



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 3P)

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 18, 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 June 20, 2019. According to the information provided, OLAW understands that between June 7, 2019 and June 13, 2019 members of two labs biopsied the tails of 43 mice over the age of 21 days. Anesthesia and/or analgesia was not provided and proper hemostasis was not achieved. It was stated that these animal activities were partially supported by PHS funds.

Corrective and preventive actions included analgesia being provided, as appropriate, by the Comparative Medicine Resources (CMR) staff. Lab personnel were re-trained on proper and compliant tail biopsy procedures and the importance of adhering to protocols as well as alternate methods of genotyping mice over 21 days. One lab elected to switch to ear notch to obtain tissue for genotyping. SOPs were developed for step-by-step details of tail biopsy, including acceptable age range for mice. Increased monitoring of lab staff by CMR veterinary staff and PAM was implemented. The PIs were 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 18, 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 June 20, 2019.

Between June 7, 2019 and June 13, 2019, members of two labs biopsied the tails of 43 mice over the age of 21 days without following procedures outlined in the Rutgers University Policy on Genotyping – Tissue Collection and not in accordance with the protocols. Anesthesia and/or analgesia was not provided by the lab staff at the time of tail biopsy, and proper hemostasis was not achieved.

The following actions were taken in response to this incident:

- Comparative Medicine Resources (CMR) veterinary staff provided analgesia, as appropriate.
- The PIs were counseled by the IACUC Executive Committee as well as Comparative Medicine Resources (CMR) veterinary staff and the Post Approval Monitoring (PAM) coordinator.
- The lab members were re-trained on proper and compliant tail biopsy procedures and the importance of adherence to protocols as well as alternate methods for genotyping mice over 21 days.
- One lab elected to switch to ear notch to obtain tissue for genotyping.
- In cases where tail biopsy will still be used, SOPs for routine lab work, including step by step details on the tail biopsy procedure itself, as well as the acceptable age range for mice undergoing the procedure and instructions for documentation of the procedure were developed and implemented by the labs.
- Increased monitoring of lab staff by CMR veterinary staff and PAM was implemented.
- 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 a portion of these animals were supported by NIH funds.

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

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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 (b) (6) 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

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Initial Report of Noncompliance

By: *[signature]*

Date: 6/20/19

Time: 10:45

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Rutgers Univ - New Brunswick

Assurance number: A3262 Campus

Did incident involve PHS funded activity? ?

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Adults tail-snipped w/o anesthesia or analgesia. 2 different PIs on 2 dates. 36 total animals.

Species involved: mouse

Personnel involved:

Dates and times: 6/7/19 + 6/13/19

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 # _____