



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

April 14, 2017

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

Dr. Martha P. Farrell
General Counsel and
Vice President of Human Resources
Schepens Eye Research Institute
243 Charles Street, Suite 812
Boston, MA 02114

Dear Dr. Farrell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 23, 2017 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 a second dose of post-operative analgesia was not administered to two mice as approved by the IACUC in the protocol. Although no animal welfare concerns were identified as a result of the noncompliance, Buprenorphine was immediately administered to the affected mice upon discovery. The associated animal activity was PHS funded.

The corrective action consisted of the Principal Investigator discussing protocol compliance with laboratory personnel and implementing a checklist which incorporates all approved post-procedural care activities for research associates to complete.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair



**Schepens Eye
Research Institute
Massachusetts Eye and Ear**

March 23, 2017

Axel V. Wolff, M.S., D.V.M.
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. Wolff,

On March 2, 2017 at 12pm, by unanimous vote a quorum of the Schepens Institutional Animal Care and Use Committee (IACUC) found that a laboratory at Schepens violated our Institute's PHS Assurance #A3177-01 and our established Schepens IACUC Policies.

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

- **Failure to administer proper post-procedure care:** On February 15, 2017, 2 cages (1 male and 1 female per cage) were found with a missed dose of Buprenorphine 1 day post optic nerve crush procedure. The mice received their initial dose at 9am the morning of the procedure, however did not receive the second dose as approved in the protocol they were working under. The veterinary staff found the mice when they were fully recovered and appeared healthy and showed no signs of pain and distress. The veterinary staff immediately notified the responsible person, who 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.

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

- Immediately upon finding that the mice had not received the required dose of Buprenorphine, the Veterinary Technologist contacted the lab. The lab immediately administered the second dose of Buprenorphine. The IACUC Chair contacted the PI to ensure that the issue was discussed with all lab members. The PI responded back to the Chair that their current protocol, under which this procedure was performed, stated that Buprenorphine would be administered every 8-12 hours for 24 hours. However, the lab was in the process of writing the renewal of their protocol and upon discussion with the Veterinarian it was determined that only one dose of Buprenorphine was required following optic nerve crush and this was written into their renewal protocol that was still under review (approved 2/23/17). However, the approved protocol under which this work was being performed was never amended to change the frequency and duration of Buprenorphine administration following optic nerve crush. The PI met with the laboratory and reviewed the importance of following each protocol specifically as approved and stated that no changes can be made to the animal procedures unless approved by amendment. The PI is now also requiring the Fellows to complete a checklist for each procedure that outlines the post-procedure care for each study to ensure no confusion in the future.



Harvard Medical School Affiliate

The Committee reviewed the issue of non-compliance at a convened meeting and voted unanimously that no further action would be required.

If you have any further comments or questions, please contact me at Martha_farrell@meei.harvard.edu or by phone at [redacted] telephone # [redacted]

Sincerely,



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

cc: Meredith Gregory-Ksander, Ph.D., IACUC Chair
[redacted] Secondary individual Co-Director of Research and Animal Facility Director
[redacted] Secondary individual Animal Facility Associate Director
AAALAC

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, April 10, 2017 7:43 AM
To: Secondary individual
Subject: RE: Schepens (A3177-01) Report of Non-Compliance (Case HH)

Thank you for this report [REDACTED] We will respond soon.

Axel Wolff, M.S., D.V.M.
 Director, Division of Compliance Oversight
 OLAW

From: Secondary individual mailto:Secondary individual@MEEI.HARVARD.EDU]
Sent: Sunday, April 09, 2017 10:48 AM
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> Secondary individual Secondary individual@meei.harvard.edu; [REDACTED]
 Secondary individual@MEEI.HARVARD.EDU
Subject: Schepens (A3177-01) Report of Non-Compliance (Case HH)

Dr. Wolff,

Attached please find a letter from our Institutional Official, Martha Pyle Farrell, reporting an issue of non-compliance (Case HH) that occurred at Schepens Eye Research Institute (Assurance Number: A3177-01 - D16-00112).

Please note that the issue occurred in mice on an NIH-funded project.

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

Thanks,

Secondary individual
 Senior IACUC Administrator

Schepens Eye Research Institute/Massachusetts Eye and Ear Infirmary
 20 Staniford Street
 Boston, MA 02114
 Secondary individual@meei.harvard.edu
 Office: telephone # [REDACTED]

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