



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 5, 2019

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

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 January 23, 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 November 28, 2018. According to the information provided, OLAW understands that on November 14, 2018, during semi-annual inspection of the facility, it was noted that cage cards for 15 mice indicated that they had been administered alpha hemolysin toxin from *S. aureus*, although this substance was not included in the protocol. The lab manager confirmed that the mice were, in fact, administered this toxin and that this assay was inadvertently left off the protocol at the time of triennial review, as it had not been performed in several years. It was noted that this study was supported by NIH funds

Corrective and preventive actions included euthanasia of the involved mice. The lab manager confirmed that going forward all animal experiments performed by animal research staff will only be scheduled after having been verified by the lab manager and their research administrator (who is an IACUC member). The lab manager and the PI were counseled by the IACUC Chair. The lab manager and the PI confirmed that this assay will no longer be conducted.

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. Please be sure that costs associated with the non-compliance are not charged to the grant. 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)

January 23, 2019

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 mice were administered a compound off protocol. The IACUC Manager first reported the incident via telephone call on November 28, 2018.

On November 14, 2018, during semi-annual inspection of the facility, it was noted that cage cards for 15 mice indicated that they had been administered alpha hemolysin toxin from *S. aureus*, although this substance was not included in the protocol. The lab manager confirmed that the mice were, in fact, administered this toxin and that this assay was inadvertently left off the protocol at the time of triennial review, as it had not been performed in several years.

The following actions were taken in response to this incident:

- The mice were euthanized.
- The lab manager confirmed that going forward all animal experiments performed by animal research staff will only be scheduled after having been verified by the lab manager and their research administrator (who is an IACUC member).
- The lab manager and the PI were counseled by the IACUC Chair.
- The lab manager and the PI were instructed to submit an amendment to add this assay to the current protocol; however, they confirmed that this assay will no longer be conducted.
- At its regular 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 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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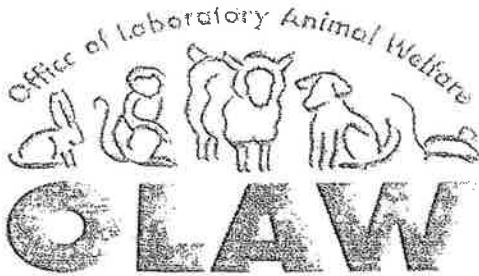
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Initial Report of Noncompliance

By: BMDate: 11/28/18Time: 3:00

(b) (6)

Name of Person reporting: (b) (6)Telephone #: (b) (6)Fax #: (b) (6)Email: (b) (6)Name of Institution: Rutgers U. - NewarkAssurance number: A3158Did incident involve PHS funded activity? ?Funding component: Was funding component contacted (if necessary): What happened? 15 mice in cage labeled "dosed w/MRSA toxin". This toxin not in current protocol.Species involved: mousePersonnel involved: ResearcherDates and times: 11/14/18Animal deaths: Projected plan and schedule for correction/prevention (if known): Projected submission to OLAW of final report from Institutional Official:

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Case #