



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

April 23, 2018

Re: Animal Welfare Assurance
A4365-01 [OLAW Case 3Q]

Stephan S. Monroe, Ph.D
Associate Director for Laboratory
Science and Safety
Centers for Disease Control
1600 Clifton Road NE (b)(6)
Atlanta, GA 30333

Dear Dr. Monroe,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 16, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Centers for Disease Control and Prevention. According to the information provided, OLAW understands that seven rats died after receiving the wrong dose of anesthesia. Anesthesia boosts were given although this was not approved in the protocol and there was no documentation of giving anesthesia, dosage, or recovery observations. The unexpected deaths had not been reported as required to the veterinary staff, the Institutional Animal Care and Use Committee, and the Animal Care and Use Program Office.

The corrective actions consisted of requiring the laboratory to perform animal activities under direct supervision of a veterinarian until the staff is proficient in conducting anesthesia. The Principal Investigator and staff were retrained on proper administration of injectable anesthesia, on documentation of anesthesia and recovery, on providing heat during recovery, and on promptly reporting adverse events.

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 institution to comply with the PHS Policy.

Sincerely,

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

cc: IACUC Chair

(b)(6)



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

April 16, 2018

PHS Assurance #A4365-01

Dr. Brent Morse
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Morse,

During a routine Post Approval Monitoring (PAM) visit on February 21, 2018, the PAM liaison found upon record review that several rat deaths had occurred unexpectedly when investigative staff were performing anesthetic procedures on the protocol. The PAM liaison notified the Deputy Chief veterinarian and the senior clinical veterinarian was immediately assigned to gather information and work with the principal investigator (PI) to identify the cause of these deaths. When questioned, the PI reported that seven deaths in rats from anesthesia had occurred on the protocol. Upon direct observation of investigator procedures, CDC veterinarians and the PAM liaison determined that investigative staff: were providing the wrong dose of anesthesia; were not documenting in the clinical record the administration of anesthesia, dosage, or recovery observations; and provided boosts of anesthesia that was not approved in the protocol. In addition, the PI did not promptly report this animal welfare issue to CDC veterinarians, the IACUC, or the Animal Care and Use Program Office per IACUC policy.

In response to this incident, the Deputy Chief veterinarian mandated that procedures on this protocol could only be performed under direct supervision by a CDC veterinarian until skills competencies of investigative staff in anesthetic procedures are assured. CDC veterinarians are currently retraining the principal investigator and staff on the protocol in the following areas:

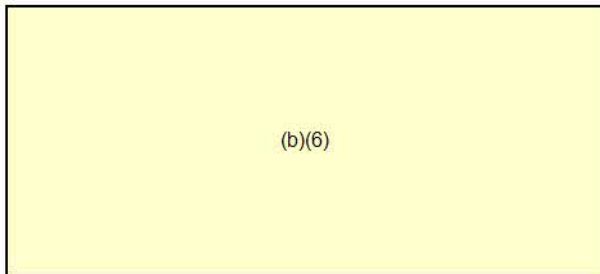
- Proper administration of chemical anesthesia
- Documentation of anesthesia in clinical records
- Documentation of anesthesia recovery
- Providing an external heat source during recovery
- Prompt reporting of adverse events

The CDC-Atlanta IACUC discussed these noncompliances with the protocol and the *Guide* at the March 8, 2018 meeting. The committee voted to report these incidents to OLAW. Upon the

corrective actions outlined above, the committee did not feel that any other actions were needed at this time.

Sincerely,

4/16/2018



(b)(6)

Centers for Disease Control and Prevention

X

Stephan S. Monroe

Stephan S. Monroe, PhD
Assoc Dir Lab Science & Safety
Signed by: PIV

Stephan S. Monroe, PhD
Institutional Official
Associate Director for Laboratory Science
and Safety

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, April 19, 2018 10:14 AM
To: (b)(6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Incident report submission for CDC-ATL (PHS Assurance# A4365-01)

Thank you for this report, (b)(6) We will respond soon.

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

From: (b)(6)
Sent: Thursday, April 19, 2018 10:06 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Monroe, Steve (CDC/OD/OADLSS) (b)(6); Maines, Taronna (b)(6)

(b)(6)

Subject: Incident report submission for CDC-ATL (PHS Assurance# A4365-01)

Dear Dr. Morse and colleagues,

Please find attached an incident report for submission.

Thank you,

(b)(6)

(b)(6)

Centers for Disease Control and Prevention
1600 Clifton Road NE (b)(6) Atlanta, GA 30333

(b)(6)

Telework Tuesdays, Fridays



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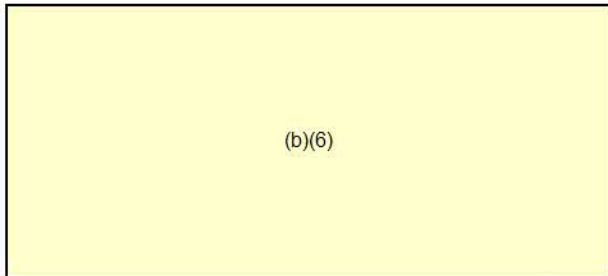
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Centers for Disease Control and Prevention

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Stephan S. Monroe

Stephan S. Monroe, PhD
Assoc Dir Lab Science & Safety
Signed by: PIV

Stephan S. Monroe, PhD
Institutional Official
Associate Director for Laboratory Science
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