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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

June 20, 2018

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

Dr. Bryan A. Wolf
Executive Vice President and Chief Scientific Officer
Children's Hospital of Philadelphia
(b) (4) 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 June 14, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Children's Hospital of Philadelphia. According to the information provided, OLAW understands that more blood was taken from a rabbit than approved in the protocol. There were no adverse effects on the animal.

The corrective action consisted of counseling the Principal Investigator to conduct procedures as described in the approved protocol.

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

A3442-36

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Children's Hospital of Philadelphia
RESEARCH INSTITUTE

3615 Civic Center Blvd. • Philadelphia, PA 19104 • 215-590-3800 • research.chop.edu

Bryan A. Wolf, M.D. Ph.D.
Executive Vice President & Chief Scientific Officer
Edmond F. Notebaert Endowed Chair in Pediatric Research
Executive Offices
Suite 15128, The Roberts Center for Pediatric Research
2716 South Street
Philadelphia, PA 19146-2305
T 215-590-2869 F 267-425-1081

June 14, 2018

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:

> On 5/31/18, an excess amount of blood was collected from an animal assigned to IACUC protocol 18-001285 ("Peripheral Artery Stenting in Rabbit Model", supported by NIH5R01EB023921-02). The protocol is approved for an amount of blood to be withdrawn not to exceed 0.5% of body weight. The volume that was collected was 0.76% of the body weight. This volume did not adversely affect the animal's health or wellbeing.

This incident was discussed at our regularly scheduled monthly IACUC meeting on 6/11/18. The Committee voted for the following action:

1. The PI will be required to meet with the AV, IACUC chair and IACUC Administrative Director to discuss compliance.
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

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, June 19, 2018 2:02 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Assurance D16-00280 A3442-01_- Report of Noncompliance

Thank you for this report. We will send a response soon.

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

From: (b) (6)@email.chop.edu]
Sent: Tuesday, June 19, 2018 12:55 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)@email.chop.edu>; 'Eisenlohr, Laurence' <eisenlc@pennmedicine.upenn.edu>; (b) (6) (b) (6)@email.chop.edu>
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,
(b) (6)

(b) (6)

Children's Hospital of Philadelphia

Report Compliance Concerns Anonymously
To report compliance concerns anonymously,
contact the Compliance Hotline 1-866-246-7456 or
www.mycompliancereport.com (use "CHOP" as the access ID).