



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

October 18, 2022

Re: Animal Welfare Assurance
A3368-01 [OLAW Case 12J]

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 October 7, 2022 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's Wisconsin National Primate Research Center. Your letter supplemented the information in the preliminary telephone report on September 26, 2022. According to the information provided, OLAW understands that between June 2021 and March 2022, two macaques underwent leukapheresis three times, but the protocol only allowed up to two leukapheresis procedures per animal. Neither animal exhibited any adverse side effects as a result of the additional procedure. The animals involved were supported by PHS funds.

To prevent a repeat occurrence, the process for scheduling these procedures has been altered.

The consideration of this incident by the University of Wisconsin - Madison was consistent with the philosophy of institutional self-regulation. Similarly, the action taken to prevent recurrence was 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: 2022.10.18 14:15:41 -04'00'

cc: IACUC contact

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



Research Animal Resources and Compliance

October 7, 2022

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 a protocol violation first reported to you via telephone by (b) (6) on October 7, 2022.

In this protocol violation, two macaques underwent leukapheresis three times, but the protocol only allowed up to two leukapheresis procedures per animal. Neither animal exhibited any adverse side effects as a result of the additional procedure. The process for scheduling these procedures has been altered to prevent a similar incident in the future. The animals involved were 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 (b) (6).

Sincerely,

(b) (6)

Ricki Colman, Ph.D.
Chair, LSVC ACUC

(b) (6)

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

xc:

(b) (6)

AAALAC-I

Research Animal Resources and Compliance

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>

McCoy, Devora (NIH/OD) [E]

From: (b) (6)
Sent: Tuesday, October 11, 2022 3:49 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: AAALAC International; Nadine Connor; (b) (6) RICKI COLMAN;
(b) (6)
Subject: [EXTERNAL] Incident Report from Nadine Connor @ UW-Madison
Attachments: LSVC.5.24.22.D.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dr. Morse:

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

(b) (6)

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, October 12, 2022 12:04 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Incident Report from Nadine Connor @ UW-Madison

Good afternoon (b) (6)

Thank you for sending us this final report and we will send a response soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: (b) (6)
Sent: Tuesday, October 11, 2022 3:49 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>; (b) (6)
(b) (6) RICKI COLMAN <rcolman@primate.wisc.edu>;
(b) (6)
Subject: [EXTERNAL] Incident Report from Nadine Connor @ UW-Madison

Dr. Morse:

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

(b) (6)

A3368-12J



Initial Report of Noncompliance

By: BCM

Date: 9/26/2022

Time: Voicemail

Person Reporting: (b) (6)
Telephone #: (b) (6)
Fax #:
Email:

Name of Institution: Univ. of Wisconsin (Madison) WNPRC
Assurance number: A3368-12J

Did incident involve PHS funded activity? yes

Funding component:

Was funding component contacted (if necessary):

What happened: Two NHPs were subject to three leukapheresis procedures instead of just two as approved in protocol.

Species involved: Macaque

Personnel involved: Researcher

Dates and times: June 2021 – March 2022

Animal deaths: no

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

Projected submission to OLAW of final report from Institutional Official:

< 60 days

OFFICE USE ONLY

Case #