



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

August 31, 2016

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

Dr. Alan Long
Vice President for Research
and Academic Affairs
Schepens Eye Research Institute
20 Stanford Street
Boston, MA 02114-2500

Dear Dr. Long

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 17, 2016 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 13, 2016 it was determined that a 4pm treatment was not administered to 19 rabbits as required. At 6pm, after notification, the PI administered the proper treatment to the rabbits. The following morning, one of the rabbits was found to have suffered a broken back and was euthanized. It was determined that improper handling and restraint of the rabbit by the PI may have resulted in the injury. These activities were not funded by the PHS.

Corrective actions included the IACUC restricting the PI's access to the rabbits and having the Veterinary Technician administer the required treatments. Subsequently, the IACUC determined that a new investigator must be added to the protocol who would be directly responsible for all treatments, injections, and procedures.

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,

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

cc: IACUC Contact

Dr. Elizabeth Goldentyer, Director Eastern Sector, USDA, APHIS, AC

Morse, Brent (NIH/OD) [E]

From: Secondary Individual <Secondary Individual@MEEI.HARVARD.EDU>
Sent: Wednesday, August 31, 2016 10:28 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: Re: Schepens (A3177-01) Report of Non-Compliance (Case GG)

Follow Up Flag: Follow up
Flag Status: Completed

Hi Dr. Morse,

I sincerely apologize for the incorrect information, the letter is not correct. This was an NIH funded project.
 Again, my apologies.

Secondary Individual
 IACUC Coordinator

On Aug 30, 2016, at 3:19 PM, OLAW Division of Compliance Oversight (NIH/OD) wrote:

Hello Secondary Individual

In your email below you state that this was an NIH-funded project, but in Dr. Long's letter it is stated that it was a "non-NIH-funded protocol". Please clarify. Thank you.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM
 Animal Welfare Program Specialist
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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From: Secondary Individual [mailto:Secondary Individual@MEEI.HARVARD.EDU]
Sent: Thursday, August 25, 2016 8:37 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: Long, Alan; Gregory, Meredith; Secondary Individual; Secondary Individual
Subject: Schepens (A3177-01) Report of Non-Compliance (Case GG)

Dr. Wolff,

Attached please find a letter from our Institutional Official, Dr. Alan Long, reporting an issue of non-compliance (Case GG) that occurred at Schepens Eye Research Institute (Assurance Number: A3177-01).

Please note that the issues occurred in rabbits on an NIH-funded project.

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

Best,

Secondary Individual

IACUC Coordinator

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

A3177-15

Alan Long, Ph.D.
Vice President, Research & Academic Affairs
Institutional Official
20 Staniford Street • Boston, MA 02114
617.573-3009
alan_long@meci.harvard.edu

August 17, 2016

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 July 19, 2016 at 9am, 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 adhere to the approved protocol:** On July 13, 2016 at approximately 5:45pm, the Veterinary Technologist noted that a 4pm treatment of Timolol and Antibiotic drops was not administered to 19 rabbits after a gas vitrectomy procedure. The Investigator was notified and administered the 6pm dose of the therapeutic agents according to the approved protocol. The animals were observed and the missed treatments had no apparent negative impact on their overall health.
- **Adverse Event:** On July 14, 2016, at approximately 8am, the Veterinary Technologist entered the rabbit room to perform morning treatments on the animals. She immediately noted blood on the pad of one of the cages holding co-housed rabbits. Upon opening the cage, she found one of the rabbits lying on its stomach with its back legs splayed out behind it. The Technologist determined that the rabbit had most likely a broken back and that the source of blood was from the perianal region. Upon consultation with the Attending Veterinarian, the rabbit was euthanized and a necropsy was performed. The Veterinary Technologist, with the Associate Director of the Animal Facility present, performed a necropsy that revealed a broken spine, damage to the right kidney and blood clots in the bladder. The findings were reported to the Veterinarian.

Both incidents occurred while performing a study on a non NIH-funded protocol.

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

- The PI was informed of the missed treatment and returned to the Animal Facility to administer the next round of treatments according to the approved protocol.

Upon discovery of the injured rabbit, the following steps were taken:

- The PI was notified that a rabbit had been euthanized due to a broken back. Upon discussion with the PI, it was determined that the PI was the last person having contact with the rabbit,



Harvard Medical School Affiliate

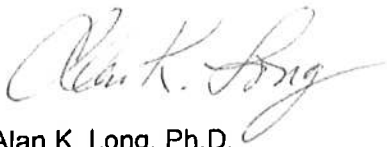
administering Timolol and Antibiotic drops. The PI did not note any injury that occurred during the treatments. Because there was concern that the PI may be having difficulty with proper handling of the rabbits potentially resulting in injury, a subcommittee (IACUC Chair, Attending Vet, Scientific member of the IACUC) decided to restrict the PI's access to the rabbits until the incident was further investigated and discussed during a specially convened meeting with the IACUC. The Veterinary Technician would administer all remaining treatments required for the rabbits in the current study.

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

- The Committee voted that in light of the missed drug treatment along with possible issues regarding proper rabbit handling, before rabbit studies can resume, the PI must amend the approved protocol to add a new Investigator with extensive experience working with, and handling/restraining rabbits. The new Investigator will be directly responsible for all aspects of the protocol, including all procedures, injections, and required treatments. The new Investigator's qualifications will be reviewed by the Associate Director and Veterinary Technologist (who would be responsible for any further training) and approved by the IACUC.

If you have any further comments or questions, please contact me at alan_long@meei.harvard.edu, or by phone at [Redacted Phone Number]

Sincerely,



Alan K. Long, Ph.D.
Vice President for Research and Academic Affairs
Institutional Official

cc: Meredith Gregory-Ksander, Ph.D., IACUC Chair
[Redacted Secondary Individual] 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: Thursday, August 25, 2016 11:18 AM
To: econdary Individu:
Subject: RE: Schepens (A3177-01) Report of Non-Compliance (Case GG)

Thank you. We'll respond soon.
 Axel Wolff

From: econdary Individu [mailto:econdary Individu@MEEI.HARVARD.EDU]
Sent: Thursday, August 25, 2016 8:37 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: Long, Alan; Gregory, Meredith; econdary Individu; econdary Individu
Subject: Schepens (A3177-01) Report of Non-Compliance (Case GG)

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Please note that the issues occurred in rabbits on an NIH-funded project.

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

Best,

Secondary Individual

IACUC Coordinator

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