



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

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Bethesda, Maryland 20817
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August 7, 2017

Re: Animal Welfare Assurance
A3231-01 [OLAW Case 1T]

Dr. Howard D. Zelaznik
Associate Vice President for Research
Purdue University
610 Purdue Mall
West Lafayette, IN 47907-2040

Dear Dr. Zelaznik,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 1, 2017 letter reporting an incident of noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at Purdue University. According to the information provided, OLAW understands that on May 11, 2017 a pig died during a procedure to place a pharyngeal tube. When difficulty placing the pharyngeal tube was encountered, the cuffed endotracheal tube was removed. The occasional flushing with saline of a lighted scope used to confirm placement of the pharyngeal tube resulted in fluid entering the lungs and led to the pig's death. Monitoring equipment had been turned off due to repeated false alarms. The use of an endotracheal tube was not referenced in the approved protocol. At the time of the incident, the activity was not supported with PHS funds.

Although work on the protocol was completed, the PI, investigator and the research group were counseled by the IACUC (PACUC) that the monitoring system should not have been turned off, but should have been replaced and that the protocol should be amended to reflect the use of the endotracheal tube. In addition, the protocol should have been made available to all personnel listed on the protocol such that the veterinary surgeon performing the procedure would have been aware that the use of the endotracheal tube was not listed in the protocol.

OLAW believes that the preventive measures put in place by Purdue University are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of this unfortunate incident and find no cause for further action by this office. Doctor Agnew will be referenced on future communication to the Institutional Official.

Sincerely,

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

cc: IACUC Contact

Dr. Elizabeth Goldentyer, Director Eastern Sector, USDA, APHIS, AC

August 1, 2017

Dr. Axel Wolff
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. Wolf:

I am providing a belated report to the Office of Laboratory Animal Welfare (OLAW) regarding an incident involving the care and use of animals at the Purdue University, West Lafayette campus. Purdue University's Assurance Number is D16-00147 (A3231-01).

The Purdue Animal Care and Use Committee (PACUC) was informed of the incident on May 11, 2017 and the incident was discussed when the committee met for its regularly scheduled meeting on May 17, 2017. As I was not in attendance at the PACUC meeting, and did not study the minutes from that meeting, the reporting of the incident was delayed. My apologies.

The use of animals in the approved protocol is supported by PHS funds. However, in this instance, the investigator reported **special inform** funds were being used to support the project over the summer months. At Purdue, vertebrate animals used in research, testing or teaching that is not funded by the PHS are still subject to the same program of oversight, based on the standards of the Guide for the Care and Use of Laboratory Animals and the Guide for the Care and Use of Agricultural Animals, as applied to PHS supported activities.

In addition to reporting this incident to OLAW, it will also be reported to the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

Unexpected Death of Swine, Protocol 1112000344, "Challenges To Porcine Vocal Fold Epithelia"

On May 11, 2017 while performing surgery to place a pharyngeal tube in a pig, pig number 44-9 died. During the surgery, insertion of a lighted scope to confirm placement of the pharyngeal tube was needed. It was reported there was difficulty getting the scope past the inflated cuff on the endotracheal tube. The research group removed the endotracheal tube and then replaced the scope to continue work on the placement of the pharyngeal tube. The scope camera needed to be occasionally flushed with

saline to keep the image clear. While modifying the placement of the pharyngeal tube, it was noted that the animal stopped breathing. At that point, the group stopped the procedure and attempted to re-intubate the animal. This was unsuccessful and the animal died. The group was monitoring SPO2 and heart rate but had shut off the alarm system due to the fact that a good reading was not being obtained on the ear contact and the alarm kept sounding. Since the animal was on its back and there was no endotracheal tube in place, it was determined that the probable cause of death was fluid in the lungs from the flushing of the scope. It was reported that this was confirmed by the investigator who is a DVM, Board Certified Pathologist. The group used this animal's cadaver to finish out the procedure and determine the best course of action on the insertion of the pharyngeal tube as well as how to best avoid this issue in the future. It was determined from the loss of this animal that all animals would be kept intubated during the entire procedure which would help maintain the airway as well as keep any fluid from the flush from entering the lungs. Subsequent swine underwent the procedure that same day and no other deaths occurred.

The approved protocol stated that surgery would be performed with inhalant anesthesia administered via a nose cone. There was no reference to endotracheal intubation. As such, the procedure was not conducted as described in the PACUC approved protocol. Changes in procedures must be approved by PACUC prior to their implementation.

It was communicated from the PACUC to the PI that:

- Any new surgical procedure to be done on this study must be done on a cadaver animal prior to performing it on a live animal.
- Instead of turning the alarm system off when it was malfunctioning, time should have been taken to replace it with one that actually worked.
- The Adverse Event report that was submitted that day when the death occurred should have been written and submitted by the investigator of the protocol, not a technician on the project.

A meeting was held with the investigator and research group and the additional points noted:

- It is not anticipated that additional swine would be used under this approved protocol as the work was complete. The investigator had not yet deactivated the protocol as manuscripts were being submitted and the investigator was awaiting response.
- The appropriate course of action on May 11, 2017 would have been to suspend the use of further animals pending submission and approval of an amendment to the protocol to include the use of endotracheal intubation.
- The veterinary surgeon performing the procedure, while listed on the protocol, was not aware that use of a nose cone vs. endotracheal intubation was described in the approved protocol. Going forward, all personnel listed on the protocol need to be provided electronic access to the approved protocol.
- While work is complete, the protocol is still "active" and should be amended to include use of an endotracheal tube at the discretion of the surgeon.

Purdue University would like to reaffirm its commitment to a strong animal care and use program. It is hoped that the actions being taken will serve to strengthen the program of animal care at Purdue University.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Howard D. Zelaznik". The signature is fluid and cursive, with the first name "Howard" being more prominent.

Howard D. Zelaznik, Ph.D.,
Associate Vice President for Research & Institutional Official

Cc: Dr. J. Kritchevsky, Chair, Purdue Animal Care and Use Committee
Secondary Individual Administrator, Purdue Animal Care and Use Committee
Dr. W. Ferner, Director, Laboratory Animal Program

Secondary Individual

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