



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

January 30, 2017

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

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 January 27, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at North Dakota State University, following up on an initial January 11, 2017 telephone notification. According to the information provided, OLAW understands that an apparent miscommunication and misunderstanding between two undergraduate students resulted in the failure to perform daily observations and care to seven mice housed in an experimental room for fifteen days. Three mice died and an additional four moribund mice were euthanized as a result of the inadvertent negligence. It was also identified during the IACUC's investigation of the noncompliant incident that the period of radio frequency exposure may have been ambiguously described in the approved protocol and mice were exposed to radio frequency for a period of thirty one days instead of the IACUC-approved seven days. The associated animal activity in question was not PHS funded.

The corrective actions consisted of the IACUC terminating the protocol and transferring the animals to a holding protocol; mandating additional online and species specific hands-on training for all personnel listed on the protocol; auditing all active protocols at the facility and submitting an SOP to the IACUC on animal care coverage and communications for the facility.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair

NDSU NORTH DAKOTA
STATE UNIVERSITY

January 27, 2017

Dr. Axel V. Wolff
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Re: Noncompliance Incident- NDSU (A3244-01) Protocol A14051 financial informatic

Dear Dr. Wolff:

The Public Health Service Policy and the USDA Animal Welfare Act require that laboratory animals be observed and cared for on a daily basis and that husbandry practices be documented. The purpose of this letter is to report an incident of serious noncompliance in which mice were not being observed or cared for daily.

On Monday, January 9, 2017 the graduate student working under Protocol A14051 contacted Dr. Walden, Attending Veterinarian, to report that 7 mice had died or were euthanized. The IACUC Chair, IACUC Administrator, and Attending Veterinarian met with the research group on Tuesday, January 10, 2017 to gather more information. The following information was obtained from the meeting:

- On Friday, December 23, 2016 the following events took place:
 - Seven mice were moved from the main housing room to the experimental room (adjacent to main housing room)
 - An experiment was started on December 23, 2016 which involved exposing these 7 mice to radio frequency.
 - The mice were placed in the room by the graduate student and one undergraduate student (undergraduate A). There were a total of 38 mice under Protocol A14051 in this facility at the time these 7 were moved.
 - The graduate student sent an email to the following members of the research group: the principal investigator (PI), one faculty member role, one staff member role, and one undergraduate student (undergraduate B). The email stated that 7 animals had been moved to the experimental room. The email asked undergraduate B to contact "the person that looks after the mice" to let them know a group had been placed in the experimental room. (NB- The last day of finals at NDSU was on December 16, 2016.)
- Undergraduate B stated that he did not see the email sent by the graduate student.
- The only reply to the email was received on January 2, 2017 and was from the faculty member role.

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

- Two undergraduates (undergraduate B and undergraduate C) were assigned to care for the animals in the main housing area over the holiday break.
- This facility houses animals for 2 investigators.
- Undergraduate B is listed on all active protocols in the facility.
- Undergraduate B left town on December 15, 2016 and returned on January 6, 2017. The care of the animals was left to undergraduate C who was not listed on protocol A14051. Undergraduate C had completed IACUC training and was listed on the other active protocols but was not familiar with Protocol A14051 procedures. Undergraduate C was unaware the animals were in the experimental room.
- The graduate student stopped by the experimental room on Saturday, December 24, 2016 to observe the animals and check the experimental equipment.
- The 7 animals in the experimental room were not observed again until January 8, 2017.
- Undergraduate B went to care for the animals on Sunday, January 8, 2017.
- Undergraduate B contacted the graduate student to report that he had found 3 deceased mice and 4 in poor condition.
- The remaining 4 mice were euthanized by undergraduate B as directed by the graduate student.
- The PI reported that he had retired from North Dakota State University as of December 31, 2016.

The research group had met prior to the noncompliance meeting and started working on corrective actions for the facility which included revising the room log to include a location to indicate when animals are taken from the room and placing a sign on the door of the experimental room when animals were present.

Per the IACUC's request, the research group submitted room logs, experiment records, animal health records, and documentation regarding animal care coverage over the holiday break. In review of the room logs it was noted that the PI's initials were not on the room logs. When asked if he had visited the rooms, he stated he had not been to the facility since the animals were placed there in May 2016. The room logs only included documentation of visits and observations from undergraduate students B and C.

In reviewing the submitted documents the IACUC Office discovered a potential protocol deviation. The experimental records showed that animals were being exposed to radio frequency for 31 days. The approved IACUC protocol language was not concise. The protocol stated "Listed below is an example of a study that may be performed." The example indicated the exposure time would be 7 days. The IACUC approved the protocol believing that the exposure time would be 7 days at the parameters listed. The PI believed the protocol was approved to explore different parameters.

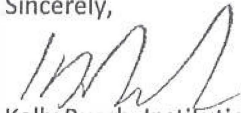
The matter was brought to the IACUC during a regularly scheduled meeting on January 19, 2017. The IACUC reviewed the submitted documentation. The IACUC vote was unanimous for the following actions: a) terminate Protocol A14051 and transfer the animals to the NDSU holding protocol, b) all personnel listed on the protocol must complete additional online training and meet with IACUC personnel following the training, c) all personnel listed on the protocol must update their species specific, hands-on training, d) all active protocols at the facility will be audited, and e) an SOP regarding animal care coverage and communications for the facility must be submitted to the IACUC by Thursday, February 2, 2017.

I also held a meeting with the Attending Veterinarian, IACUC Chair, IACUC Administrator, and the Associate Vice President for Sponsored Programs Administration on January 19, 2017. During the meeting we discussed the current training program and documentation. We also discussed the role of students in conducting animal research.

The IACUC is responsible for the assessment and oversight of the institution's program components and facilities. The IACUC does not currently have a formal post-approval monitoring program. The committee relies on routine procedures (e.g. protocol annual updates, facility inspections, and AV facility rounds) to serve as our post-approval monitoring. The IACUC is in the process of revising and improving the training program to more clearly delineate expectations regarding the supervision of and delegation to students involved in animal research. The IACUC will explore ways to incorporate more aspects of post-approval monitoring into their practices. In addition, the IACUC will work to ensure that approved protocols include clearly stated study procedure parameters that are understood by both the researcher and the IACUC.

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

Sincerely,



Kelly Rusch, Institutional Official

Vice President Research and Creative Activity

cc: Robert Gibbens, Regional Director-USDA Animal Care-Western Division
Vacant, Veterinary Medical Officer
Neil Dyer, IACUC Chair
Scott Walden, Attending Veterinarian

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, January 30, 2017 8:17 AM
To: secondary individu
Subject: RE: NDSU (A3244-01) Report of Noncompliance

Thank you for this report, secondary indivi 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: Friday, January 27, 2017 5:00 PM
To: Wolff, Axel (NIH/OD) [E] <WolffA@OD.NIH.GOV>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: acwest@aphis.usda.gov; Kelly Rusch <kelly.rusch@ndsu.edu>; Secondary individual @ndsu.edu; Neil Dyer <neil.dyer@ndsu.edu>; Scott Walden <scott.walden@ndsu.edu>
Subject: NDSU (A3244-01) Report of Noncompliance

Please see attached.

secondary indivi

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
Fargo, ND 58108-6050

Street/Delivery Address:

1735 NDSU Research Park Dr.
Fargo, ND 58102

Phone telephone #

Fax telephone #

secondary individ@ndsu.edu
www.ndsu.edu/research



Initial Report of Noncompliance

By: Neera Gopee

Date: 1-11-17

Time: 2:45 PM

Name of Person reporting: Secondary individual

Telephone #: telephone #

Fax #:

Email:

Name of Institution: North Dakota State University

Assurance number: A3244-01

Did incident involve PHS funded activity? No

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

7 mice relocated to lab were not cared for from 12-23-16 to 1-8-17. Three died and 4 were euthanized.

Species involved: mice

Personnel involved: research personnel

Dates and times:

Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

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Case # _____