



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

February 27, 2019

Re: Animal Welfare Assurance
A3158-01 [OLAW Case 1H]

Judith A. Neubauer, Ph.D.
Associate Vice President for Research Regulatory Affairs
University of Medicine and Dentistry of New Jersey
New Jersey Medical Schools
65 Bergen Street
SSB 519, PO Box 1709
Newark, NJ 07101-1709

Dear Dr. Neubauer,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 22, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Rutgers University. Your letter supplements the information in the initial phone report on February 4, 2019. According to the information provided, OLAW understands that on October 19, 2018 it was determined that several cages of mice were placed on a fasting protocol when the approved protocol required the administration of a normal diet. Fasting was to be limited to the experimental group. It was noted that this study was not supported by PHS funds.

Corrective and preventive actions included the lab members and the PI reviewing the approved protocol, including reviewing the assignment of animals to control and experimental groups and how to indicate this designation to University Comparative Medicine Resources on cage cards.

The prompt consideration of this matter by Rutgers University was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issues were appropriate. 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,

(b) (6)

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

cc: IACUC Chair
Laszlo M. Szabo, Esq., Dir. Office of Regulatory Affairs

February 22, 2018

Via Email

Brent C. Morse, DVM, DACLAM
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
morseb@mail.nih.gov

Re: Animal Welfare Assurance Number D16-00098 (A3158-01)

Dear Dr. Morse,

Rutgers, The State University of New Jersey hereby makes the final report for the following incident, reported to OLAW via telephone on February 4, 2019. On October 19, 2018, the University's Comparative Medicine Resources (CMR) office observed that several cages of mice were placed on a fasting protocol when the approved protocol required the administration of a normal diet. Fasting was to be limited to the experimental group. Non-compliance was limited to this incorrect assignment of fasting and no other animal welfare issues were observed.

The following actions were taken in response to this incident:

- Lab members and the Principal Investigator re-reviewed the approved protocol, including review of the assignment of animals to control and experimental groups, and how to indicate this designation to CMR on cage cards.
- At its regularly convened meeting on December 11, 2018, the IACUC reviewed and discussed this incident and unanimously voted to report this matter to OLAW. The IACUC also voted to accept the above noted corrective actions.

Please note that this study was not supported by NIH funds.

Sincerely,

(b) (6)

Judith Neubauer, Ph.D.
Institutional Official
Associate Vice President for Research Regulatory Affairs

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, February 25, 2019 8:53 AM
To: Laszlo Szabo; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Judith Neubauer; (b) (6)
Subject: RE: Final reports for Assurance # D16-00098 (A3158-01)

Thank you for providing these final reports Mr. Szabo. We will send official responses soon.

Best regards, Brent Morse

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

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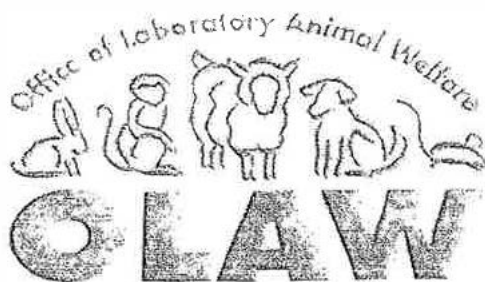
From: Laszlo Szabo [mailto:lszabo@ored.rutgers.edu]
Sent: Saturday, February 23, 2019 2:55 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Judith Neubauer <neubauer@rwjms.rutgers.edu>; (b) (6)
(b) (6)
Subject: Final reports for Assurance # D16-00098 (A3158-01)

Division of Compliance Oversight,

Attached are three final reports for reportable events under Assurance # D16-00098 (A3158-01). Please let me know if you have any questions.

Regards,

--
László M. Szabó, Esq.
Director, Office of Research Regulatory Affairs
"Your resource in the responsible conduct of research."
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675 Hoes Lane West, (b) (4)
Piscataway, NJ 08854
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Nothing in this email is intended as legal advice of counsel



Initial Report of Noncompliance

By: [Signature]Date: 2/4/19Time: 9:00Name of Person reporting: Laylo S. [Signature]Telephone #: [Redacted]Fax #: [Redacted]Email: [Redacted]Name of Institution: Rutgers U. - NewarkAssurance number: A3158Did incident involve PHS funded activity? NoFunding component: [Redacted]Was funding component contacted (if necessary): [Redacted]

What happened? Mult. cage w/o food \leq 24 hrs. "Special Diet". Caretaker assumed food provided by researcher

Species involved: MicePersonnel involved: CaretakerDates and times: 10/19/18Animal deaths: NoneProjected plan and schedule for correction/prevention (if known): [Redacted]Projected submission to OLAW of final report from Institutional Official: [Redacted]

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Case # [Redacted]