



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) 480-3387

January 4, 2022

Re: Animal Welfare Assurance
A3368-01 [OLAW Case 11Q]

Dr. Nadine Connor
Associate Vice Chancellor
for Research Policy and Compliance
University of Wisconsin-Madison
(b) (4) Bascom Hall – 500 Lincoln Drive
Madison, WI 53706

Dear Dr. Connor,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 30, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Wisconsin - Madison. Your letter supplemented the information in the preliminary telephone report on the same day. According to the information provided, OLAW understands that in August 2021, a macaque received an overdose of an agent prescribed for diabetes mellitus when a more concentrated formulation of the drug was given than what was prescribed. Root cause analysis showed that this occurred because a more concentrated formulation of the agent was ordered, but the concentration was not changed in the electronic health records (EHR) system and the concentration of the agent was not checked prior to administration. In order to prevent a similar incident in the future, several changes have been made to the EHR system, the drug ordering, receiving, and labeling processes. In addition, veterinarians were reminded of the importance of notifying the veterinary technicians when a different concentration of a drug is ordered. All veterinary staff received training on these new procedures. The animal was not adversely affected by the inadvertent overdose. The animal involved was supported by PHS funds.

The consideration of this matter by the University of Wisconsin - Madison was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to address the issue and prevent recurrence were appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -

S

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

Digitally signed by Brent C.
Morse -S
Date: 2022.01.04 10:51:19
-05'00'

cc: IACUC contact

Dr. Robert M. Gibbens, USDA; APHIS, AC



A3368-11Q

November 30, 2021

Dr. Brent Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7892

Dear Dr. Morse:

The University of Wisconsin-Madison, in accordance with Assurance **A3368-01** and PHS Policy IV.F.3, provides this report of an incident first reported to you via telephone by Dr. Janet Welter on November 29, 2021.

In this incident, a macaque received an overdose of an agent prescribed for diabetes mellitus when a more concentrated formulation of the drug was given than what was prescribed. Root cause analysis showed that this occurred because a more concentrated formulation of the agent was ordered, but the concentration was not changed in the electronic health records (EHR) system and the concentration of the agent was not checked prior to administration. In order to prevent a similar incident in the future we have made several changes. Our EHR system has been upgraded to include two additional columns, "Concentration" and "Concentration Units", so staff administering treatments can quickly and easily double check the drug concentration when preparing treatments. When ordering drugs, vet staff will now use an order form that will make it obvious when a new concentration of the drug is ordered, and whenever a new concentration of a drug is received, a sticker that says "Stop - Check Concentration" will be placed on the drug boxes and bottles. When different concentrations of the same drug are available in our facilities, a "Stop - Check Concentration" will be placed on all of the boxes and bottles. In addition, veterinarians were reminded of the importance of notifying the veterinary technicians when a different concentrations of a drug is ordered. All veterinary staff received training on these new procedures at one of their weekly meetings. The animal was not adversely affected by the inadvertent overdose. The animal involved was supported by PHS funds.

The LSVC ACUC discussed this incident in full committee and determined that the corrective steps taken were appropriate. If you have further questions, please feel free to contact either of us or Dr. Janet Welter.

Sincerely,

(b) (6)

Ricki Colman, Ph.D.
Chair, LSVC ACUC

Research Animal Resources Center

396 Enzyme Institute University of Wisconsin-Madison 1710 University Avenue Madison, Wisconsin 53726-4087
608/262-1238 Fax: 608/265-2698 Email: help@rarc.wisc.edu <http://www.rarc.wisc.edu>

(b) (6)

Nadine P. Connor, Ph.D.
Professor and Oros Family Chair in Communication Sciences & Disorders
Associate Vice Chancellor for Research Policy & Compliance
Institutional Official

xc: (b) (6)
Janet Welter
AAALAC-I

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, December 10, 2021 7:58 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Incident Report from Nadine Connor @ UW-Madison

Thank you for these 6 reports, (b) (6) We will send responses soon.

Axel Wolff

From: (b) (6)
Sent: Wednesday, December 8, 2021 2:24 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: AAALAC International <accredit@AAALAC.org>; Nadine Connor <nadine.connor@wisc.edu>; RICKI COLMAN <rcolman@primate.wisc.edu>; (b) (6) Janet Welter <welter@rarc.wisc.edu>
Subject: [EXTERNAL] Incident Report from Nadine Connor @ UW-Madison

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dr. Morse:

Please see the attached incident final report from Nadine Connor @ UW-Madison. Thanks!

(b) (6)



Initial Report of Noncompliance

By: (b) (6)

Date: 11/30/2021

Time: 3:50

Name of Person reporting: Janet Welter, DVM, AV

Telephone #: (b) (6)

Fax #: (b) (6)

Email: (b) (6)

Name of Institution: University of Wisconsin - Madison
Assurance number: A3368 WNPRC

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? One macaque received an overdose of metformin due to unnoticed ↑ concentration. No adverse health issues.

Species involved: Macaque

Personnel involved: _____

Dates and times: August 2021

Animal deaths: No.

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

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY
Case # _____