



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) 480-3387

February 4, 2020

Re: Animal Welfare Assurance
#A3165-01 [OLAW Case 1E]

Dr. James J. Tomasek
Vice President for Research and
Dean of Graduate College
University of Oklahoma Health Sciences Center
1000 Stranton L. Young Blvd., (b) (4)
Oklahoma City, OK 73111

Dear Dr. Tomasek,

Thank you for your response to my letter from January 24, 2020. Your self-report letter from February 3, 2020 details the corrective actions for the incident involving administration of a substance to mice that was not protocol approved and the mortality that occurred. A summary of the corrective actions is provided below.

- The PI submitted an amendment which describes changes that will alleviate the risk of death and significantly minimize discomfort in mice.
- The amendment clarifies that mice will receive appropriate analgesics throughout the experiments.

The IACUC reviewed the amendment and approved it on January 31, 2020. Based on the information provided in your letter of response, the Office of Laboratory Animal Welfare (OLAW) is satisfied that the IACUC has provided a corrective action plan to prevent recurrence of this incident. We appreciate having been 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



The University of Oklahoma

Health Sciences Center

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

February 3, 2020

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892
jacquelyn.tubbs@nih.gov
olawdco@mail.nih.gov

Dear Dr. Tubbs:

The University of Oklahoma Health Sciences Center (OUHSC) appreciates your request for additional information in response to the final report of an incident that was provided to OLAW on January 14, 2020, involving a non-PHS funded project.

During its general Committee meeting on January 08, 2020, the IACUC reviewed a summary of the events and decided to report the incident to OLAW. In order to correct or prevent the recurrence of this incident, the Director of the Office of Animal Welfare Assurance (OAWA) met with the Principal Investigator (PI) on December 5 to review the instance of noncompliance. In response, the PI agreed to discontinue the activity until it could be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC).

The IACUC subsequently reviewed an amendment to the animal protocol, which described changes that will alleviate the risk of death and significantly minimize discomfort in mice. To further ensure mice will not experience any pain or distress, the amendment clarifies that mice will receive appropriate analgesics throughout these experiments. The IACUC approved the amendment on January 31, 2020. The IACUC considers this matter completely resolved with the approval of this amendment.

The University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. If you have any questions regarding this report or the IACUC's actions, please contact me at the number below or Eric Howard, PhD, IACUC Chair, at Eric-Howard@ouhsc.edu.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

James J. Tomasek, Ph.D.
Vice President for Research
Institutional Official



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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

January 24, 2020

Re: Animal Welfare Assurance
#A3165-01 [OLAW Case 1E]

Dr. James J. Tomasek
Vice President for Research and
Dean of Graduate College
University of Oklahoma Health Sciences Center
1000 Stranton L. Young Blvd., (b) (4)
Oklahoma City, OK 73111

Dear Dr. Tomasek,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 14, 2020 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 following up on an initial January 9, 2020 notification by telephone.

According to the information provided, this Office understands that the OUHSC Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: administration of a substance intended to induce systemic inflammation that was not approved in the animal protocol. This substance was administered to 35 mice on December 3, 2019, and the next day, animal care staff found most of these mice dead. The deaths were reported to the attending veterinarian, which lead to the Director of the Office of Animal Welfare Assurance (OAWA) being notified. The OAWA Director met with the PI and research associate on December 5th. The PI agreed to discontinue the administration of the substance until the activity could be reviewed and approved by the IACUC. The PI submitted an amendment for IACUC review of these experiments on December 10th. The final report states that on January 8, 2020 the IACUC reviewed a summary of the events and decided to report the incident to OLAW. It is noted the letter indicates these activities are not PHS funded.

Based on its assessment of this explanation, OLAW understands that the OUHSC has reviewed the summary of events but it is not clear what measures have been taken to correct or prevent recurrence of this incident. Please describe what corrective and preventative actions have been taken and approved by the committee. We appreciate being informed of these matters and look forward to receiving the requested information by **February 21, 2020**.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



A3165-1E
No open cases

The University of Oklahoma

Health Sciences Center

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

January 14, 2020

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892
morseb@mail.nih.gov
olawdco@mail.nih.gov

Dear Dr. Morse:

The University of Oklahoma Health Sciences Center (OUHSC), in accordance with Assurance D16-00104 and PHS Policy IV.F.3., provides this final report of an incident that my designee reported to you on January 09, 2020, involving a non-PHS funded project. The University's final report is as follows:

On December 3, 2019, a research associate administered a substance intended to induce systemic inflammation to approximately 35 mice. The administration of this substance was performed in a manner not described in the animal protocol. On December 4, animal care staff found the majority of these mice dead in their cages. The animal care staff promptly reported the deaths to the attending veterinarian, who then informed the Director of the Office of Animal Welfare Assurance (OAWA). The OAWA Director met with the Principal Investigator (PI) and the research associate on December 5, and the PI agreed to discontinue the administration of this substance to animals until the activity could be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC). The PI submitted an amendment to the animal protocol for IACUC review of these experiments on December 10. The OAWA Director advised the IACUC of this issue shortly thereafter.

During its general Committee meeting on January 08, 2020, the IACUC reviewed a summary of the events and decided to report the incident to OLAW.

The University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. If you have any questions regarding this report or the IACUC's actions, please contact me at the number below or Eric Howard, PhD, IACUC Chair, at Eric-Howard@ouhsc.edu.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

James J. Tomasek, Ph.D.
Vice President for Research
Institutional Official

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Tuesday, January 14, 2020 11:34 AM
To: Budda, Madeline L (HSC); OLAW Division of Compliance Oversight (NIH/OD)
Cc: Tomasek, James J. (HSC); Howard, Eric W. (HSC); (b) (6)
Subject: RE: Final Report

Thank you for submitting this report Dr. Budda. We will send an official response 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: Budda, Madeline L (HSC) [mailto:Madeline-Budda@ouhsc.edu]
Sent: Tuesday, January 14, 2020 11:31 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Tomasek, James J. (HSC) <James-Tomasek@ouhsc.edu>; Howard, Eric W. (HSC) <Eric-Howard@ouhsc.edu>; (b) (6)
Subject: Final Report

Dear Dr. Morse,

Please see the attached report to follow up on our phone conversation last week.

Regards,

Madeline

Madeline L Budda, DVM, MS, DACLAM
Director, Office of Animal Welfare Assurance
University of Oklahoma Health Sciences Center
Madeline-Budda@ouhsc.edu
(b) (6)

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