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The University of Oklahoma

Health Sciences Center

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

June 11, 2018

Brent Morse, DVM
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892
brent.morse@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 report of an environmental chamber HVAC failure that resulted in the death of all mice in the environmental chamber. These mice were assigned to one of two animal use protocols entitled, "Coupling Factor 6 in Cold-induced Kidney Dysfunction and Hypertension" and "Anti-Aging Gene Klotho: A Novel Therapeutic Target for Calcific Aortic Valve Disease." This incident was telephonically reported to OLAW on February 22, 2018, by Ron Banks, DVM, Director of the Division of Comparative Medicine. Mice impacted by this incident were directly supported by the following NIH grants: R01 HL118558, R01 DK093403, and R01 HL122166. The NIH funding components have been notified that there were no charges to NIH grants for animal activities associated with this incident.

The mice affected by this HVAC failure were housed within an IACUC-approved environmental chamber in accordance with the investigator's research activities. Animal care staff and research staff on these protocols monitored animal health daily (minimum) and recorded the environmental conditions daily (minimum). On Sunday, February 18, 2018, 11:11 am, animal care staff recorded environmental chamber conditions within the approved range. On Monday morning, February 19, 2018, at 8:10 am, animal care staff found the temperature to be 109°F and observed all mice in the chamber dead.

The Principal Investigator, the IACUC Chair, the Director of the Office of Animal Welfare Assurance, the Director of the Division of Comparative Medicine, and I were promptly notified. It was determined that the air conditioning system for the environmental chamber had failed, resulting in the rise in temperature. The chamber's local audible alarm system was reporting, but there was no automated alarm call-out for this chamber.

Following this incident, the environmental chamber was disengaged and subsequently disassembled. Under my direction, the Division of Comparative Medicine performed a campus-wide review for any other animal housing facilities that were without automated call-out. We have determined this was the only such facility that did not have automated call-out option.

Brent Morse, DVM
June 11, 2018
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In its general meeting held on March 14, 2018, the HSC's IACUC reviewed the event and determined this was an isolated mechanical incident. Should you have any questions regarding this report, please contact Eric Howard, PhD, IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

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

CC: Eric Howard, PhD, IACUC Chair
Ron Banks, DVM, Director, Division of Comparative Medicine
Sandra Nettleton, Director of Compliance

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 11, 2018 10:24 AM
To: Tomasek, James J. (HSC)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report

Thank you for this report, Dr. Tomasek. We will send a reply soon.

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

From: Tomasek, James J. (HSC) [mailto:James-Tomasek@ouhsc.edu]
Sent: Monday, June 11, 2018 9:56 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Howard, Eric W. (HSC) <Eric-Howard@ouhsc.edu>; Banks, Ron E (HSC) <Ron-Banks@ouhsc.edu>; Nettleton, Sandra L (HSC) <Sandra-Nettleton@ouhsc.edu>; (b) (6)
Subject: Final Report

Dear Dr. Morse,

Please find attached the final report to the preliminary report provided to you February 22, 2018.

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
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The University of Oklahoma

Health Sciences Center

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

March 29, 2018

Norma G. DeGuzman
Senior Grants Management Specialist
GMB, NIDDK, NIH
6707 Democracy Blvd. Rm 7004
Bethesda, MD 20817
email: norma.deguzman@nih.gov

Dear Ms. DeGuzman,

As the Institutional Official for the University of Oklahoma Health Sciences Center's (OUHSC) Animal Care and Use Program I am notifying you officially, through Ms. Valorie Owens, the OUHSC Organizational Official, of the death of 138 mice that were part of Dr. Zhongjie Sun's grant R01 DK093403 "Molecular mechanisms of kidney aging." These deaths occurred the evening of February 18, 2018, due to the failure of the cooling system of the environment chamber in which these mice were housed resulting in overheating of the chamber.

A preliminary report of this incident has been provided to the Office of Laboratory Animal Welfare. For information on this preliminary report please contact Brent Morse, DVM; Director, Division of Compliance Oversight, OLAW. As part of our reporting to OLAW we must notify the NIH funding agency "in cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges. NIH requires that reports contain a certification that no unallowable costs were charged to NIH grant funds during a period of noncompliance" (Section 4.1.1.5.1 Reporting to OLAW).

In this incident, the period of noncompliance was February 18 and 19 when the environment chamber overheated. I have confirmed that the per diem charges that accrued on February 18 and 19 were not charged to Dr. Zhongjie Sun's grant. Therefore, no charges for unauthorized animal activities have been charged to Dr. Sun's grant R01 DK093403.

I do need to correct an error in our preliminary reporting to you on this incident. The number of mice deaths originally associated with this grant was reported preliminarily to you to be 41; however, further review of per diem costs revealed the number of deaths to be 138 mice.

Please respond to Ms. Valorie Owens, OUHSC Organizational Official, that you have received this correspondence and are in agreement that there were no charges for unauthorized animal activities charged to Dr. Sun's grant R01 DK093403.

Sincerely,

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

cc: Valorie Owens, Director of Sponsored Programs, OUHSC
Zhongjie Sun, MD, PhD, Professor, Department of Physiology, OUHSC
Krystyna E. Rys-Sikora, PhD, NIDDK

865 Research Parkway, Suite 450
Oklahoma City, Oklahoma 73104 • (405) 271-1083 • FAX (405) 271-8655

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Friday, March 30, 2018 8:37 AM
To: Rys-Sikora, Krystyna (NIH/NIDDK) [E]
Subject: RE: Official Notification: R01 DK093403, Dr. Sun - Molecular mechanisms of kidney aging *RSRCH019017*

Good morning Krystyna,

Thank you for contacting OLAW and for providing the information. By law we are required to allow institutions "reasonable time" to report incidents and corrective measures to our office. We expect to have a final report from OUHSC within about 60 days. When we receive their report we will copy you on our final letter to them or any other correspondence. Thank you again.

Regards, Brent

Brent C. Morse, DVM, DACLAM
 Acting Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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From: Rys-Sikora, Krystyna (NIH/NIDDK) [E]
Sent: Thursday, March 29, 2018 4:00 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: Deguzman, Norma (NIH/NIDDK) [E] <norma.deguzman@nih.gov>; Deguzman, Norma (NIH/NIDDK) [E] <norma.deguzman@nih.gov>; Rys-Sikora, Krystyna (NIH/NIDDK) [E] <ryssikok@niddk.nih.gov>; Tomasek, James J. (HSC) <James-Tomasek@ouhsc.edu>; Sun, Zhongjie (HSC) <Zhongjie-Sun@ouhsc.edu>
Subject: FW: Official Notification: R01 DK093403, Dr. Sun - Molecular mechanisms of kidney aging *RSRCH019017*

Dear Dr. Morse,

~ Brent,

This is an acknowledgement that NIDDK has been made aware of the OLAW noncompliance incident has occur at the University of Oklahoma Health Sciences Center's (OUHSC) and the initial and final report have been forwarded to the NIDDK Grants management specialist, Norma Deguzman, and the Program Officer oversee grant R01 DK093403 (PI Sun). The Program officer has also spoken to the institution official on the phone about the incident and reporting to OLAW. It is our understanding that official procedures have been followed in the reporting.

Please let me know the results of your investigation and if there is any way that we can assist.

Thank you,

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Valorie Owens
Director of Sponsored Programs
Office of Research Administration | The University of Oklahoma Health Sciences Center
865 Research Parkway, UH 865450 | Oklahoma City, OK 7310435699
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Initial Report of Noncompliance

By: *aw*Date: *2/23/18*Time: *10:00*Name of Person reporting: *Ron Barnes*Telephone #: [REDACTED]

Fax #:

Email:

Name of Institution: *U of Oklahoma H.S.C.*Assurance number: *A3165*Did incident involve PHS funded activity? *?*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

*Environmental chamber A.C. failed + 138 mice died,
Not alarmed initially*

Species involved: *Mice*

Personnel involved:

Dates and times:

Animal deaths:

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

Repair equipment

Obtained by Rise

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____