



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

November 5, 2019

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

Dr. S. David Kimball
Institutional Official
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 October 17, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Rutgers University. Your letter supplements the information in the initial report by phone on April 23, 2019. According to the information provided, OLAW understands that on January 9, 2019, the University's Comparative Medicine Resources (CMR) reported that lab personnel had temporarily stored 16 mice in cages in an unapproved area and that there was a lack of available surgical records, including documentation of post-operative analgesia. It was stated that these animals were not supported by PHS funds.

Corrective and preventive actions included requiring the PI and lab personnel to re-review the protocol and to be re-trained on relevant animal handling and post-operative analgesia procedures as per the IACUC policies. The PI was also counseled.

The consideration of this matter by Rutgers University was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent reoccurrence were appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC Contact

October 17, 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 April 23, 2019. On January 9, 2019, the University's Comparative Medicine Resources (CMR) reported that lab personnel did not adhere to protocol procedures as follows: temporarily storing 16 mice in cages in an unapproved animal area and lack of available surgical records, including documentation of post-operative analgesia.

The following actions were taken in response to this incident:

- The PI was counseled by the IACUC Executive Committee as well as Comparative Medicine Resources (CMR) veterinary staff and the Post Approval Monitoring (PAM) Coordinator.
- The Principal Investigator and all lab personnel were required to re-review the protocol and undergo re-training on the use of relevant animal handling and post-operative analgesia procedures as per the IACUC policies.
- At its regularly convened meeting on February 20, 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.

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 1, 2019 7:17 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: final reports for Rutgers Assurance D16-00169 (A3262-01)

Thank you for these reports, (b) (6) Dr. Morse will send responses soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Thursday, October 31, 2019 2:56 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 six 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)

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Thursday, October 17, 2019 8:31 AM
To: (b) (6)
Subject: RE: OLAW open compliance cases

Thank you (b) (6) We will await the A3262 cases.

Sincerely, 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, October 16, 2019 4:55 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: RE: OLAW open compliance cases

Dear Dr. Morse,

Thank you for the follow up email on the open cases under both Assurances. We apologize for the delay. The final reports for the cases under Assurance # A3158 have now been sent to the Division of Compliance Oversight email address. The final reports for the cases under Assurance # A3262 will be forthcoming soon.

Please note that I have removed Laszlo Szabo, as he is no longer in an IACUC related role at the university.

Thanks,
(b) (6)

(b) (6)

From: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Sent: Wednesday, October 16, 2019 1:48 PM

To: [REDACTED] (b) (6)

Subject: OLAW open compliance cases

Importance: High

Dear [REDACTED] (b) (6)

OLAW has six open cases under Assurance # A3262 and six more open cases under Assurance # A3158. These cases date back to April 2019 thru June 2019. Please submit either final reports, interim reports, or justification for further delay. We want to work with you to finalize these but we also need to show diligence and timeliness in our follow-up. Thank you.

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.



Initial Report of Noncompliance

By: *egm*

Date: *4/23/19*

Time: *1:15*

Name of Person reporting: (b) (6)

Telephone #:

Fax #:

Email:

Name of Institution: *Rutgers U. - New Brunswick*

Assurance number: *A3262*

Campus

Did incident involve PHS funded activity? *No*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? *16 mice taken to PI's area not listed in protocol. No record of post-op analgesia admin. Buprenorphine dose not as per protocol*

Species involved: *mice*

Personnel involved: *PI*

Dates and times: *1/16/19*

Animal deaths: _____

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

*A. amendment
Retraining*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____