

## DEPARTMENT OF HEALTH & HUMAN SERVICES

## PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL:

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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

July 23, 2020

Re: Animal Welfare Assurance A3169-01 [OLAW Case G]

Dr. James Grover
Interim Vice President for Research
University of Texas at Arlington
701 S. Nedderman Street,

(b) (4)
Box 19162
Arlington, TX 76013

Dear Dr. Grover,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 16, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Texas at Arlington (UT Arlington). This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the UT Arlington Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol. The final report states a Research Assistant failed to follow procedures for monitoring the health status of three end-stage ALS mice. Monitoring of these animals included health checks twice a day in addition to providing supportive care. The ACF Manager reported the mice were checked only once on June 13, 2020 and this was verified by the IACUC via cage card documentation and facility access reports. At a regular meeting of the IACUC on July 8, 2020 the committee determined this incident was a serious deviation from the *Guide*. The IACUC accepted and approved the following corrective actions to prevent recurrence:

- The principal investigator (PI) will retrain lab personnel on the correct protocol procedures and animal monitoring.
- The PI will institute an online sign-off sheet for heath checks and ensure it is completed twice daily.
- The sign-off sheet will be checked daily by a second lab member to ensure health checks have been completed.
- The PI will conduct and maintain documentation of monthly lab meetings dedicated to animal care and protocol procedures. The record must be available to the IACUC upon request.

It is noted that this research is supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the University of Texas at Arlington 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.

Page 2 – Dr. Grover July 23, 2020 OLAW Case A3169-G

Sincerely,

Jacquelyn T. Digitally signed by Jacquelyn T. Tubbs -S

Date: 2020.07.24 08:40:36
-04'00'

Jacquelyn T. Tubbs, DVM Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact

July 16, 2020

Axel Wolff, DVM Director, Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health Rockledge 1, Suite 360 6705 Rockledge Drive Bethesda, MD 20892

Dear Dr. Wolff:

The University of Texas at Arlington, in accordance with assurance A3169-01 and PHS Policy IV.F.3., provides this report of non-compliance.

This report of non-compliance arose from the failure of a Research Assistant to follow protocol procedures to appropriately monitor the health status of three end-stage ALS mice. This project conducted under the IACUC-approved protocol, "Dysregulation of mitochondrial function and Ca signaling in ALS and other disease conditions" is funded by an NIH grant: 1R01NS105621-01A1. The Principal Investigator (PI) on the protocol is Dr. Jingsong Zhou.

The mice were end-stage and required supportive care and health check twice a day. The ACF Manager reported that the mice had only been checked once on June 13, 2020, which was confirmed by the IACUC via cage card documentation and facility access reports.

At a regular meeting of the IACUC on July 8, 2020, the IACUC concluded that the failure to monitor the three mice according to protocol is a serious deviation from the provisions of The Guide for the Care and Use of Laboratory Animals, Eighth Edition (2011) requiring the use of humane endpoints and the U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training regarding avoidance or minimization of discomfort, distress, and pain.

The IACUC accepted and approved the following corrective and preventive actions submitted by the PI for review at the July 8th meeting:

- The PI will retrain lab personnel on correct protocol procedures and animal monitoring;
- The PI instituted an online sign-off sheet for health checks that is kept in a shared drive where all lab members can access it and ensure it is completed twice daily;
- The sign-off sheet will be checked daily by a second lab member to ensure health checks have been performed;

 The PI will conduct and maintain documentation of monthly lab meetings dedicated to animal care and protocol procedures. Documentation will include dates and subjects of meetings as well as a list of those who attended. The record must be available to the IACUC upon request.

The IACUC determined that the above actions are necessary to ensure the welfare of research animals and are appropriate for the particular infraction and the PI's understanding of animal research regulations and policies.

This project is also funded by the Department of Army. Therefore, a report has also been made to the Animal Care and Use Review Office (ACURO) as required.

UT Arlington and the IACUC are committed to animal research that is conducted under the highest scientific, humane, and ethical principles, and the corrective actions described above are designed to meet the University's high standard of research integrity. Should you have any questions regarding this report, or if further information is required, please contact Michael Roner, PhD, IACUC Chair, at (b) (6) or roner@uta.edu.

Thank you for your consideration of this matter,

Sincerely,



James P. Grover
Interim Vice President for Research
Institutional Official for Animal Care & Use Program
The University of Texas at Arlington

## Wolff, Axel (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Friday, July 17, 2020 7:19 AM

To:

Cc:

OLAW Division of Compliance Oversight (NIH/OD)

Subject:

RE: Final Report

Thank you for this report,

(b) (6) We will send a response soon.

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

From:

(b) (6)

Sent: Wednesday, July 15, 2020 6:18 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Subject: Final Report

To the Division of Compliance Oversight:

Please see attached final report and let me know if you have any questions.

Thank you,

