



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) 402-2803

January 13, 2017

Re: Animal Welfare Assurance
A3693-01 [OLAW Case E]

Dr. Keith LeJeune
Senior Vice President for Research
And Development
Allegheny-Singer Research Institute
320 East North Avenue
Pittsburgh, PA 15212-4772

Dear Dr. LeJeune,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 12, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Allegheny-Singer Research Institute, following up on an initial telephone notification on September 23, 2016. According to the information provided, OLAW understands that a rabbit experiencing an adverse event was inappropriately euthanized with subcutaneous Fatal Plus IV, a method not approved by the IACUC and contrary to the recommendations of the AVMA Guidelines on Euthanasia: 2013 Edition. The unconscious animal was later euthanized by administering intracardiac Fatal Plus IV and death was verified by the absence of a heart beat followed by a bilateral thoracotomy. The associated animal activity in question was not PHS funded.

The corrective action consisted of mandatory re-training of the responsible Principal Investigator and research personnel on the relevant noncompliance issues related to this incident.

The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals at the Allegheny-Singer Research Institute are commendable and avoid the perception of a double standard. 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
Dr. Elizabeth Goldentyer, Director Eastern Sector, USDA, APHIS, AC



AHN Research Institute
320 East North Avenue
Pittsburgh, PA 15212-4722

January 12, 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
6705 Rockledge Drive
Bethesda, MD 20892-7982

RE: **Funding Source:** [redacted] **ocial informa**
Name of Institute: Allegheny Singer Research Institute
Assurance #: D16-00408 (A3693-01)
PI: Keith Cook M.D.
IACUC Application: "Antibacterial Perfluorocarbon Ventilation in a Rabbit Model" (1010)

Dear Dr. Wolff,

This letter is provided to OLAW in follow up to a preliminary report provided by phone September 23, 2016 regarding non-compliance that occurred at Allegheny Singer Research Institute (Assurance #: A3693-01). The noncompliance consisted of a failure to adhere to the approved protocol, which is defined as a serious deviation by The Guide.

On August 30, 2016, one of the study animals underwent experimental procedures and had a clinical adverse event (cyanosis) that required euthanasia (per approved protocol). The research staff did not use the approved protocol method of euthanasia nor was it in accordance with AVMA Guidelines. Rather than administering Fatal Plus IV, it was administered subcutaneously. The animal was unconscious but still alive after 1 hour. Research staff recognized the issue and immediately sought veterinarian assistance. Veterinarian staff ensured deep sedation and administered Fatal Plus intracardiac, as IV access could not be gained to euthanize the animal. Death was confirmed by verifying no heart beat for one minute and a bilateral thoracotomy was performed. This veterinarian staff-administered procedure was performed per AVMA guidelines.

The IACUC discussed the incident and accepted a corrective action plan (CAP) that required PI and Research Staff mandatory re-training in the areas of non-compliance.

If you have any questions, please do not hesitate to contact me.

Sincerely,



Keith LeJeune, PhD
SVP Research & Innovation
Institutional Official
Keith.Lejeune@ahn.org

Phone Number

cc: Keith Cook, PhD, PI
Kevin Kelly, MD, PhD, IACUC Chairman
Roger Sembrat, VMD, IACUC Attending Veterinarian
Secondary Individual, System Compliance
AAALAC
File

Gopee, Neera (NIH/OD) [E]

From: Gopee, Neera (NIH/OD) [E]
Sent: Thursday, January 12, 2017 3:15 PM
To: 'Keith Lejeune'
Cc: Kevin M. Kelly
Subject: RE: Update request on preliminary noncompliance report for A3693

Thank you for this report Dr. LeJeune. We will send an official response soon.

Best Regards,
 Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT
 Veterinary Medical Officer
 Office of Laboratory Animal Welfare
 National Institutes of Health

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From: Keith Lejeune [mailto:Keith.LeJeune@ahn.org]
Sent: Thursday, January 12, 2017 2:50 PM
To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Cc: Kevin M. Kelly <Kevin.KELLY@ahn.org>
Subject: RE: Update request on preliminary noncompliance report for A3693

Neera,

Please find the attached letter which will also be provided via US mail.

Keith

From: Gopee, Neera (NIH/OD) [E] [mailto:neera.gopee@nih.gov]
Sent: Tuesday, January 10, 2017 3:21 PM
To: Keith Lejeune
Cc: Kevin M. Kelly
Subject: [EXTERNAL] Update request on preliminary noncompliance report for A3693
Importance: High

Dear Dr. LeJeune,

I am writing with regards to the non-compliance incident was reported by the you via telephone on September 23, 2016, involving the performance of an unapproved method of euthanasia in a rabbit which experienced adverse effects at the Allegheny-Singer Research Institute. To date we do not have a record of receiving further information regarding this preliminary report. OLAW requests that if there is a final or interim report available, please forward it to the OLAW Division of Compliance Oversight (NIH/OD) olawdco@od.nih.gov at your earliest convenience.

If you have any questions or concerns regarding this matter, please do not hesitate to contact me.

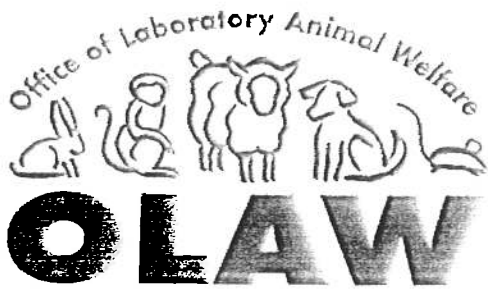
Best Regards,

Neera

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

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Initial Report of Noncompliance

By: Nelia Ghee

Date: 9-23-16

Time: 1:55 PM

Name of Person reporting: Keith Lejeune

Telephone #:

Fax #:

Email:

Phone Number

Name of Institution: Allegheny Singer Research Institute

Assurance number: D16-00408 (A3693-01)

Did incident involve PHS funded activity? No

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

A Rabbit experiencing an adverse event was euthanized by a method not approved in protocol.

Species involved: rabbit

Personnel involved:

Dates and times: 8-30-16

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____