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

February 15, 2019

Re: Animal Welfare Assurance
#A3045-01 (OLAW Case 1T)

Sheila L. Vrana, Ph.D.
Associate Dean for Research
Penn State University – Hershey Medical Center
Office of Research Affairs, H138
500 University Drive, PO Box 850
Hershey, PA 17033-0850

Dear Dr. Vrana,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 14, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Pennsylvania State University- Hershey Medical Center, following up on an initial telephone report on February 6, 2019. According to the information provided, OLAW understands that a technician was monitoring a post-operative sheep overnight when the animal developed complications with its implanted heart pump. Another employee had noticed the problem and informed the technician who failed to contact the veterinarian immediately as had been directed. The animal showed signs of distress and the veterinarian was called six hours later.

The immediate action taken by the veterinarian was to euthanize the sheep. The preventive action consisted of the Institutional Animal Care and Use Committee (IACUC) requiring that all animal care staff acknowledge receipt of verbal and written animal care instructions and that any employee monitoring post-operative animals call the veterinarian regarding concerns. The technician involved has left the institution.

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 IACUC to comply with the PHS Policy and recommends that the responsibility to call a veterinarian regarding animal concerns be extended to all individuals. We assume that contact information for the veterinary staff as well as information on how to report concerns is posted in the animal areas. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair

PENNSTATE HERSHEY
Milton S. Hershey Medical Center

PENNSTATE HERSHEY
College of Medicine

Sheila L. Vrana, Ph.D.
Associate Dean for Research

February 14, 2019

Brent C. Morse, D.V.M.
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare
Division of Compliance Oversight
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-6910

Re: Failure to monitor animals post-procedurally as necessary to ensure well-being, failure of animal care and use personnel to carry out veterinary orders; Animal Welfare Assurance D16-00024 (A3045-01); DOD-funded.

Dear Dr. Morse,

The Pennsylvania State University College of Medicine, in accordance with Assurance D16-00024 (A3045-01) and PHS Policy IV.F.3., provides this report of a noncompliance regarding an incident in which an animal care technician neglected to appropriately monitor and follow veterinary orders while monitoring the health status of an animal that had undergone a surgical procedure. This incident was first reported to you via phone call by Dr. Ronald Wilson on 02/06/2019.

It was brought to the attention of the IACUC that on December 18, 2018, an animal care technician was providing overnight care for a sheep that had recently undergone a survival Fontan pump implantation surgery. The animal developed pump complications, and the animal care technician did not follow explicit verbal and written instructions to contact the clinical veterinarian if specific clinical signs developed. The clinical veterinarian could then assess the animal's health status in the event of pump failure, and if indicated, euthanize the animal. The pump failed during the night and the animal developed signs of distress; however, the animal care technician did not call the veterinarian for approximately 6 hours, despite being informed by another assistant that the pump had failed. Once notified, the veterinarian arrived within 30 minutes of the phone call and humanely euthanized the animal.

To address the situation, the IACUC recommended the following corrective action plan:

1. All animal care staff should confirm their receipt of verbal and written instructions for care, such as to contact the clinical veterinarian under specified conditions. (The animal care technician identified in this event resigned shortly after the incident, so no additional recommendations were made to that individual.)

2. A part-time employee who recognized that the pump had failed informed the animal care technician of the failure, and assumed that the individual would follow through and call the clinical veterinarian. It is recommended that all employees assisting with the post-operative care of these animals, regardless of part-time vs. full-time status, be encouraged to contact a clinical veterinarian if there is concern about an animal's condition.

The findings of the investigation were reviewed at a convened meeting of the IACUC on January 28, 2019. The IACUC recommended to the IO that the incident be reported to OLAW.

Please feel free to contact me if you require additional information.
Sincerely,

(b) (6)

Sheila Vrana, PhD
Institutional Official
Institutional Animal Care and Use Committee

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, February 15, 2019 7:28 AM
To: Vrana, Sheila; OLAW Division of Compliance Oversight (NIH/OD)
Cc: IACUC; IACUCChair; Wilson, Ronald; svrana@psu.edu
Subject: RE: Communication from Penn State College of Medicine

Thank you for providing this report Dr. Vrana. 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

-----Original Message-----
From: Vrana, Sheila [mailto:svrana@pennstatehealth.psu.edu]
Sent: Thursday, February 14, 2019 5:39 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: IACUC <IACUC@pennstatehealth.psu.edu>; IACUCChair <IACUCChair@pennstatehealth.psu.edu>; Wilson, Ronald <rwilson2@pennstatehealth.psu.edu>; svrana@psu.edu
Subject: Communication from Penn State College of Medicine

Dear Dr. Morse,
Please see attached communication that was communicated to you by Dr Wilson on Feb. 6.
Thank you,
Sheila Vrana

Sheila L. Vrana, Ph.D.
Associate Dean for Research
Associate Professor of Pharmacology
Penn State College of Medicine
500 University Drive, Box 850, H138
Hershey PA 17033-0850
(b) (6)
svrana@psu.edu

A3045-1T

Office of Laboratory Animal Welfare

OLAW

Initial Report of Noncompliance

By: [redacted]

Date: 2/6/19 Time: 2155

Name of Person reporting: Ron Wilson, A/V
Telephone #: [redacted] (b) (6)
Fax #:
Email:

Name of Institution: Penn St. Hershey
Assurance number: A3045

Did incident involve PHS funded activity? No
Funding component: _____
Was funding component contacted (if necessary): _____

What happened? During post op, artificial heart stopped + was restarted but stopped again that night, but animal care member did not contact Vet as instructed. Sheep was euthanized.

Species involved: Ovis aries
Personnel involved: Animal Care
Dates and times:
Animal deaths: Euthanized

Projected plan and schedule for correction/prevention (if known): _____
Animal care tech. resigned

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #_____