



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

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

February 1, 2018

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

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 24, 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 and corrects the information in the initial phone report on October 19, 2017. According to the information provided, OLAW understands that on August 18, 2017 it was determined that a lab had been performing work on a protocol that had expired on July 31, 2017. This activity was not currently funded by the PHS.

Corrective actions included stopping work on the expired protocol and transferring the animals to a Comparative Medicine Resources (CMR) Holding Protocol. The animals were then moved to a collaborator's protocol approved to use the same strains and procedures as the expired protocol. A triennial protocol was submitted and approved.

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 issue 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,

Signature

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

cc: IACUC Chair

Secondary Individual

Dir. Office of Regulatory Affairs

January 24, 2018

Axel Wolff, 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. Wolff,

Rutgers University wishes to make a final report regarding an incident in which work was conducted on an expired protocol. Secondary Individual IACUC Manager, first reported the incident via telephone call on October 19, 2017.

On August 18, 2017, it was discovered that a lab had been performing work on a protocol that had expired on July 31, 2017. This occurred during a transition to a new web-based protocol system and this triennial submission was inadvertently overlooked and delayed.

The following actions were taken in response to this incident:

- Work was stopped on the expired protocol.
- The remaining animals were initially moved to the Comparative Medicine Resources (CMR) Holding Protocol and then were moved to a collaborator's protocol (approved to use the same strains and procedures as the expired protocol).
- The triennial protocol was submitted and approved.
- At its regular meeting on September 19, 2017, the IACUC reviewed and discussed this incident and unanimously voted to report this matter to OLAW. The IACUC also voted to accept the actions noted above as corrective actions and recommended no further action regarding this incident.

Please note that while this study was not supported by NIH funds, in accordance with our Assurance, we report all serious concerns to OLAW. At the time of preliminary report to OLAW, it was believed NIH funds were used during the period of expiration. However, it has since been clarified that although the account associated with the protocol had been funded by a NIH award, that award ended in February 2017, long before the protocol expired. The expenses incurred during the period of expiration were not charged to any NIH awards.

Please contact me with any questions.

Sincerely,

Signature

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: Wednesday, January 31, 2018 7:58 AM
To: Secondary Individual; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Secondary Individual; Judith Neubauer; Secondary Individual
Subject: RE: three final reports for Assurance # D16-00098 (A3158-01)

Thank you for these reports Secondary Individual. 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

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: Secondary Individual [mailto:Secondary Individual@ored.rutgers.edu]
Sent: Tuesday, January 30, 2018 2:46 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Secondary Individual @ored.rutgers.edu; Judith Neubauer <neubauer@rwjms.rutgers.edu>; Secondary Individual
Secondary Individual@ored.rutgers.edu
Subject: three 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.

Thank you,

Secondary Individual

IACUC Manager
Office of Research Regulatory Affairs
RWJMS Research Tower

Room #

675 Hoes Lane West
Piscataway, NJ 08854

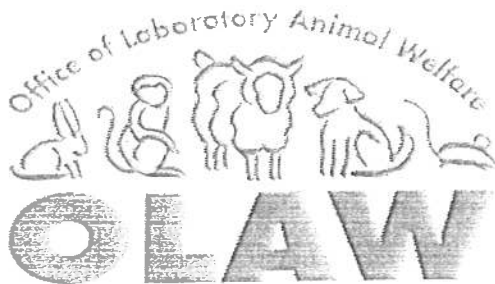
Phone: Phone Number

Fax: Phone Number

email: Secondary Individual@rutgers.edu

web: <http://orra.rutgers.edu/>

"Your resource in the responsible conduct of research."



Initial Report of Noncompliance

By: *BGM*

Date: *10/19/17*

Time: *3:05*

Name of Person reporting:

Secondary Individual

Telephone #:

Phone Number

Fax #:

Email:

Name of Institution:

Assurance number:

Rutgers U. (Newark)
A3158

Did incident involve PHS funded activity?

Funding component:

Was funding component contacted (if necessary):

Yes (see letter)

What happened?

PI did not submit de-novo protocol for renewal. Protocol expired on 7/30/17. Surgery + water restriction procedures during expiration period.

Species involved:

Personnel involved:

Dates and times:

Animal deaths:

8 July 30th

expiration. Animal procedures took place until 8/18/17

Projected plan and schedule for correction/prevention (if known):

Projected submission to OLAW of final report from Institutional Official:

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Case #