



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 13, 2020

Re: Animal Welfare Assurance
#A3012-01 (OLAW Case 1H)

William Wasilenko, Ph.D.
Associate Dean for Research
Eastern Virginia Medical School
721 Fairfax Avenue, (b) (4)
Norfolk, VA 23507

Dear Dr. Wasilenko,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 10, 2020 letter reporting a serious deviation from the provisions of the Guide for the Care and Use of Laboratory Animals at Eastern Virginia Medical School. According to the information provided, OLAW understands that eight weanling mice had died and others were moribund due to not having food or not being able to reach the food. A graduate student had weaned the mice and failed to either provide any food or failing to put diet gel/wet food on the floor of the cage. The student had been involved with prior mouse colony management noncompliance and had been directed to undertake retraining.

The immediate action taken upon discovery consisted of giving the surviving mice subcutaneous fluids and diet gel. The Institutional Animal Care and Use Committee (IACUC) determined that the student had a history of incompetence in mouse breeding and colony management and revoked access to the animal facility and colony management responsibilities. The student may work on other animal activities only under direct supervision by the Principal Investigator (PI). The laboratory's colony management standard operating procedure was revised, the PI and staff will be retrained on mouse colony management, and new laboratory staff must take training in colony management before working with the mice. If future problems occur with the laboratory's colony management, there may be negative impacts on continuation of the research.

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 IACUC to comply with the PHS Policy on Humane Care and Use of Laboratory Animals and commends the institution for taking the appropriate stringent actions commensurate with 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

February 10, 2020

Brent C. Morse, D.V.M., DACLAM
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, Maryland 20892-7982

Dear Dr. Morse:

RE: Reportable Incident
Eastern Virginia Medical School (EVMS), Norfolk, Virginia
Animal Welfare Assurance Number D16-00007 (formerly A3012-01)

I am writing to inform OLAW of an incident reported to the EVMS Institutional Animal Care and Use Committee (IACUC) Office on January 21, 2020. This report is submitted in accordance with document NOT-OD-05-034, *Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals*, which states that reportable situations include "conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals." The investigator's research is supported by institutional funds and grants funded by NIH and the American Heart Association (AHA).

The evening of January 17, 2020, a graduate student weaned mice assigned to this research project. As per the IACUC-approved protocol, the mice were weaned at 21 days of age. The morning of January 18, 2020, the Division of Comparative Medicine (CompMed) staff found that 8 of the weaned pups had died. One cage was found with no food, resulting in 2 deaths. The mice in 3 additional cages were too small to feed from the food hopper and no diet gel/wet chow was added to the cages as an alternate feeding source, resulting in 6 deaths. Additionally, all living mice were moribund. The CompMed staff administered subcutaneous fluids to the surviving animals and supplied their cages with diet gel. The Principal Investigator (PI) confirmed the reported deaths and stated that the graduate student has been retrained on the IACUC mouse breeding policy, along with the lab-specific mouse breeding colony management standard operating procedure (SOP) approved by the IACUC on January 16, 2020. The student signed the SOP on December 10, 2019 to attest to the training.

The incident was discussed in detail during the February 6, 2020 IACUC meeting. The Committee further substantiated that the graduate student had been directly involved with several previously reported colony management concerns, although no animal deaths resulted from those incidents. The IACUC unanimously agreed that the recent report confirms a chronic pattern of breeding and colony management deficiency with the laboratory in particular and a concerning pattern of ineptitude and lack of focus on the part of the student. **Consequently, the following sanctions/mandates were approved by the IACUC and are effective immediately.**

Research

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1. The graduate student's access to the CompMed animal facility has been revoked indefinitely.
 - a. He is restricted indefinitely from all colony management activities (i.e., breeding and weaning).
 - b. He is only allowed in the CompMed animal facility to perform other unrelated animal activities under the direct supervision of the PI only. If the PI is not able to supervise the student, he is not to be in the facility.
2. The lab-specific colony management SOP approved by the IACUC on January 16, 2020 must be revised to state that all weaning will occur in the morning (i.e., before 12 noon) and wet chow will be placed in each cage of weaned pups until the next scheduled cage change.
3. Prior to the March 5, 2020 IACUC meeting, the PI and all members of the laboratory must be retrained by the CompMed staff on the proper tenets and techniques of mouse colony management.
4. Going forward, all new members of the laboratory (i.e., students, staff, and volunteers) must be trained on colony management by the CompMed staff before the individual is authorized to breed or wean animals in the mouse colony.
5. If additional colony management concerns are reported to and confirmed by the IACUC, more global restrictions will be imposed, which may negatively affect and ultimately jeopardize the PI's research.

I, along with the IACUC and the CompMed staff, sincerely regret the unexpected deaths; however, we believe that the corrective action plan outlined above is sufficient to prevent a reoccurrence, to the extent possible.

Please do not hesitate to contact me should you have questions and/or concerns regarding this matter.

Sincerely,

(b) (6)

William J. Wasilenko, Ph.D.
Vice Dean for Research and Institutional Official
EVMS Office of Research
855 W. Brambleton Avenue
E. V. Williams Hall, (b) (4)
Norfolk, Virginia 23507
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wasilewj@evms.edu

WJW/cbh

cc: Principal Investigator
Frank A. Lattanzio, Ph.D., IACUC Chair
Mario C. Rodríguez, D.V.M., M.S., CompMed Attending Veterinarian
(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 12, 2020 6:29 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: EVMS #D16-0007 - REPORTABLE INCIDENT

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: Tuesday, February 11, 2020 2:28 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Wasilenko, William J. <WasileWJ@EVMS.EDU>; (b) (6) Rodriguez, Mario C. <RodrigMC@EVMS.EDU>; (b) (6)
Subject: EVMS #D16-0007 - REPORTABLE INCIDENT
Importance: High

Dear Dr. Morse:

RE: Reportable Incident
Eastern Virginia Medical School (EVMS), Norfolk, Virginia
Animal Welfare Assurance Number D16-0007 (formerly A3012-01)

The attached report is sent on behalf of William J. Wasilenko, Ph.D., Vice Dean for Research and Institutional Official. A copy of the report will be sent to the Principal Investigator under separate cover. Please do not hesitate to contact me or Dr. Wasilenko if you have questions about or required additional information regarding this report.

Kindest regards,

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(b) (6)