

Secondary Individual

Signature

January 22, 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 a drug was administered to animals off protocol. [REDACTED] IACUC Manager, first reported the incident via telephone call on October 19, 2017.

On July 24, 2017, rapamycin was administered to at least three mice, but this administration was not specified in the protocol.

The following actions were taken in response to this incident:

- The PI and PI's lab members were counseled by the Executive Director of Comparative Medicine Resources (CMR) and the Clinical Veterinarian, CMR.
- The PI counseled the lab members and ensured that the lab members will read and understand exactly what is permitted in the currently approved versions of all protocols.
- An amendment to add rapamycin will be submitted and approved, should the PI decide to perform these experiments in the future.
- 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.

Please contact me with any questions.

Sincerely,

[REDACTED]
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

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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; 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/>

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Initial Report of Noncompliance

BY: 

Date: 10/19/17

Time: 3:10

Name of Person reporting:

Secondary Individual

Telephone #:

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): _____

What happened? PI administered drug to mice (3)
~~that~~ was not in protocol.

Species involved: Mice

Personnel involved: PI

Dates and times: 7/24/17

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 # _____