 5:08 PM
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
**Cc:** Farrell, Martha Pyle <Martha_Farrell@MEEI.HARVARD.EDU>; D'Amore, Patricia <patricia_damore@meei.harvard.edu>; Gregory, Meredith <Meredith_Gregory@MEEI.HARVARD.EDU>; Ortega, Marie <Marie_Ortega@MEEI.HARVARD.EDU>
**Subject:** Schepens Eye Research Institute (D16-00112) Report of Non-Compliance (Case LL)

Dr. Morse,

Attached please find a letter from our Institutional Official, Martha Pyle Farrell, reporting an issue of non-compliance (Case LL) that occurred at Schepens Eye Research Institute (Assurance Number: D16-00112).

This occurred in mice on an NIH funded protocol.

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

Thanks,

(b) (6)