



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

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Office of Laboratory Animal Welfare
Rockledge One, Suite 360
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Bethesda, Maryland 20817
Telephone: (301) 496-7163
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November 16, 2017

Re: Animal Welfare Assurance
A3165-01 [OLAW Case Y]

Dr. James Tomasek
Vice President for Research
The University of Oklahoma Health Sciences Center
1000 Stanton L. Young Blvd, Room 121
Oklahoma City, OK 73117

Dear Dr. Tomasek,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 3, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The University of Oklahoma Health Sciences Center (OUHSC), following up on an initial telephone notification on October 30, 2017. According to the information provided, OLAW understands that twenty eight adult and three neonatal mice were inappropriately euthanized by a research associate who failed to assure death following carbon dioxide asphyxiation, contrary to IACUC policies and the recommendations of the AVMA Guidelines on Euthanasia: 2013 Edition. Animal care personnel immediately reported the noncompliance to the research associate and program veterinarian. All animals were promptly euthanized in accordance with institutional policies by animal care staff and the program veterinarian immediately halted the responsible research associate's approval to work with animals. An IACUC subcommittee assigned to investigate the incident, noted that the research associate has been noncompliant in the past and failed to complete required remedial training. The associated animal activity in question was not PHS supported.

The corrective actions consisted of the following:

- (1) Rescinding the responsible research associate's animal use privileges at OUHSC.
- (2) Revoking the Principal Investigator's laboratory as an authorized animal procedure location and requiring that all future animal work be conducted in procedure rooms within the institution's vivarium.
- (3) The Principal Investigator submitting an amendment to the protocol to include a comprehensive description of the euthanasia methods, inclusive of the procedures used to assure death in mice of all ages.
- (4) Mandating that all new animal users listed on the Principal Investigator's approved protocols complete the hands-on mouse techniques workshop.

Your prompt and thorough resolution of this matter is commendable and consistent with the PHS philosophy of monitored self-regulation. We appreciate having been informed about this matter and find no cause for further action by this Office.

Page 2 – Dr. Tomasek
November 16, 2017
OLAW Case A3165-Y

Sincerely,

A handwritten signature in black ink, appearing to read "Neera V. Gopee".

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair

Secondary Individu

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- 3) The failure of the research associate to follow published IACUC policies regarding euthanasia methodology require that the PI amend all animal use protocols, as necessary, to specifically and succinctly describe the methods of primary and secondary euthanasia method for all age groups of mice and to submit the amendments to the IACUC for review and approval.
- 4) Report the incident to OLAW.

On October 11, 2017, the IACUC reviewed a summary of the incident and the recommendations of the Subcommittee. The PI attended the IACUC meeting to discuss the incident and to answer questions of the Committee. At the conclusion of the discussion, the IACUC determined that: 1) the research associate held full responsibility for the continuing non-compliant behavior; and 2) this incident was not indicative of an OUHSC Animal Care and Use Program programmatic deficiency. The IACUC voted unanimously to approve the Subcommittee's recommendations.

While the University considers this matter closed and believes that the PI has clearly recognized the gravity of the circumstances relative to continued privileges of animal care and use; the University has engaged the following long-term actions to oversee the PI's activities to ensure adherence to IACUC-approved protocols:

- The PI's research laboratory can no longer be used as an approved animal procedure location, all future animal work must occur in procedure rooms located within the institution's animal care facilities.
- Any new individual employed by the PI and on an IACUC-approved protocol to handle mice must complete a hands-on mouse techniques workshop offered by the University's Office of Animal Welfare Assurance.

If you have any questions regarding this report, please contact me or Eric Howard, PhD, IACUC Chair, at Eric-Howard@ouhsc.edu.

Thank you for your consideration of this matter.

Sincerely,



James Tomasek, PhD
Vice President for Research
Institutional Official
The University of Oklahoma Health Sciences Center

CC: Eric Howard, PhD, IACUC Chair
Ron Banks, DVM, Director of the Division of Comparative Medicine
Secondary Individual Director of Compliance
Secondary Individual Assistant General Counsel and University Privacy Official

Gopee, Neera (NIH/OD) [E]

A3165-Y

From: Gopee, Neera (NIH/OD) [E]
Sent: Tuesday, November 07, 2017 1:11 PM
To: Tomasek, James J. (HSC); OLAW Division of Compliance Oversight (NIH/OD)
Cc: Howard, Eric W. (HSC); Banks, Ron E (HSC); Secondary Individual Secondary Individual
Subject: Secondary Individual
RE: Final Report

Thank you for this final report Dr. Tomasek. We will send an official response soon.

Best Regards,
Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Tomasek, James J. (HSC) [mailto:James-Tomasek@ouhsc.edu]
Sent: Tuesday, November 07, 2017 12:03 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>; Howard, Eric W. (HSC) <Eric-Howard@ouhsc.edu>; Banks, Ron E (HSC) <Ron-Banks@ouhsc.edu>; Secondary Individual @ouhsc.edu; Secondary Individual dary Inc@ouhsc.edu; Secondary Individual @ouhsc.edu
Subject: Final Report

Dear Dr. Gopee,

Please find attached the final report to the preliminary report provided to you October 30, 2017.

Sincerely,

Jim Tomasek

James J. Tomasek, Ph.D.
Vice President for Research
David Ross Boyd Professor of Cell Biology

University of Oklahoma Health Sciences Center
Office of the Vice President for Research
865 Research Parkway, Room #
Oklahoma City, OK 73104

Phone: Phone Number
Fax: Phone Number

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A3165-Y



Initial Report of Noncompliance

By: Neera Gope

Date: 10-30-17

Time: 1:52 PM

Name of Person reporting:

Secondary Individual

Telephone #:

Phone Number

Fax #:

Email:

Name of Institution:

University of Oklahoma Health Science

Assurance number:

A3165-01

Did incident involve PHS funded activity? No

Funding component: 11

Was funding component contacted (if necessary): _____

What happened?

Failed CO₂ euthanasia of 3 neonatal mouse pups and failure to assume death by a 20% method. per IACUC policy and AVMA Guideline 9/28 adult mice

Species involved: mice

Personnel involved: Research staff

Dates and times:

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 # _____