



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

January 6, 2020

Re: Animal Welfare Assurance  
#A3262-01 (OLAW Case 3W)

Dr. S. David Kimball  
Senior Vice President,  
Research & Economic Development  
Rutgers, State University of New Jersey  
3 Rutgers Plaza  
New Brunswick, NJ 08901

Dear Dr. Kimball,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 16, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Rutgers, The State University of New Jersey following up on an initial November 20, 2019 notification by telephone.

According to the information provided, this Office understands that Rutgers, The State University of New Jersey Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: unexpected deaths of 67 mice on an infectious disease protocol that occurred between August 24, 2019 and August 27, 2019. The cause of the mortality was not determined. QC testing had been performed on the inoculum prior to infection and a lower dose than had been previously used was administered. Investigative results revealed the protocol personnel did not realize the standard daily checks performed by the animal care staff did not suffice as the additional required post-infection checks. Therefore, only the standard animal care staff daily checks were performed over the weekend, but the additional specific post-infection care checks were not. It is noted that this research is not PHS funded. On October 16, 2019 at its regular meeting, the IACUC reviewed and discussed the incident and unanimously voted to report this matter to OLAW and voted to accept the corrective actions listed below. The corrective actions included:

- Counseling of the PI and protocol personnel by the IACUC Executive Committee as well as Comparative Medicine Resources (CMR) staff.
- Clarification provided ensuring that the protocol personnel are responsible for all post-infection checks and that these checks must be documented separately from, and in addition to, daily animal care staff checks.
- Submission of an amendment to the protocol to clarify and add more detail to humane endpoints.

Based on its assessment of this explanation, OLAW understands that Rutgers, The State University of New Jersey has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. Although this activity was not PHS funded, the application of the expectations of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of these matters and find no cause for further action by this Office.

*Page 2 – Dr. Kimball*  
*January 6, 2020*  
*OLAW Case A3262-3W*

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM  
Veterinary Medical Officer  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact

December 16, 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 D16-00169 (A3262-01)

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 November 20, 2019. An unexpected loss of 67 mice on an infectious disease protocol occurred between August 24, 2019 and August 27, 2019. The cause of the mortality was investigated but could not be determined. QC testing had been performed on the inoculum prior to infection and a lower dose than had been used previously was administered. Further investigation indicated misunderstanding regarding weekend observations – the protocol personnel did not realize that the standard daily checks performed by the animal care staff did not suffice as the additional required post-infection checks. As a result of this misunderstanding, only the standard animal care staff daily checks were performed over the weekend but the additional specific post-infection care checks were not.

The following actions were taken in response to this incident:

- The PI and protocol personnel were counseled by the IACUC Executive Committee as well as Comparative Medicine Resources (CMR) staff.
- It was clarified that protocol personnel are responsible for all post-infection checks and that these must be documented separately from, and in addition to, daily animal care staff checks.
- An amendment to the protocol to clarify and add more detail to humane endpoints was submitted.
- At its regular meeting on October 16, 2019, 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 research is not funded by PHS.

Please contact me with any questions.

Sincerely,

(b) (6)

S. David Kimball, Ph.D.  
Institutional Official  
Senior Vice President, Research & Economic Development  
Vice President, Innovation & Research Commercialization

**Morse, Brent (NIH/OD) [E]**

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, December 19, 2019 8:04 AM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** (b) (6)  
**Subject:** RE: final reports for Rutgers Assurance D16-00169 (A3262-01)

Thank you for providing these reports (b) (6) We will send official responses soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
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:** (b) (6)  
**Sent:** Wednesday, December 18, 2019 5:05 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** final reports for Rutgers Assurance D16-00169 (A3262-01)

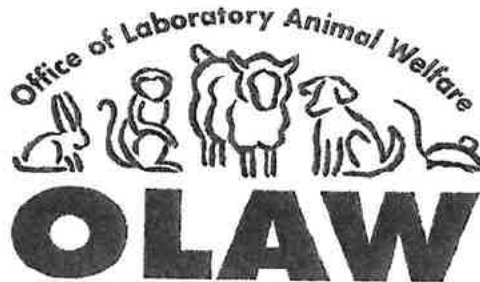
Division of Compliance Oversight,

Attached are eight final reports for reportable events under Assurance # D16-00169 (A3262-01).

Please let us know if you have any questions.

Thank you,  
(b) (6)

(b) (6)



## Initial Report of Noncompliance

By: aw

Date: 11/20/19

Time: 10:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Rutgers

Assurance number: A3262

Did incident involve PHS funded activity? No

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

Infectious disease protocol; 67/130 mice died. Confusion on who conducted checks. Never happened before.

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths: 67

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

Amend protocol, more frequent monitoring

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_