



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 3R)

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: mice bearing tumors that exceeded endpoints specified in the protocol and related IACUC policy. The final report states that it appears the lab waited for Comparative Medicine Resources (CMR) notifications that the endpoints had been met or exceeded to euthanize the mice, despite being counseled multiple times by CMR. It is noted that this research is PHS funded. On July 17, 2019 at its regular meeting, the IACUC reviewed and discussed this incident. The Committee voted to report this matter to OLAW and voted to accept the corrective actions listed below. The corrective actions include the following:

- PI and lab manager were counseled by the IACUC Executive Committee as well as the CMR staff.
- Lab underwent retraining by the Post Approval Monitor.
- Lab instituted a daily check sheet for tumor monitoring documentation.

Based on its assessment of this explanation, OLAW understands that Rutgers, The State University of New Jersey Animal has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. 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



IACUC Office  
Rutgers University Animal Care  
RWJMS, Research Tower  
Rutgers, The State University of New Jersey  
675 Hoes Lane West, Room 115  
Piscataway, NJ 08854

<http://orad.rutgers.edu/iacuc>

p. 732-235-6081

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 July 17, 2019, the IACUC discussed an incident in which tumors in mice exceeded the endpoints specified in the protocol and the related IACUC policy. It appeared that the lab waited for (Comparative Medicine Resources) CMR notifications that the endpoints had been met or exceeded to euthanize the mice, despite being counseled multiple times by CMR.

The following actions were taken in response to this incident:

- The PI and lab manager were counseled by the IACUC Executive Committee as well as CMR staff.
- The lab underwent re-training by the Post Approval Monitor.
- The lab instituted a daily check sheet for tumor monitoring documentation.
- 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 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]**

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**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

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**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? Yes

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

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

What happened?

Tumors too big on mice, lab staff waited for necy to assess mice, lab staff didn't measure tumors

Species involved: Mice

Personnel involved: Lab staff

Dates and times:

Animal deaths:

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

Retrain, counsel to check tumor size

Projected submission to OLAW of final report from Institutional Official:

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