



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

September 20, 2017

Re: Animal Welfare Assurance
A3194-01 [OLAW Case 1M]

Emily Holmes, Ph.D.
Vice President, Research Services
Scripps Research Institute
10550 North Torrey Pines Road
Mail TPC 8
La Jolla, CA 92037

Dear Dr. Holmes,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 19, 2017 letter reporting an adverse event involving rats at The Scripps Research Institute, following up on an initial telephone report on June 12, 2017. According to the information provided, OLAW understands that seven rats died in an alcohol vapor chamber due to overexposure. Although the number of animals was within the expected mortality on the approved protocol, it was higher than usual. Contributing factors included a broken airflow gauge, inadequate adjustment of a vapor flow post, and absence of a key laboratory member who managed the chambers.

The corrective actions consisted of revising the chamber standard operating procedure (SOP) to include description of the chambers and possible problems, emergency contacts, and a detailed description of chamber operation and animal care. Chamber information will be collected automatically and staff will be notified if values are outside of expected parameters, new airflow gauges will be installed when studies are completed, door sensors were installed to monitor staff activity, and monthly meetings will be held with vapor chamber and animal resources staff to discuss chamber activity and compliance with the SOP.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



IACUC Office

10550 North Torrey Pines Road
La Jolla, California 92037
Mail Drop: TPC 3
iacuc@scripps.edu

A3194-1M
Obtained by Rise for Animals. Uploaded 08/31/2020
Retrieved from Animal Research Laboratory Overview (ARLO)

CONFIDENTIAL

September 19, 2017

Brent Morse, D.V.M.
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Dr.
Bethesda, MD 20892-7982
olawdco@mail.nih.gov

RE: Animal Welfare Assurance #A3194-01

Dear Dr. Morse:

We are writing to finalize the oral report to OLAW on June 12, 2017, regarding animal deaths within protocol-approved alcohol vapor chambers maintained by the TSRI Alcohol Research Center Animal Models Core (ARC). These chambers are used to model ethanol dependence and withdrawal and have been in use at TRSI for many years. Protocols using this model include justification for an expected attrition rate between 20-25%. During the past year, approximately 400 animals have been placed within these chambers. An overview of the event and the IACUC response is provided below.

- 1) On May 19, 2017, 3 of 6 rats maintained in chamber 1B experienced overexposure to alcohol vapor; the study involved a total of 24 animals maintained within chambers 1A, 1B, 3A, and 3B. The overexposed animals were removed from the chamber and treated for overexposure with one subsequently found dead on May 20, 2017. On June 06, 2017, 6 of 8 rats maintained within chambers 4A and 4B were overexposed and were found dead within the chambers. These incidents involved a total of 32 rats, with a loss of 7 (22%), which is higher than the norm, but still within justified attrition rates.
- 2) A review of these incidents by the IACUC could not identify a single contributing factor, but rather a combination of issues contributed to the overexposures. These were:
 - a defective airflow gauge
 - replacement of clogged chamber tubing followed by inadequate adjustment of vapor flow post replacement
 - an unplanned leave of absence by the primary individual responsible for oversight of chambers.


3) As a result of these findings the ARC made the following changes:

- revised the chamber SOP to provide:
 - an introduction to the experimental applicability of the vapor chamber model and a description of errors that have been observed with their usage over the years
 - a comprehensive listing of emergency contacts
 - a detailed step-by-step protocol for chamber operation including adjustment of vapor levels, monitoring of experimental animals within the chambers, and treatment of animals recognized as overexposed
- automated collection of chamber information (including airflow and alcohol drip rate, chamber alcohol levels, chamber humidity and temperature) so that responsible staff is notified when parameters are outside the expected and documented ranges
- initiated a program to install new airflow gauges as studies are completed
- added chamber door sensors to accurately monitor personnel activity specific for maintenance of these chambers when animals are present
- initiated monthly meetings of vapor chamber staff and Department of Animal Resources personnel involved in chamber health monitoring in order to review chamber activity, ensure that the SOP is being followed, and to implement further training or chamber workflow improvements discussed at these meetings as a means of continually optimizing the SOP and its execution.

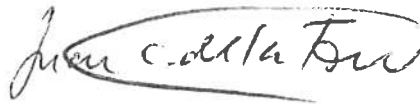
4) These studies were supported in part by NIH grants P60AA006420 and R01AA022977 with no unallowable costs charged to this award.

The Scripps Research Institute remains committed to ensuring the proper care and treatment of animals used in research and teaching at the institution. If you require any further information, please contact us at iacuc@scripps.edu.

Sincerely,



Emily Holmés, Ph.D.
Vice President, Research Services
Institutional Official



Juan Carlos de la Torre, Ph.D.
Chair, Institutional Animal Care and Use
Committee
Professor, Dept. of Immunology and
Microbial Science

Thank you for this report. We will send a response soon.

From: Secondary Individual [mailto:Secondary Individual@scripps.edu]
Sent: Tuesday, September 19, 2017 4:22 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Juan Carlos de la Torre <juanct@scripps.edu>; Secondary Individual @scripps.edu; Emily Holmes <eholmes@scripps.edu>
Subject: Animal Welfare Assurance #A3194-01

Dear Dr. Morse,

Attached please find correspondence from Drs. Emily Holmes and Juan Carlos de la Torre regarding the above referenced matter. Please let me know if you have any questions or difficulty with the file.

Best,
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Secondary Individual:
Admin. Specialist to Emily Holmes, Ph.D.
Office of Research Services | The Scripps Research Institute
Phone Number: [redacted] | Email: [redacted]@scripps.edu

A3194-1M



Initial Report of Noncompliance

By: aw

Date: 6/12/17

Time: 12:00

Name of Person reporting: Secondary Individual

Telephone #: Phone Number

Fax #:

Email:

Name of Institution: scripps Research Institute

Assurance number: A3194

Did incident involve PHS funded activity? ?

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

4 rats dead in vapor chamber. May have failure in pump.

Species involved: Rat

Personnel involved:

Dates and times:

Animal deaths: 4

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____