

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

July 29, 2021

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 480-3387

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

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 July 9, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Wisconsin-Madison. Your letter supplemented the information contained in an initial telephone report to this office on July 8, 2021. According to the information provided, OLAW understands that a macaque was given a higher than intended dose of corticosteroids to treat gastrointestinal inflammation. The concentration of the drug listed in the institution's electronic health record (EHR) system was lower than the concentration available in the animal area. The discrepancy was discovered after two days of treatment by an animal caretaker. No adverse effects to the animal involved were noted. The macaque involved in this incident was supported by PHS funds.

A root cause analysis was conducted that led to the following corrective and preventive measures: (1) Veterinary staff must ensure that all available concentrations of a given agent are uploaded into the EHR prior to making the agent available for administration. (2) The individual administering the agent must verify that the available concentration is appropriate for use prior to administration. (3) Inventory sheets will be posted in each treatment area to ensure that all staff know what agents and concentrations are available. The Institutional Animal Care and Use Committee discussed the incident at a convened meeting and considered the corrective steps taken to be appropriate.

OLAW appreciates the consideration of this matter by the University of Wisconsin-Madison which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely, Robyn M. Engel - Digitally signed by Robyn M. Engel -S Date: 2021.07.30 07:25:31 - 04'00'

Robyn M. Engel, DVM Animal Welfare Program Specialist Office of Laboratory Animal Welfare

cc: IACUC contact



July 9, 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 July 8, 2021.

In this incident, a macaque was prescribed a corticosteroid to reduce GI inflammation. The concentration of the corticosteroid in the WNPRC Electronic Health Record (EHR) system was lower than the concentration available in the animal area, thus the animal received a higher than intended dose of the drug for two days until the discrepancy was discovered by an animal caretaker.

A root cause analysis evaluation indicated that the incident occurred because the appropriate concentration of the agent was not available in the animal area and was not verified prior to administration. This analysis led to the conclusion that veterinary staff must ensure that all available concentrations of a given agent are uploaded into the EHR prior to making the agent available for administration. In addition, the individual administering the agent must verify that the concentration indicated on the bottle is appropriate for that use before preparing the agent for administration. The analysis also revealed that inventory sheets should be posted in each treatment area to ensure that all staff know what agents and concentrations are available. No adverse effects to the animal involved were noted. 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,

Ricki Colman, Ph.D. Chair, LSVC ACUC (b) (6)

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 http://www.rarc.wisc.edu by Rise for Animals. Uploaded to Animal Research Laboratory Overview (ARLO) on 08/01/2022



(b) (6)

Nadine P. Connor, Ph.D. Associate Vice Chancellor for Research Policy & Compliance Institutional Official

xc:

Janet Welter AAALAC-I

Wolff, Axel (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Monday, July 19, 2021 7:38 AM
To:	(b) (6)
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: Incident Reports from Nadine Connor @ UW-Madison

Thank you for these reports. We will send responses soon.

Axel Wolff, M.S., D.V.M. Deputy Director, OLAW

(b) (6)

From: Sent: Monday, July 12, 2021 11:51 AM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Cc: AAALAC International <accredit@AAALAC.org>; Nadine Connor <nadine.connor@wisc.edu>; (b) (6) (b) (6) RICKI COLMAN <rcolman@primate.wisc.edu>; Janet Welter <welter@rarc.wisc.edu> Subject: Incident Reports from Nadine Connor @ UW-Madison

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Dr. Morse:

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

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