



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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 15, 2017

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

Dr. Keith LeJeune
Senior Vice President for Research
And Innovation
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 June 28, 2017 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the Allegheny Singer Research Institute. According to the information provided, it is understood that another AVMA-approved euthanasia method was used in place of the one in the IACUC-approved protocol "Generating a Predictive Mathematical (In Silico) Computer Based Model Based on Measurable Changes in Diabetes Progression" (998). There were no animal welfare concerns. The activity was not PHS-supported.

Corrective actions included amending the protocol to add the euthanasia method. The PI and Research staff were also retrained in the areas of non-compliance. The staff will verify compliance with the protocol before conducting animal procedures.

OLAW believes that the corrective measures by the Allegheny Singer Research Institute are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring, self-correction, and self-reporting. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

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

cc: IACUC Contact



**Allegheny
Health Network**

Allegheny-Singer Research Institute
320 East North Avenue
Pittsburgh, PA 15212-4772

July 28, 2017

Axel V. Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare, National Institutes of Health
6705 Rockledge Drive, Rockledge 1, Suite 360 MSC 7982
Bethesda, MD 20892-7982

RE: **Funding Source** **Financial information**
Name of Institute: Allegheny Singer Research Institute
Assurance #: D16-00408 (A3693-01)
PI: Rita Bottino, Ph.D.
IACUC Application: "Generating a Predictive Mathematical (In Silico) Computer Based Model Based on Measurable Changes in Diabetes Progression" (998)

Dear Dr. Wolff,

This is letter to report 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 a serious deviation as required by The Guide.

Upon internal quality assurance monitoring, it was found that the euthanasia method being conducted was not approved by the IACCU and another AVMA approved method of euthanasia was being. The IACUC has since approved the method of euthanasia through an amendment to the protocol and no animal welfare issues were present since the method was approved by the AVMA.

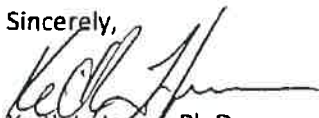
The Committee discussed this issue at the convened meeting on July 20, 2017. It was determined that no animals were harmed, an AVMA method of euthanasia was used, and the protocol was amended upon discovery of the discrepancy.

The IACUC discussed the incident and accepted the following corrective action plan (CAP) that was implemented:

- The PI and Research Staff received mandatory re-training in the areas of non-compliance
- Utilizing a verification step that prior to any planned procedures are conducted, the staff will ensure they are what is in the current protocol and that all individuals involved with animal research are aware of the approved procedures

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

Sincerely,


Keith LeJeune, Ph.D.
SVP Research & Innovation
Institutional Official

c: Rita Bottino, Ph.D., PI
Kevin Kelly, MD, PhD, IACUC Chairman
Roger Sembrat, VMD, IACUC Attending Veterinarian
Secondary individual System Compliance
AAALAC

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 14, 2017 11:05 AM
To: Secondary individual OLAW Division of Compliance Oversight (NIH/OD)
Cc: Keith Lejeune; Secondary individual
Subject: RE: Notification of noncompliance-Allegheny Singer Research Institute: D16-00408 (A3693-01)

Thank you for sending these two reports. We will send official responses soon.

Regards, Brent Morse

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

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From: Secondary individual [mailto:Secondary individual@ahn.org]
Sent: Monday, August 14, 2017 10:07 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Keith Lejeune <Keith.LeJeune@ahn.org>; Secondary individual@ahn.org
Subject: Notification of noncompliance-Allegheny Singer Research Institute: D16-00408 (A3693-01)

Name of Institute: Allegheny Singer Research Institute
Assurance #: D16-00408 (A3693-01)

To Whom It May Concern:

Attached please find reports of noncompliance regarding the determination of serious noncompliance by the IACUC for two internally funded animal protocols (#1009-PI: Nick Giannoukakis and #998-PI: Rita Bottino) for Allegheny Singer Research Institute (D16-00408 (A3593-01)).

If you have any questions, please let me know.

Regards,
 Secondary individual

Secondary individual

Director, Clinical Research and Regulatory Affairs
 AHN Research Institute
 Allegheny Health Network

phone: telephone # ; cell: telephone #
 fax: telephone #

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