



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>

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 22, 2017

Re: Animal Welfare Assurance
#A3244-01 (OLAW Case J)

Dr. Kelly Rusch
Vice President for Research,
and Creative Activity
North Dakota State University
1735 NDSU Research Park Drive
Fargo, ND 58105-5756

Dear Dr. Rusch,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 21, 2017 letter reporting the suspension of an animal activity at North Dakota State University. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action after determining 12 bats died during hibernation because the temperature of their chamber had been changed. The investigator failed to submit the carcasses to the Veterinary Diagnostic Laboratory (VDL) and did not notify the IACUC or Attending Veterinarian (AV).

The corrective actions consisted of the IACUC suspending all captive bat protocols, directing the investigator to provide standard operating procedures (SOP) for bat husbandry and hibernation, and to identify a faculty member to oversee the protocol during the investigator's absence. The SOPs were submitted, the suspension was lifted, the bat research will be monitored by the IACUC and AV, and the IACUC will develop an SOP stating that animals which die unexpectedly must be submitted to the VDL for necropsy.

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 on Humane Care and Use of Laboratory Animals.

Sincerely,

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair
Robert Gibbens, D.V.M., Western Regional Director USDA-APHIS-AC

NDSU NORTH DAKOTA
STATE UNIVERSITY

June 21, 2017

Robert M. Gibbens, DVM
Regional Director-Animal Care
Western Region
USDA/APHIS/AC
2150 Centre Ave
Building B, 3W11
Fort Collins, CO 80526

Re: Report of Noncompliance and protocol suspension at North Dakota State University (Registration NO. 45-R-0002)

Dear Dr. Gibbens,

The purpose of this letter is to report the suspension of Protocols A15052 *Social Behavior Dominance in Hierarchies in Big Brown Bats, Eptesicus fuscus* and A16069 *Impacts of Personality, Group Density, and Familiarity on Social Interactions in Big Brown Bats, Eptesicus fuscus*. Protocols A15052 and A16069 were suspended by the IACUC during convened meeting on May 25, 2017.

On May 12, 2017 the Principal Investigator for Protocols A15052 and A16069 reported an adverse event (AE) to the IACUC. The AE report stated that 12 big brown bats had died while in hibernation under protocol A16069. The 5 initial bats had been found dead at the base of their cages on March 24, 2017. The report stated the temperature of the refrigerator had been altered from the default temperature. The PI stated the reason for the delay in reporting the incident was due to [REDACTED] Privacy

[REDACTED] The graduate student had reported to deaths to her via email but the email was missed.

Later in the day on May 12, 2017, the PI reported that she had been informed that the remaining bats in the colony had died. The email reported that in late April the remaining bats were removed from hibernation and moved to an outside aviary. Those remaining bats died over a 10 day period.

Background: The annual update for Protocol A16069 was submitted on March 6, 2017. The annual update reported that 3 bats had died during hibernation. The report stated that following the deaths, the feeding frequency had been changed from every 3 weeks to every 2 weeks. The IACUC Office requested the animals be brought to the Veterinary Diagnostic Laboratory (VDL) for necropsy. The PI replied the carcasses had been frozen. The VDL stated frozen samples would not be adequate. The PI

OFFICE OF THE VICE PRESIDENT FOR RESEARCH AND CREATIVE ACTIVITY
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NDSU is an EO/AA university.

was instructed that any animal that dies unexpectedly should be sent to VDL for necropsy and the death be reported to the IACUC and AV offices.

Despite the instruction to bring animals to VDL for necropsy, the carcasses were not submitted to VDL from the other death loss until May 15, 2017. The sample was tested for rabies, which was negative, however, due to the advanced stage of autolysis further evaluation (histopathology) was not performed.

The IACUC chair, administrator, and attending veterinarian met with the PI (via Skype), the department chair, and the graduate student on May 23, 2017. The group discussed the incident, the care of the animals, and housing conditions.

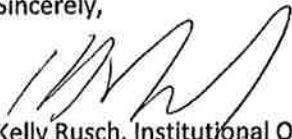
The AE was reported to the IACUC during a convened meeting on May 25, 2017. The IACUC voted to suspend all captive bat protocols (A15052 and A16069). The IACUC requested the PI provide SOPs for bat husbandry and hibernation and name a faculty member to oversee the protocols until the PI returns from [Privacy]

The SOPs were submitted and reviewed by the IACUC at their June 15, 2017 meeting and the suspension of Protocols A15052 and A16069 was lifted. The IACUC and AV Offices will work closely with any additional captive bat research to ensure the SOPs are being followed.

In addition, the IACUC will develop an SOP that requires animals that die unexpectedly under a research protocol be brought to the VDL for necropsy.

If you have any questions regarding this incident, please contact the IACUC Office at [telephone #]

Sincerely,



Kelly Rusch, Institutional Official

Vice President Research and Creative Activity

cc: Thomas Secor, DVM, Veterinary Medical Officer
Axel Wolff, Director, Division of Compliance Oversight, OLAW
Dr. Neil Dyer, Interim Attending Veterinarian
Dr. Kendall Swanson, Interim IACUC Chair

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, June 22, 2017 7:22 AM
To: secondary individual
Subject: RE: NDSU Report of Protocol Suspension (45-R-0002)

Thank you for this report. We will respond soon.

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
OLAW

From: secondary individual [mailto:secondary.individual@ndsu.edu]
Sent: Wednesday, June 21, 2017 5:59 PM
To: acwest@aphis.usda.gov; thomas.secor@aphis.usda.gov
Cc: Rusch, Kelly <kelly.rusch@ndsu.edu>; Dyer, Neil <neil.dyer@ndsu.edu>; Swanson, Kendall <kendall.swanson@ndsu.edu>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: NDSU Report of Protocol Suspension (45-R-0002)

Please see attached.

secondary individual

Secondary individual

Research Compliance Administrator
Institutional Animal Care and Use Committee
Research Integrity and Compliance
North Dakota State University

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