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

September 3, 2019

Re: Animal Welfare Assurance
#A3508-01 (OLAW Case G)

Mr. Don Burman
Medical Center Director
VA Medical Center–Omaha
4101 Woolworth Avenue
Omaha, NE 68105

Dear Mr. Burman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of a 26 August 2019 memorandum from Dr. Hamel, ACOS/R, reporting an adverse event within the animal care and use program at the VA – Nebraska-Western Iowa Health Care System, Omaha. According to the information provided, OLAW understands that on April 5, 2019 a pig died subsequent to a procedure. Prior to death the animal had been closely monitored and administered analgesics. On April 8th another pig began to show similar symptoms and was euthanized on April 10th. The IACUC decided to have the PI stop work on the protocol until the deaths were investigated. On April 12th the Facility Director ordered that the PI stop work on the protocol. On April 16th a third pig was euthanized after showing similar signs as the previous swine.

Corrective actions included the PI describing possible reasons for the complications to the IACUC. Based on this and necropsy results, the IACUC approved a protocol amendment addressing the issues presented by the PI. The remaining two pigs were euthanized and necropsy results provided to the VMO, IACUC Chair and ACOS for review. The remaining animals were to be tested for rotavirus as a possible contributing factor. The PI has now been allowed to proceed with the proposed plan of action.

The prompt consideration of this matter by the VA – Nebraska-Western Iowa Health Care System, Omaha was consistent with the philosophy of institutional self-regulation. OLAW concurs that the incident warranted reporting. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

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

cc: IACUC contact
(b)(6)
Frederick G. Hamel, Ph.D., ACOS/R

Department of Veterans Affairs

Memorandum

Date: 26 August 2019

From: Frederick G. Hamel, Ph.D.

Subj: Unanticipated adverse event

To: Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

This letter details the events surrounding the unanticipated death of a swine at our facility.

1. The VMO notified ACSO/R that a subject (swine) had died on 04/05/2019. Prior to the swine's death it had been observed to have stopped eating and was being monitored closely for pain and distress. Analgesics were administered to alleviate pain and distress. The necropsy showed the stomach wall had eroded with contents leaking into the peritoneal space. On 04/08/2019 another subject (swine) began to show similar symptoms and was euthanized on 04/10/2019. The VMO contacted the PI to discuss the death of the swine. The death of the swine was discussed during the next IACUC committee meeting. The IACUC made the decision to have the PI stop work on the protocol until the deaths are investigated. On 04/12/2019 the ACOS/R, Research Administrative Officer (RAO) notified the RCO of the situation. At that time the RCO, ACOS/R and RAO notified the Facility Director. The Facility Director ordered that the PI stop work on the protocol. On 04/16/2019 a third subject (swine) was euthanized after showing similar symptoms as the previous swine.

2. The PI provided a memo to the Omaha VAMC IACUC on April 30, 2019. The document contained the description of what he felt was the possible reason for complications, along with necropsy results of the swine. The PI gave an overview at the next IACUC meeting with a proposed amendment. The IACUC took the following actions:

A. There was a unanimous vote to approve the amended protocol, addressing modifications reviewed at the previous meeting.

B. There was also a unanimous vote that there were no serious or continuing non-compliance issues.

C. The IACUC approved the PI's proposed plan to move forward including the sacrifice and necropsy of the two-surviving treated swine to determine if the animals developed damage to the organ compared to the other animals. This was only after the IO lifted the hold on the protocol, which was to be contingent on a positive response from ORO. These results were to be forwarded to the VMO, IACUC Chair and ACOS for review before any further experiments.

D. The committee voted that the remaining animals be tested for rotavirus as a possible contributing factor.

3. Omaha VA reported to ORO on the status of IACUC's review:

A. Necropsies were performed on the two remaining pigs after the institutional official lifted the hold on the protocol.

B. The IACUC Committee reviewed and approved the amendment provided by the PI at their last meeting.

C. After consultation with the VMO, the PI was allowed to proceed with the proposed plan of action.

4. ORO issued a memo concuring with the actions taken to address the deficiencies and commending the significant efforts taken by your institution to maintain the highest standards of animal care. The case was closed.

Please let me know if you need any further information. Thank you.

Sincerely,

Frederick G. Hamel, Ph.D.
ACOS/Research
Research Integrity Officer (RIO)
Omaha Veterans Affairs Medical Center

A3508-G

Office of Laboratory Animal Welfare

OLAW

Initial Report of Noncompliance

By: [signature]

Date: 4/18/19 Time: 3:35

Name of Person reporting: Frederick Hamel, PhD ACOS

Telephone #: (b)(6)

Fax #:

Email: (b)(6)@va.gov

Name of Institution: Omaha VA

Assurance number: A3508

Did incident involve PHS funded activity? ?

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? Unexpected mortality in pigs after pancreatic injections.

Species involved: Sus scrofa

Personnel involved: Researcher

Dates and times:

Animal deaths: Yes

Projected plan and schedule for correction/prevention (if known): _____

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case #_____

Office of Laboratory Animal Welfare

OLAW

Division of Compliance Oversight

Record of Call for Case # A3508-G

Date & Time	Message	Initials
8/20/19 3:20	Left VM for ACOS (Dr. Hamel) requesting final or interim report.	
8/29/19 10:00	Dr. Hamel will send a final report soon.	