



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) 402-7065

September 9, 2019

Re: Animal Welfare Assurance
A3307-01 [OLAW Case V]

Dr. Michael P. Diamond
Professor of Obstetrics and Gynecology
Leon Henri Charbonnier Endowed Chair
Associate Dean for Research
Senior Vice President for Research
Georgia Regents University
1120 Fifteen Street
Augusta, GA 30912

Dear Dr. Diamond:

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 30, 2019 letter describing a noncompliance at your institution, which was not preceded by a preliminary report to OLAW. According to the information provided, our office understands that on August 29, 2019 two cages of mice were found with no water. One cage has two dead animals. The investigator had removed the mice from the vivarium for euthanasia but was not able to complete the euthanasia in a timely manner and failed to provide the animals with food and water. It appears the animals were housed in the laboratory overnight, but while the area was approved by the IACUC for surgeries, it was not approved for overnight housing of animals.

Immediate corrective measures included care of the surviving mice until they were able to be humanely euthanized. Vivarium access for the responsible individual was removed until retraining is completed. In addition, a group training session for all laboratory members is planned

OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Please contact our office if the corrective actions are not carried out as described. In addition, please ensure that no charges are made to the PHS grant for any unauthorized activities. We appreciate having been informed of this matter and find no cause for further action by this office at this time.

Sincerely;

(b) (6)

for

Nicolette Petervary, VMD, DACAW
Veterinary Medical Officer
Office of Laboratory Animal Welfare

cc: IACUC Chair



AUGUSTA
UNIVERSITY

Medical College of Georgia
Department of Physiology
1120 15th Street, CA-3124
Augusta, GA 30912

August 30, 2019

Michael P. Diamond, M.D., Institutional Official
Professor of Obstetrics and Gynecology
Leon Henri Charbonnier Endowed Chair
Associate Dean for Research, Medical College of Georgia
Senior Vice President for Research

Dear Dr. Diamond:

This letter is a report of an adverse event reported on Thursday August 29, 2019. The Attending Veterinarian responded to a report from a BioSafety Technician who was inspecting a research laboratory that is approved for mouse surgery. There were two cages of mice (4 mice per cage) with no water in the water bottles; one cage had two dead animals. The research investigator (RI) responsible for the cages was identified by information on the "cage cards" and was contacted by the Attending Veterinarian. An "Incident Report" describing the details of the event was submitted to the IACUC Office by the Post Approval Monitor, who had been called to attend to the welfare of the mice.

- The RI stated to the AV that he had removed the mice from the vivarium to euthanize them to practice a specific "tissue harvest technique". He indicated that he checked the food and water when he first relocated the cages to the research lab but then he was not able to complete the euthanasia procedure as planned. He neglected to ensure that the mice continued to have a supply of food and water.
- Although the Animal Use Protocol included the use of the lab space for surgery, communication between the AV and the IACUC confirmed that the research laboratory where the mice were housed had not been approved for overnight housing of animals.

The corrective actions are as follows:

- The remaining mice were immediately provided with water and relocated until a decision was made on their disposition. Ultimately all mice were euthanized since they could not be re-introduced into the vivarium.
- Vivarium access for the RI responsible for the animals has been removed until the person can be re-trained on animal welfare and proper procedures and responsibilities for removal of animals from the vivarium.
- The PHS funded Principal Investigator (PI) for the protocol was informed of the actions of the RI.
- The AV will inform the IACUC when the RI has completed their re-training.
- Laboratory Animal Services is in the process of identifying all employees authorized to work

with animals who use the laboratory space designated to the PI. A group training session on procedures associated with moving animals from the vivarium and maintaining them in a laboratory will be scheduled.

The incident report and corrective actions taken so far will be included in the agenda for the next meeting of the IACUC, scheduled for September 19th, 2019. The IACUC will determine whether further corrective action is necessary. The incident will remain an agenda item until all corrective actions have been completed. For reporting purposes, our Assurance Number (A3307-01) is provided.

Submitted on behalf of the IACUC,

(b) (6)

A rectangular grey box redacting the signature of Ruth B.S. Harris.

Ruth B.S. Harris, PhD
Regents Professor
IACUC Chair

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, September 03, 2019 7:41 AM
To: SVPRESEARCH; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Diamond, Michael; Harris, Ruth; (b) (6)
Subject: RE: Augusta University unexpected adverse event report - Assurance number: A3307-01/D16-00197

Thank you for providing this final report Dr. Diamond. We will send an official response soon.

Best regards, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: SVPRESEARCH [mailto:SVPRESEARCH@augusta.edu]
Sent: Friday, August 30, 2019 4:21 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Diamond, Michael <michael.diamond@augusta.edu>; Harris, Ruth <RUHARRIS@augusta.edu>; (b) (6)
Subject: Augusta University unexpected adverse event report - Assurance number: A3307-01/D16-00197

Dear Dr. Morse:

I am writing to inform you of an adverse event that occurred at Augusta University yesterday, the acute response, and corrective action plans. Details are provided in the attached letter from our IACUC Chair Ruth Harris, PhD. Please do not hesitate to contact us with any questions.

Sincerely,

Michael P. Diamond, M.D., Institutional Official
Professor and Chair, Department of Obstetrics and Gynecology
William H. Brooks, M.D., Distinguished Chair
Associate Dean for Research, Medical College of Georgia
Senior Vice President for Research