

DEPARTMENT OF HEALTH & HUMAN SERVICES

FOR US POSTAL SERVICE DELIVERY: Office of Laboratory Animal Welfare 6700B Rocklodge Drive, Suite 2500, MSC 6910 Bethesda, Maryland 20892-6910 Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

February 27, 2019

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Facsinile: (301) 402-7065

Re: Animal Welfare Assurance A3158-01 [OLAW Case 11]

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, 201[9] 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 December 11, 2018 the University's Comparative Medicine Resources (CMR) found a deceased mouse outside of its cage. It was determined that it was a lab mouse and was suspected that the mouse moved outside of the cage during research handling. It was noted that this study was supported by PHS funds.

Corrective and preventive actions included the lab members, the PI, and CMR staff being re-trained in the handling of animals during cage cleaning or cage assignment, including frequency of performing census.

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. 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



Office of Research Regulatory Affairs RWJMS, Research Tower Rutgers, The State University of New Jersey 675 Hoes Lane West, Room 115 Piscataway, NJ 08854 http://orra.rutgers.edu/ p. 732-235-6081 f. 732-235-5534

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 December 11, 2018, the University's Comparative Medicine Resources (CMR) found a deceased mouse outside of its cage. An investigation, including a census count, supports the finding that this was a lab mouse (and not a rodent). It is suspected that the mouse moved out of the cage (e.g., during research handling). These mice were control animals under an approved protocol.

The following actions were taken in response to this incident:

- The Principal Investigator, lab members, as well as CMR staff, were re-trained in the handling of animals during cage cleaning or cage assignment, including frequency of performing census.
- At its regularly convened meeting on January 8, 2019, 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 supported by NIH funds, and as you requested, the grant number is: NIH U19-AI111276.

(b) (6)

Sincerely,

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

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Refrieved from Animal Research Laboratory Overview (ARLO)

Morse, Brent (NIH/OD) [E]

From: Sent:	OLAW Division of Compliance Oversight (NIH/OD) 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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

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)

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." RWJMS Research Tower 675 Hoes Lane West, (b) (4) Piscataway, NJ 08854 Office: (b) (9) | Mobile: (b) (6) | Fax: (b) (6) "*Nothing in this email is intended as legal advice of counsel**

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A3158-1I estice of Laboratory Animal West Initial Report of Noncompliance By: Time: 7:00 Date: 2 Name of Person reporting: Telephone #: Fax #: Email: Name of Institution: Assurance number: Did incident involve PHS funded activity? Funding component: Was funding component contacted (if necessary): What happened? ESL3 facility, One more found dead on floor of animal room, During Species involved: Mouse cage change, Personnel involved: Dates and times: 12 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 #