



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 11V]

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 on October 26, 2021, an adult male macaque received an IV infusion of an immunologic agent as described in the protocol. At the end of the infusion, the IV catheter was supposed to be flushed with saline but was inadvertently flushed with a small portion of the same animal's anti-retroviral therapy dose which was supposed to be administered subcutaneously. The animal experienced no adverse effects because of the IV anti-retroviral therapy dose. Root cause analysis revealed that all syringes utilized during the procedure were labeled appropriately and that this was a case of human error. In the future, anti-retroviral therapy will be administered prior to the immunological agent to eliminate the possibility of a similar incident. 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

Digitally signed by Brent C.
Morse -S
Date: 2022.01.04 11:01:06 -05'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

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



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, an adult male macaque received an IV infusion of an immunologic agent as described in the protocol. At the end of the infusion, the IV catheter was supposed to be flushed with saline but was inadvertently flushed with a small portion of the same animal's anti-retroviral therapy dose which was supposed to be administered subcutaneously. The animal experienced no adverse effects because of the IV anti-retroviral therapy dose. Root cause analysis revealed that all syringes utilized during the procedure were labeled appropriately and that this was a case of human error. In the future, anti-retroviral therapy will be administered prior to the immunological agent to eliminate the possibility of a similar incident. 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

(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

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>

Uploaded to Animal Research Laboratory Overview (ARLO) on 08/01/2022

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 Walter, 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? _____

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? Macaque receiving IV infusion. Catheter flushed w/ anti-retroviral instead of saline.

Species involved: Macaque

Personnel involved: Researcher.

Dates and times: 10/26/21

Animal deaths: No

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

Changing procedure to prevent issue.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____