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
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Bethesda, Maryland 20892-6910
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

December 26, 2018

Re: Animal Welfare Assurance
A3350-01 [OLAW Case U]

Dr. Richard S. Larson
Executive Vice Chancellor
University of New Mexico Health Sciences Center
MSC 4640 1 University of New Mexico
Albuquerque, NM 87131-5126

Dear Dr. Larson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 13, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of New Mexico Health Sciences Center, following up on an initial telephone report on December 4, 2018. According to the information provided, OLAW understands that 13 mice died of asphyxiation in an experimental smoke exposure chamber due to a technician choosing the wrong smoke exposure regimen. The mice had not received adequate air flow which led to their deaths.

The corrective actions consisted of modifying the chamber's software menu to ensure that the correct airflow mode is selected, modifying the standard operating procedures (SOP) to ensure that the pumps and air flow are correct, having staff monitor the mice, and retraining the laboratory staff on the revised SOP. A post-approval monitoring visit to the laboratory confirmed that procedures were being conducted in accordance with the protocol.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair

HEALTH SCIENCES
OFFICE OF RESEARCH

**Office of Animal Care Compliance**

December 13, 2018

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH)
Rockledge 1, Suite 360, MSC 7982, 6705 Rockledge Drive
Bethesda, MD 20892-7982
Phone: 301-594-2061
FAX: 301-402-2803
E-mail: olawdco@mail.nih.gov

Attn: Axel Wolff, DVM, Director

**RE: Assurance # D16-00228 (A3350-01) – Failure to ensure air flow in a mouse smoke exposure chamber resulting in death (e.g., unexpected animal deaths due to human error)**

As per our telephonic report to Dr. Axel Wolff on December 4, 2018, a Research Technician in a Principle Investigator's (PI's) lab failed to ensure adequate air flow to mice in a smoke exposure chamber resulting in death by asphyxiation of 13 out of 16 mice in the chamber.

This incident was discussed in the December 6th, 2018 convened Health Sciences Center (HSC) Institutional Animal Care and Use Committee (IACUC) meeting and Post-Approval Monitoring (PAM) was performed on December 12th in order to observe the new exposure procedures and to review changes to the existing Standard Operating Procedures (SOPs). The following is a description of the incident and changes to be implemented to ensure this does not happen again as submitted in a report by the PI:

**Description of incident**

Depending on the assigned aim under this approved research protocol, mice are exposed to either mainstream or secondhand cigarette smoke, using a SciReq InExpose system. The air pumps of the exposure system are controlled by computer software. Pump #1 draws air through the filter of a lit cigarette (mainstream smoke), while pump #2 draws air from the chamber containing the lit cigarette (secondhand smoke). We have two software protocols, one protocol for mainstream smoke exposure (pump #1 only) inherently draws mainstream smoke through the exposure chamber and then exhausts in the hood, and the protocol for secondhand smoke exposure activates (pump #1 puffing the cigarette and exhausting to the fume hood and pump #2 continually drawing from the second hand smoke chamber into the exposure chamber and exhausting into the hood).

When preparing for a second hand smoke exposure study, the tubing connections were formatted correctly but the technician inadvertently selected the mainstream smoke exposure protocol from the program menu rather than the secondhand smoke exposure protocol. By selecting the mainstream smoke exposure protocol and with the instrument connections formatted for second hand smoke exposure, pump # 1 was exhausting mainstream smoke directly into the hood, and since pump #2 was not activated, no air or second hand smoke was being drawn into the exposure chamber. Thus, the sixteen mice in the exposure chamber failed to receive any airflow until the technician noticed they were not moving after ~30 min in the chamber. This resulted in 13 of the 16 mice dying.
The laboratory had a detailed written SOP for conducting secondhand smoke exposure and the technician had conducted this exposure protocol successfully two weeks prior and one day prior to the exposure day of the accident. Thus, we I do not believe that lack of training contributed to the accident; however, we believe that the improvements in the smoke exposure process are required to avoid future failures of this nature.

**Changes to be implemented to ensure this does not happen again**

1. The mainstream cigarette smoke exposure protocol was deleted from the software menu, so that it cannot be inadvertently selected when conducting secondhand smoke exposure.

2. Procedures describing additional safeguards were added to both of the mainstream and secondhand smoke written SOPs that require confirming the function of the pumps and air/smoke supply to the exposure chamber before placing the mice and initiating the exposure. This process, as changed, will assure that the instrument is formatted to match the exposure protocol. The new procedures will necessitate:
    a. lighting and partially burning one cigarette prior to placing mice in the chamber, and confirming that air is being pulled from the correct origin (mainstream connection or second hand smoke chamber) and drawn into the exposure chamber and exhausted into the hood.
    b. Once the format is confirm, mice are placed in the exposure chamber, the research personnel are required to monitor the mice between cigarettes or approximately every 10 minutes to confirm viability based upon their behavior and movement within the chamber. Since it takes approximately 10 min for each cigarette to be burned, the protocol states to check the viability of the mice after each cigarette is burned.

3. All individuals conducting these exposures of mice underwent hand's-on training on Dec 12, 2018 to assure competency under the newly amended SOPs before any further exposures were conducted.

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**Post-Approval Monitoring**

The Attending Veterinarian (AV) and the Office of Animal Care Compliance (OACC) staff conducted a PAM on December 12, 2018 to observe and verify the new animal smoke exposure procedures and to review changes to the existing SOPs for those procedures. All changes are being carried out as described by the PI and were found to be acceptable.

Sincerely,

DocuSigned by:
(b) (6)
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Richard S. Larson, M.D., Ph.D., Executive Vice Chancellor, Vice Chancellor for Research

Cc:
Kevin O'Hair, D.V.M., DACLAM, Attending Veterinarian
Laura Gonzalez Bosc, Ph.D., IACUC Chair
(b) (6)

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

**From:** OLAW Division of Compliance Oversight (NIH/OD)
**Sent:** Thursday, December 20, 2018 6:53 AM
**To:** (b) (6)
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)
**Subject:** RE: Assurance # D16-00228 (A3350-01) – Failure to ensure air flow in a mouse smoke exposure chamber resulting in death (e.g., unexpected animal deaths due to human error)

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

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**From:** (b) (6)
**Sent:** Wednesday, December 19, 2018 5:41 PM
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
**Cc:** Laura Gonzalez Bosc <LGonzalezBosc@salud.unm.edu>; Kevin C O'Hair <KOHair@salud.unm.edu>; (b) (6)
(b) (6)
**Subject:** Assurance # D16-00228 (A3350-01) – Failure to ensure air flow in a mouse smoke exposure chamber resulting in death (e.g., unexpected animal deaths due to human error)

Dr. Wolf,

As previously discussed, please see the attached, signed letter about this reportable incident.

Thank you and Happy Holidays!

(b) (6)

A3350 - U

# Initial Report of Noncompliance

By: aw

Date: 12/4/18 Time: 1:30

Name of Person reporting: (b) (6) + Dr O'Hara
Telephone #: (b) (6)
Fax #:
Email:

Name of Institution: U of New Mexico
Assurance number: A3350

Did incident involve PHS funded activity? yes
Funding component: _____
Was funding component contacted (if necessary): _____

What happened? Smoke study. used aurora program + 13/18 mice died from exposure + asphyxiation

Species involved: Mouse
Personnel involved:
Dates and times:
Animal deaths: yes, 13

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

Adjust SOP, Keep only 1 program on computer, check flow retain

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #_____