



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 3X)

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: lab members not responding in a timely manner to sick animal notifications and lack of proper signage (a cage missing post-operative monitoring card) on June 19, 2019. It is noted that this research was not PHS funded. Further investigations revealed the following:

- Personnel had not been added to the protocol.
- The lab administered an analgesic that was not included on the approved protocol.
- The lab administered an expired drug to 15-20 mice during a terminal procedure.

On July 17, 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 following corrective actions. The corrective actions included:

- Counseling of the PI by the IACUC Executive Committee as well as Comparative Medicine Resources (CMR) staff.
- Development of a comprehensive lab structure and responsibility area by the PI, which includes designation of lab officers responsible for oversight, basic care and personnel education.
- Retraining of the lab by the Post Approval Monitor.
- Submission of an amendment to properly add lab members to the protocol.
- Submission of an amendment to clarify and include appropriate analgesia in the protocol.
- Discarding of the expired drug.

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

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.

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. On June 19, 2019, it was noted that lab members did not respond in a timely manner to sick animal notifications (Comparative Medicine Resources (CMR) staff needed to perform the required actions in lieu of the lab) and that a post-operative monitoring card was missing from a cage (a lab member reported that it fell off). Upon further investigation, it was determined personnel had not been properly added to the protocol (they had been named as members of the PI's research team but not specified on this individual protocol), that the lab had administered an analgesic that was not included in the approved protocol (it had previously been in the protocol but had been left out of the protocol at the time of the most recent triennial review), and that the lab had administered an expired drug to 15-20 mice during a terminal procedure.

The following actions were taken in response to this incident:

- The PI was counseled by the IACUC Executive Committee as well as CMR staff.
- The PI developed a comprehensive lab structure and responsibility area plan, including designation of lab officers responsible for oversight, basic care, and personnel education.
- The lab underwent re-training by the Post Approval Monitor.
- An amendment was submitted to properly add lab members to the protocol.
- After discussion with CMR veterinarians, an amendment was submitted to clarify and include appropriate analgesia in the protocol.
- The expired drug was discarded.
- At its regular meeting on July 17, 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?

Staff not listed on protocol. Analgesia not listed on pre- or post-op card not on cage, expired analgesics. Vets had to euthanize because not done promptly by lab staff.

Species involved: Mouse

Personnel involved:

Dates and times:

Animal deaths:

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

Retrain, lab mgr appointed, better lab oversight

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____