



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

March 15, 2019

Re: Animal Welfare Assurance  
#A3083-01 [OLAW Case 3J]

Dr. Robert Rubin  
President and Chief Executive Officer  
Lovelace Respiratory Research Institute  
2425 Ridgecrest Drive, SE  
Albuquerque, NM 87108

Dear Dr. Rubin,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 11, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Lovelace Respiratory Research Institute. According to the information provided, OLAW understands that expired analgesic was given to a pig following a painful procedure. The drug was only several months out of date and the animal did not exhibit signs of pain or distress.

The corrective actions consisted of discarding the expired drug, obtaining a new bottle, and providing the pig a dose of unexpired analgesic. All veterinarians, technicians, and Principal Investigators were retrained on disposal of expired drugs and all lock boxes and drug safes will be inventoried monthly for expired agents.

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,

 (b) (6)

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

cc: IACUC Chair



March 11, 2019

Assurance A3083-01

Brent C. Morse, DVM, DACLAM  
Acting Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institute of Health  
Rockledge 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Dear Dr. Morse,

Lovelace recognizes our responsibility to directly and promptly report adverse events on PHS funded work. This letter is to inform your office of a recent incident involving inadequate veterinary care for a pig on a BARDA funded study. The pig was inadvertently administered expired buprenorphine. The pig was exposed to a category E agent and was receiving pain management post-exposure to reduce pain and distress. The prime contract number for this study is HHSO100201500020C, the subcontract number is FY17.793.003.

The incident was investigated by the IACUC investigative subcommittee and the following details were found. The animal received a proper dose of buprenorphine at 1819 on 28Feb2019. The buprenorphine bottle intended for the next dosing was dropped and broken when the pig was due to receive it's next dose. The veterinarian on-site then retrieved a new, unopened bottle from a nearby locked safe. That bottle had an expiration date of 03Nov2018, but the veterinarian did not notice the expiry. The pig was administered the expired buprenorphine at 0100 on 01Mar2019. When the next dose was due, around 0700 on 01Mar2019, the technician noted the expired date on the bottle, returned the bottle to the pharmacy, and retrieved a new bottle. The pig was administered non-expired buprenorphine at 0701 on 01Mar2019.

During the approximate 13 hours in between the two proper doses of buprenorphine, the pig was noted to be sleeping or standing, no open-mouth breathing, with occasional coughing and mild retractions. The animal did not exhibit any signs of pain or distress (e.g., vocalization, anxiety).

The following corrective action plan was implemented following the incident:

1. All veterinarians, technicians, and principle investigators are being retrained on how to dispose of expired drugs.
2. Currently, there is no requirement for inventory of satellite lock-boxes/safes around the facility. Once the controlled drug has left the pharmacy it is the responsibility of the study director and/or principle investigator to return the drug to the pharmacy. Moving forward,

all lock boxes and safes around the facility will be inventoried on a monthly basis by the pharmacy technician.

The corrective action plan has been reviewed and approved by the Attending Veterinarian. Lovelace is committed to protecting the welfare of animals. We appreciate any guidance provided by OLAW in this regard. Should you have any questions or require more information feel free to contact the Attending Veterinarian, Tom Eggleston at (b) (6) or the IACUC Chair, Jeremy Brower at (b) (6)

Sincerely,

(b) (6)

Dr. Robert W. Rubin, PhD  
President and CEO  
Institutional Official  
Lovelace Respiratory Research Institute

**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, March 12, 2019 8:01 AM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Eggleston, Thomas; Brower, Jeremy; (b) (6)  
**Subject:** RE: OLAW non-compliance report Assurance #A3083-01

Thank you for providing this report. 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

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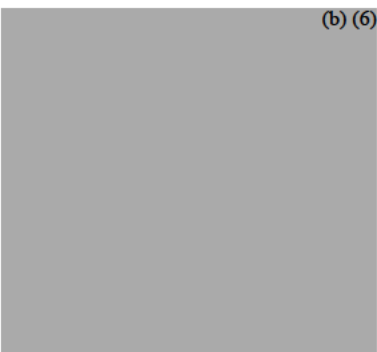
**From:** (b) (6)  
**Sent:** Monday, March 11, 2019 3:12 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Eggleston, Thomas <teggleston@lrri.org>; Brower, Jeremy <jbrower@lovelacebiomedical.org>; (b) (6)  
(b) (6)  
**Subject:** OLAW non-compliance report Assurance #A3083-01

Good afternoon Dr. Morse,

Attached to this email is a letter regarding an adverse event we are reporting to OLAW. Please review and let me know if you require any additional information at this time.

Thank you,

(b) (6)

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