



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

May 4, 2017

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

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 May 1, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals. According to the information provided, OLAW understands that pigs were subjected to a tail vein bleed although this activity had not yet been approved by the Institutional Animal Care and Use Committee (IACUC). The Attending Veterinarian (AV) was attempting to show the investigators how to conduct the procedure but there was no training protocol in place to cover the activity.

The corrective action consisted of the AV submitting a newly developed training protocol to allow the conduct of procedures such as the tail vein bleed. The IACUC recommended that the Principal Investigator (PI) and AV consult the literature and subject matter experts to assist with mastering the technique. A protocol amendment was submitted for IACUC review and the Institutional Official will counsel the AV and PI on institutional policies and procedures regarding animals.

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.

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

A3244-I

NDSU NORTH DAKOTA
STATE UNIVERSITY

May 1, 2017

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

Re: Report of Noncompliance at North Dakota State University (Registration No. 45-R-0002)

Dear Dr. Gibbens,

The Animal Welfare Act and Public Health Service Policy require the IACUC review and approve, require modifications in (to secure approval), or withhold approval of components of proposed activities, related to the care and use of animals. The purpose of this letter is to report an incident of noncompliance in which a procedure (submitted in a change request) under Protocol A17010 was conducted prior to the change request being approved.

A change request for protocol A17010 was reviewed at the IACUC meeting on March 16, 2017. The change request included an alternate blood collection (tail vein bleed) method for sows. The Principal Investigator and Attending Veterinarian indicated during the IACUC meeting that neither of them had experience with tail vein bleeds in swine. The IACUC recommended that they consult with others in the swine industry and conduct a literature search due to their lack of experience and the size of the animals (500 pounds). The IACUC stated the PI would need to be trained in the procedure. The change request was moved to designated review pending requested revisions. An email outlining the requested revisions was sent to the PI on Friday, March 17th. The IACUC Office contacted the Principal Investigator, Attending Veterinarian, and IACUC Chair regarding the consultation and literature search on March 21st. The Principal Investigator responded via email and the Attending Veterinarian in-person, that they had attempted the procedure and found it to be inadequate for blood collection. The revised change request had not yet been submitted and therefore the change in protocol was not yet approved.

The Attending Veterinarian indicated that he considered the discussion at the IACUC meeting to be a verbal approval from the IACUC to conduct the training for tail vein bleeds in sows. NDSU policy requires all live vertebrate animal use to be reviewed and approved by the IACUC. At the time of the tail vein bleed, NDSU did not have a training protocol. An institutional training protocol was submitted by the Attending Veterinarian on April 5, 2017. Once this protocol is approved it will allow the Attending Veterinarian to conduct training for procedures in which he is qualified.

OFFICE OF THE VICE PRESIDENT FOR RESEARCH AND CREATIVE ACTIVITY
NDSU Dept 4000 | PO Box 6050 | Fargo ND 58108-6050 | 701.231.6542 | Fax 701.231.6736 | www.ndsu.edu/research

Shipping address: 1735 NDSU Research Park Drive, Fargo, ND 58102

I will meet with the Principal Investigator and the Attending Veterinarian to discuss this incident and review university policies and procedures for proper use of animals.

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: Vacant, V.M.O
Axel Wolff, Director, Division of Compliance Oversight, OLAW
Neil Dyer, IACUC Chair

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, May 04, 2017 10:03 AM
To: secondary individu
Subject: RE: NDSU Noncompliance Report (45-R-002)

Thank you for this report secondary individ We will respond soon.

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

From: secondary individ [mailto:secondary individ@ndsu.edu]
Sent: Thursday, May 04, 2017 9:42 AM
To: acwest@aphis.usda.gov
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Dyer, Neil <neil.dyer@ndsu.edu>
Subject: NDSU Noncompliance Report (45-R-002)

Please see attached.

secondary individ

Secondary individual

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

Research 1
Dept. 4000, PO Box 6050
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