



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) 480-3387

October 19, 2021

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

Dr. Michael Zwick  
Senior Vice President  
Rutgers, The State University of New Jersey  
33 Knightsbridge Road, (b) (4)  
Piscataway, NJ 08854

Dear Dr. Zwick,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 29, 2021 letter reporting an adverse event at Rutgers, The State University of New Jersey following up on an initial September 28, 2021 notification by telephone.

According to the information provided, this Office understands that the Rutgers Animal Care and Use Committee (ACUC) determined that an adverse event occurred with respect to: the deaths and required euthanasia of immunocompromised mice. The final report states beginning July 12, 2021, small numbers of mice on the same protocol were unexpectedly found dead or determined to be in poor condition and were euthanized. Investigative results revealed the animals were maintained on Hydropacs containing acidified water and the vendor supplying the Hydropacs failed to perform adequate quality control testing. It was determined the water pouches had a pH of 2.1 instead of 2.8. It is believed the chronic use of low acidified water resulted in gut dysbiosis with secondary overgrowth of commensal bacteria leading to death of the animals. In response to these findings, the following actions occurred:

- Any animals identified as being in poor condition were treated or euthanized.
- The Principal Investigator (PI) and lab members worked with Comparative Medicine Resources (CMR) staff to investigate the issue and monitor the remaining animals.
- Remaining animals in the colony were put on a course of antibiotics and their condition improved over time. CMR increased routine monitoring of animals in the colony as it is expected to take additional time for these animals to recover gut homeostasis.
- The vendor resumed quality control testing of this product and CMR will do internal pH tests of the water pouches at routine intervals.

The IACUC reviewed and discussed these incidents and unanimously voted the matter reportable to OLAW. The committee also voted to accept the above corrective actions. It is noted that these animals were supported by PHS funding.

Based on its assessment of this explanation, OLAW understands that the Rutgers, The State University of New Jersey has implemented appropriate measures to correct and prevent recurrences of these problems. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T.  
Tubbs -S

Digitally signed by Jacquelyn  
T. Tubbs -S  
Date: 2021.10.19 14:25:03  
-04'00'

Jacquelyn Tubbs, DVM, DACLAM  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



**RUTGERS**

Rutgers, the State University of New Jersey  
IACUC Administrative Office  
675 Hoes Lane West, room 115  
Piscataway, NJ 08854

orad.rutgers.edu  
NewarkIACUC@rutgers.edu  
NewBrunswickIACUC@rutgers.edu  
732.235.6081

September 29, 2021

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, The State University of New Jersey, hereby makes the final report for the following incident, reported to OLAW via telephone on September 28, 2021, in which approximately 161 immunocompromised mice died or were euthanized over a two-month period. Beginning July 12, 2021, small numbers of animals on the same protocol started being unexpectedly found dead or identified as in poor condition and euthanized. After extensive testing and investigation, it was determined that the animals are maintained on Hydropacs containing acidified water and the vendor providing the Hydropacs had failed to perform adequate quality control testing; the water pouches were found to have a pH of 2.1 instead of pH 2.8. The chronically low acidified water presumably led to gut dysbiosis with secondary overgrowth of commensal bacteria leading to death of the animals.

The following actions were taken in response to this incident:

- Any animals identified as being in poor condition were treated or euthanized.
- The PI and lab members worked very closely with Comparative Medicine Resources (CMR) staff to investigate the issue and monitor remaining animals.
- Remaining animals in the colony were put on a course of antibiotics and their condition improved over time. CMR has increased routine monitoring of animals in the colony as it is expected to take additional time for these animals to recover gut homeostasis.
- The vendor has resumed quality control testing of this product and CMR will do internal pH tests of the water pouches at routine intervals.
- At its regular meeting on September 14, 2021, the IACUC reviewed and discussed these incidents and unanimously voted to report this matter to OLAW. The IACUC also voted to accept the above noted corrective actions.

Please note that these animals were supported by NIH funds.

Please contact me with any questions.

Sincerely,

(b) (6)

Michael E. Zwick, Ph.D.  
Institutional Official  
Senior Vice President for Research

**Wolff, Axel (NIH/OD) [E]**

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, October 4, 2021 7:03 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: final reports for Rutgers Assurance D16-00098 (A3158-01)

Thank you for these reports, (b) (6) We will send responses soon.  
Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

**From:** (b) (6)  
**Sent:** Friday, October 1, 2021 5:00 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** final reports for Rutgers Assurance D16-00098 (A3158-01)

Division of Compliance Oversight,

Attached are final reports for two reportable events under Assurance # D16-00098 (A3158-01).

Please let us know if you have any questions.

Thank you,

(b) (6)



## Initial Report of Noncompliance

By: BCM

Date: 9/28/2021

Time: 4:50

Name of Person reporting: (b) (6)  
 Telephone #: (b) (6)  
 Fax #:  
 Email:

Name of Institution: Rutgers Univ  
 Assurance number: A31585

Did incident involve PHS funded activity? Yes  
 Funding component:  
 Was funding component contacted (if necessary):

What happened? Immunocompromised mouse colony had unexplained deaths or morbidity requiring euthanasia starting in mid-July 2021. Determined that vendor-provided acid water had pH of 2.1 instead of 2.8, as required. Possible cause of mortality and morbidity. Vendor had stopped quality-control testing.

Species involved: Mus  
 Personnel involved: None  
 Dates and times:  
 Animal deaths: yes, approx. 160 mice died or had to be euthanized.

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

Removed vendor water and replaced with proper pH water. Vendor is once again testing water pH.

Projected submission to OLAW of final report from Institutional Official:

< 60 days

OFFICE USE ONLY  
 Case #