



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

July 27, 2017

Re: Animal Welfare Assurance
A3428-01 [OLAW Case 10]

Lisa K. Saladin, Ph.D.
Interim Provost and Vice President for
Academic Affairs
Medical University of South Carolina
179 Ashley Avenue, Room #
Charleston, SC 29425-0020

Dear Dr. Saladin,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 25, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Medical University of South Carolina, following up on an initial report on June 1, 2017. According to the information provided, OLAW understands that sixty mice were given a drug not described on the approved protocol. The drug posed a potential health risk to staff.

The corrective action consisted of amending the protocol and creating a standard operating procedure addressing the handling of chemicals not covered by a safety profile and staff was retrained on handling hazardous chemicals. The Principal Investigator and laboratory manager were counseled on using only agents approved on 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,

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair



Office of the Provost
179 Ashley Avenue
Colcock Hall
MSC 002
Charleston SC 29425-0020
Tel 843 792 3031
Fax 843 792 5110
www.musc.edu

July 25, 2017

Axel V. Wolff, MS, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Re: Follow-up Status Report for Office of Laboratory Animal Welfare
Species: Mice
Contract: HHSN275201400004C

Dear Dr. Wolff:

We are writing to provide a follow up status report conveying institutional review and resolution by the IACUC at the Medical University of South Carolina (Animal Welfare Assurance #A3428).

A preliminary report was submitted to OLAW by the IACUC Chair, Dr. Rupak Mukherjee, on June 1, 2017.

The IACUC received a report on May 4, 2017, indicating that animals on an active protocol were administered an unapproved drug as a substitute for an approved drug that was unavailable at the time. Upon investigation, it was confirmed that the unapproved drug was administered by a laboratory technician, under authorization by the laboratory manager, to 60 mice with the first dose in February and a second dose in March. While animal welfare was not compromised by this switch in drugs, there was the potential for increased risks to personnel posed by the substituted drug that would have been addressed through the IACUC review process. This incident was reported to the IACUC at a convened meeting on May 25, 2017.

An amendment to the protocol adding the drug was submitted in March (after unapproved use, but prior to notification of the non-compliance to the IACUC) and approved in mid-May. The laboratory has since instituted global Standard Operating Procedures for all chemicals that are not otherwise covered by a specific safety profile, and all lab personnel have undergone additional training in appropriate handling of potentially hazardous chemicals. The PI and laboratory manager also received IACUC communication reiterating that all compounds administered to animals must be approved on the protocol prior to any use in the lab.

The PI and lab manager responded to the IACUC with all steps taken to prevent a recurrence, which was shared with the IACUC at the next convened meeting on June 29, 2017. After discussion of the PI's response, the IACUC determined that appropriate actions had been taken and agreed that the case was resolved.

Axel V. Wolff, MS, DVM
July 25, 2017
Page two

The Medical University of South Carolina works to maintain the highest standards in all aspects of its operations and is concerned about any instances of non-compliance. We are constantly examining our programs for quality improvement opportunities, and believe that the corrective actions taken in this case effectively addressed the noted concerns. We would appreciate further guidance on this subject, should you feel it is appropriate.

Sincerely,



Lisa K. Saladin, PT, Ph.D.
Executive Vice President for Academic Affairs and Provost

cc: Rupak Mukherjee, Ph.D. – Chair, Institutional Animal Care and Use Committee
 Suzanne Craig, DVM – Director, Division of Laboratory Animal Resources
 Secondary Individual – Vice President for Research
 Secondary Individual – Associate Provost for Research Compliance and Regulatory Affairs
 Secondary Individual – Director, Office of Research Integrity
 Secondary Individual Program Manager

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, July 27, 2017 7:19 AM
To: Secondary Individual
Subject: RE: Report of Non-Compliance A3428

Thank you for this report. We will respond soon.
Axel Wolff

From: Secondary Individual [mailto:Secondary Individual@muscul.edu]
Sent: Wednesday, July 26, 2017 6:17 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Report of Non-Compliance A3428

This message was sent securely by MUSC

Dr. Wolff,

Please find attached our report on the outcome of a non-compliant event at the Medical University of South Carolina. We look forward to your input on the handling of the incident by the MUSC IACUC.

Please let me know if you have any difficulty with the attached file.

Secondary Individual

IACUC Program Manager
Office of Research Integrity
Medical University of SC

Secondary Individual@muscul.edu
phone: Phone Number
Harborview Office Tower
19 Hagood Ave., Room #
MSC 857
Charleston ~ SC ~ 29425-8570

This message was secured via TLS by MUSC.

Wolff, Axel (NIH/OD) [E]

A3428-10

From: Wolff, Axel (NIH/OD) [E]
Sent: Thursday, June 01, 2017 9:58 AM
To: 'Mukherjee, Rupak D.'
Subject: RE: Report of animal protocol noncompliance

Thank you for this preliminary report, Dr. Mukherjee. I will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff

From: Mukherjee, Rupak D. [mailto:mukherr@musc.edu]
Sent: Thursday, June 01, 2017 9:54 AM
To: Wolff, Axel (NIH/OD) [E] <WolffA@OD.NIH.GOV>
Cc: Secondary Individual @musc.edu
Subject: Report of animal protocol noncompliance

This message was sent securely by MUSC

Axel V. Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health

Dear Dr. Wolff,

HHSN275201400004C

The IACUC received a report on May 4, 2017, indicating that animals on an active protocol were administered an unapproved drug as a substitute for an approved drug that was unavailable at the time. Upon investigation it was confirmed that the unapproved drug was administered by a laboratory technician, under authorization by the laboratory manager, to 60 mice in February and again in March. While animal welfare did not appear to be compromised by this switch in drugs, there were increased risks to personnel posed by the substituted drug that would have been addressed through the IACUC review process. This incident was reported to the IACUC at a convened meeting on May 25, 2017.

An amendment to the protocol adding the additional drug was submitted in March (after unapproved use, but prior to notification of this use to the IACUC) and approved in mid-May. The laboratory has since instituted global Standard Operating Procedures for all chemicals that are not otherwise covered by a specific safety profile, and all lab personnel have undergone additional training in appropriate handling of potentially hazardous chemicals. The PI and laboratory manager have also been reminded that all compounds administered to animals must be approved on the protocol prior to any use in the lab.

A final report will be submitted after a recheck of the laboratory records and safety procedures is completed and after the IACUC reviews the plan of correction determining that all appropriate remedial actions have been taken to prevent a recurrence.

Please let me know whether you'd need any additional information regarding this report.

Thanking you,
Sincerely,

Rupak Mukherjee, Ph.D.

Chair, IACUC

Associate Professor

Departments of Surgery and Pediatrics

Medical University of South Carolina

Charleston, SC

Phone: Phone Number

FAX: Phone Number

This message was secured via TLS by MUSC.