



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

August 10, 2020

Re: Animal Welfare Assurance
A3944-01 [OLAW Case 1S]

Dr. Sandra Harris-Hooker
Vice President and Executive Vice Dean
For Research and Academic Administration
Morehouse School of Medicine – Atlanta University Center
720 Westview Drive - SW
Atlanta, GA 30310

Dear Dr. Harris-Hooker,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 5, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Morehouse School of Medicine following up on an initial June 18, 2020 notification by email.

According to the information provided, this Office understands that the Morehouse School of Medicine Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol. The final report states on June 10, 2020 a substance (protocol approved) was administered to rats by intramuscular (IM) route. The routes of administration approved on the protocol included intraperitoneal (IP) or subcutaneous (SQ). One rat died shortly after injection; the report states the animal was sedated at the time of injection. The injections were performed for 10d but no notes were present on the cage cards. Postmortem exam and findings could not confirm if the cause of death was from IM injection. It is stated that sedation of the animal also cannot be ruled out as cause of death. The IACUC approved the following corrective actions:

- Retraining of laboratory staff on handling rats and proper technique for SQ injections to minimize the use of anesthetics.
- Assessment of all rats that received IM injections for cellulitis. No abnormal findings were observed.
- Permission was granted to the laboratory to continue SQ injections after retraining.
- Post-approval monitoring is scheduled to be conducted by September 30, 2020.

It is noted that the final report did not include the funding source involving the incident. In the future, please include the source of funding and provide grant numbers for all PHS, NSF or NASA supported work. Based on its assessment of this explanation, OLAW understands that the Morehouse School of Medicine has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Page 2 – Dr. Harris-Hooker
August 7, 2020
OLAW Case A3944-1S

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



Office of the Executive Vice Dean

August 5, 2020

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Morse:

Morehouse School of Medicine, in accordance with Assurance A3944-01 and PHS Policy IV.F.3., provides this final report of noncompliance that resulted in an adverse event in which 1 rat died immediately following an injection procedure via a non-approved injection route. This incident was first reported to Dr. Axel Wolff, MS, DVM OLAW, via email on June 18, 2020.

Situation and Assessment

On June 10, 2020, an approved substance was administered to rats via the intramuscular (IM) route which was not in compliance of the intraperitoneal or subcutaneous (SQ) route approved by IACUC. One rat which was sedated at the time of injection died shortly after the injection. The injections were performed for 10 days, but no notes were provided on the cage cards. A necropsy was performed to determine the cause of death. Unfortunately, postmortem findings cannot confirm the cause of death was due to the IM injection. We also cannot rule out that death might have been caused by sedation.

The corrective actions to prevent recurrences and approved by the IACUC are detailed as follows:

1. The laboratory staff was retrained on handling rats and on the proper technique for SQ injections to minimize the use of anesthetics.
2. All rats injected via the IM route were checked for cellulitis at the site of injection. No abnormal findings were observed.
3. The laboratory was permitted to continue SQ injections after re-training.
4. Post-Approval Monitoring for this laboratory is planned to be conducted by September 30, 2020.

The Morehouse School of Medicine Institutional Care and Use Committee believes its investigation was thorough, and the corrective actions were appropriate to prevent a similar occurrence. Should you have any questions regarding this report, please contact Sharon Francis, Ph.D., IACUC Chair at sfrancis@msm.edu

Sincerely,

(b) (6)

Sandra Harris-Hooker, Ph.D.
Executive Vice Dean for Research and Academic Administration
Professor, Department of Pathology and Anatomy
Institutional Official

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 19, 2020 7:06 AM
To: Francis, Sharon
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Adverse Event Preliminary Report

Thank you for this report, Dr. Francis. We will open a new case file.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Francis, Sharon <sfrancis@msm.edu>
Sent: Thursday, June 18, 2020 3:55 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Adverse Event Preliminary Report

Good afternoon,

Please accept this preliminary report for an adverse event concerning animal welfare at Morehouse School of Medicine, Assurance # D16-00537 (A3944-01).

Event:

On Wednesday, June 10, 2020 a Principal Investigator administered an approved substance to a rat via a route different than what was approved by IACUC. One animal died shortly after the injection. The injections were performed for 10 days, but no notes were provided on the cage cards.

Corrective actions:

The laboratory personnel was retrained. Principal Investigator was advised to modify his protocol to include the new injection route. Further corrective actions will be discussed by the IACUC.

I would like to request 45 days to submit a final report.

Sharon C. Francis, PhD | Assistant Professor
Department of Physiology | Investigator, Cardiovascular Research Institute

Morehouse School of Medicine | 720 Westview Drive, SW, Research Wing, (b) (4) Atlanta, Georgia 30310
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