



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

December 19, 2018

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

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 December 5, 2018 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 November 28, 2018. According to the information provided, OLAW understands that on June 21, 2018 it was determined that 10-12 cages of mice were being fed a special diet not described in the protocol and that bedding had been removed from these cages without IACUC approval during an approved fasting procedure. Also, required observational records during the fasting period were not being kept. The animals were not assigned to a project funded by the PHS.

Corrective and preventive actions included counseling of the PI by the IACUC Chair and the Director of Comparative Medicine Resources. The PI was required to retrain lab members to avoid recurrence of these issues and to stop removing bedding from the cages until an alternative is found. An amendment was approved by the IACUC to add the special diet to the protocol. It was determined that overnight monitoring of the animals was unnecessary and that an amendment should be submitted to remove this requirement but that documentation of observations as stated in the protocol is still required. The Post Approval Monitor will make two unannounced visits to the lab three months apart.

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

Obtained by Rise for Animals. Uploaded 08/31/2020

Retrieved from Animal Research Laboratory Overview (ARLO)

December 5, 2018

Brent Morse, DVM
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: Animal Welfare Assurance Number D16-00098 (A3158-01)

Dear Dr. Morse,

Rutgers University wishes to make a final report in which off protocol work was conducted and observation records were not properly kept. The IACUC Manager first reported the incident via telephone call on November 28, 2018.

On June 21, 2018, the following issues were noted: mice were being fed a special diet that was not described in the approved protocol, bedding was removed during an approved fasting procedure (to prevent ingestion of bedding) but the removal of bedding was not described in the approved protocol, records documenting multiple daily observations during the approved fasting period were not being kept. Approximately 10-12 cages were affected by these issues.

The following actions were taken in response to this incident:

- The PI was counseled by the IACUC Chair and Director of Comparative Medicine Resources (CMR).
- CMR staff is looking into cages that would prevent direct contact with feces and urine and the PI was instructed to stop removing bedding while this caging issue is being resolved.
- An amendment to add the special diet to the protocol was submitted and approved.
- The IACUC discussed the need to monitor animals as frequently as was stated in the approved protocol (four times daily) and it was determined that it is unnecessary for animal welfare to monitor the animals overnight and that it introduced unnecessary disruption of animals from other laboratories housed in the same room. The PI was instructed to submit an amendment to remove overnight monitoring from the protocol, although documentation of required observations is still required.
- The PI was required to re-train lab members to avoid recurrence of these issues.
- It was determined that the Post Approval Monitor would make two unannounced visits to this lab three months apart to ensure that the lab is maintaining required records and documenting monitoring of the animals.
- At its regular meeting on July 10, 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.

Please contact me with any questions.

Sincerely,

(b) (6)

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

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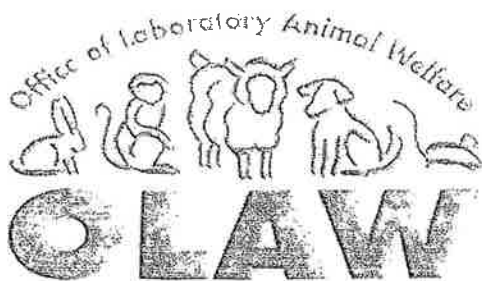
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Initial Report of Noncompliance

By: *[Signature]*

Date: 11/28/18

Time: 3:00

(b) (6)

Name of Person reporting: *[Redacted]*Telephone #: *[Redacted]*

(b) (6)

Fax #:

Email:

Name of Institution: Rutgers U. - NewarkAssurance number: A3158Did incident involve PHS funded activity? No

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

*Fed special diet not in protocol
 & bedding removed during fasting period;
 not observed 4x/d as in protocol*

Species involved: *mice*Personnel involved: *Researcher*Dates and times: *6/21/18*

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 # _____