



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 B 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

May 28, 2019

Re: Animal Welfare Assurance
A3442-01 [OLAW Case 3D]

Dr. Bryan A. Wolff
Executive Vice President, and
Chief Scientific Officer
Children's Hospital of Philadelphia
Abramson Research Building, (b) (4)
3615 Civic Center Boulevard
Philadelphia, PA 19104

Dear Dr. Wolf,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 17, 2019 letter reporting an incident of noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at Children's Hospital of Philadelphia. According to the information provided, OLAW understands that it was recently determined that pre-operative buprenorphine was not administered to 25 mice that had undergone subcutaneous osmotic pump implantation. Post-operative monitoring did not indicate any adverse events for these animals. It was noted that the mice were on a project that was PHS funded.

Corrective actions included the IACUC Post-Approval Monitor meeting with the PI and the responsible research staff member. Further PAM reviews will be scheduled. Also, research team members will be required to attend a training session with the PAM.

OLAW believes that the corrective measures put in place by Children's Hospital of Philadelphia are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring and self-reporting. OLAW appreciates being informed of these issues and finds no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



Children's Hospital of Philadelphia

RESEARCH INSTITUTE

2716 South Street Philadelphia, PA 19146 • 215-590-3800 • research.chop.edu

A3442-3D

Bryan A. Wolf, M.D. Ph.D.
Executive Vice President & Chief Scientific Officer
Edmond F. Notebaert Endowed Chair in Pediatric Research
Executive Offices
Suite 15123, The Roberts Center for Pediatric Research
2716 South Street
Philadelphia, PA 19146-2305
T 215-590-2869 F 267-425-1081

May 17, 2019

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

Dear Dr. Wolff:

The Children's Hospital of Philadelphia (CHOP), in accordance with Assurance D16-00280 (A3442-01) and PHS Policy IV.F.3., submits this report of noncompliance regarding the following incident:

During the recent IACUC Semiannual Inspection and Program Review, it was discovered that pre-operative analgesics were not administered to twenty-five mice who had undergone subcutaneous osmotic pump implantation procedures. These animals were assigned to IACUC protocol 17-000853 ("Targets for Therapy of Congenital Hyperinsulinism Mouse", supported by 1R43DK111304-01A1). The protocol is approved for administration of Buprenorphine (0.05 mg/kg) prior to creating an incision. Post-operative monitoring observations did not indicate any adverse events for these animals.

The IACUC Post-Approval Monitor met with the PI and research staff member who was responsible for these mice. There was a misunderstanding with regard to the analgesia plan and the research team has indicated that buprenorphine will be administered to all animals that undergo the osmotic pump implantation procedure in the future. A PAM review that includes observation of this procedure will be scheduled.

This incident was discussed at our regularly scheduled monthly IACUC meeting on 5/13/2019. The Committee voted for the following action:

1. Research team members will be required to attend a training session focused on IACUC protocols and compliance with the IACUC Post-Approval Monitor.
2. A report of this incident will be made to the Office of Laboratory Animal Welfare (OLAW), with a copy to AAALAC International.

CHOP is committed to quality animal care. We believe that these steps are appropriate to address the noncompliance issue that was identified. However, if you would like us to take any additional measures or require additional information, please do not hesitate to contact me, the Attending Veterinarian (Laike Stewart, DVM, DACLAM), or our IACUC Chair (Laurence C. Eisenlohr, VMD, PhD).

Sincerely,

(b) (6)

Bryan A. Wolf, M.D., Ph.D.
Institutional Official
Executive Vice President & Chief Scientific Officer

cc: AAALAC International

(b) (6)

Laurence C. Eisenlohr, VMD, PhD
Laike Stewart, DVM, DACLAM

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, May 21, 2019 2:26 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Wolf, Bryan; Stewart, Laike S; (b) (6) 'Eisenlohr, Laurence'; (b) (6)
Subject: RE: OLAW Assurance D16-00280 A3442-01_ - Report of Noncompliance

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, May 20, 2019 12:32 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Wolf, Bryan <WOLFB@email.chop.edu>; Stewart, Laike S <STEWARTL3@EMAIL.CHOP.EDU>; (b) (6)
(b) (6) 'Eisenlohr, Laurence' <eisenlc@pennmedicine.upenn.edu>; (b) (6)
(b) (6)
Subject: OLAW Assurance D16-00280 A3442-01_ - Report of Noncompliance
Importance: High

Dear OLAW,

Attached to this email please find a report of noncompliance with the PHS Policy. We look forward to your review of this matter.

Thank you,

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(b) (6)