

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 Fassimile: (301) 480-3387

April 11, 2022

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

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 March 29, 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 July 6, 2021. According to the information provided, OLAW understands that 27 marmosets across two protocols underwent blood collection for oral glucose tolerance test (OGTT) during which larger than 0.2ml per samples were collected across the 5 draws. In no case was the maximum single draw volume percent of 15% of total available blood volume exceeded. The animals involved were supported by PHS funds.

Corrective and preventive measures: one of the protocols has been terminated as the study was completed. For the other protocol, blood draws for the glucose tolerance test were revised to state: One test= 5 samples that combined will not exceed 15% of total available blood volume.

The consideration of this incident 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 -

Digitally signed by Brent C. Morse -S Date: 2022.04.11 11:26:33

=04'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC contact

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

March 29, 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 series of related incidents first reported to you via telephone by Dr. Janet Welter on September 9, 2021.

These incidents involved protocol approved blood collection for oral glucose tolerance test (OGTT) in marmosets. Per the blood collection section of the protocol for this test, the maximum single draw volume for one test was stated as '~0.2 ml x 5 samples'. The max single draw volume (percent) row listed 15% of total available blood volume. Elsewhere in the blood collection section it was stated that routine blood draws may occur and listed the 15% maximum as a potential single-draw volume.

A total of 27 marmosets across two protocols underwent blood collection for OGTT during which larger than 0.2ml per samples were collected across the 5 draws. In no case was the maximum single draw volume percent of 15% of total available blood volume exceeded. These larger samples were collected for assay validations and additional testing. It was assumed this was permitted under the routine blood draw category. However, the experimental narrative had failed to note that blood might be needed to develop/refine bioassays.

One of the protocols has been terminated as the study was completed. For the other protocol, blood draws for the glucose tolerance test were revised to state: One test = 5 samples that combined will not exceed 15% of total available blood volume. Additionally, in the Experimental Narrative, it is stated that blood collection may be needed for bioassay development/refinement. 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 Dr. Janet Welter.

Sincerely,

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(b) (6)

Nadine P. Connor, Ph.D. 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: Monday, April 4, 2022 7:32 AM (b) (6) To: Cc: OLAW Division of Compliance Oversight (NIH/OD) Subject: RE: Incident Report from Nadine Connor @ UW-Madison (b) (6) We will respond soon. Thank you for this report, Axel Wolff (b) (6) From: Sent: Friday, April 1, 2022 2:57 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) 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)



Division of Compliance Oversight

Record of Call for Case # A 3368-11 I

Date & Time	Message	Initials
3/2/22	Spoke W/Dr. Welter, She	(b) (c
3/2/22	Spoke W/Dr. Welter, She will provide final report	

Morse, Brent (NIH/OD) [E]

From:

Morse, Brent (NIH/OD) [E]

Sent:

Wednesday, December 22, 2021 8:31 AM

To:

Janet Welter

Subject:

Three open OLAW cases?

Importance:

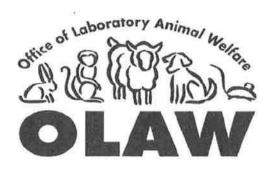
High

Hi Janet,

Not sure if our wires got crossed, but I have three open cases that you reported on July 6th. They involve a sheep; mice given human buprenorphine, and; 27 marmosets (at WNPRC) that had too much blood taken for glucose tolerance tests. Please update me on the status of these reports. Thank you.

Best regards, Brent

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health



Initial Report of Noncompliance

By: BCM

Date:	7/6/2021	Time: 4:00
	Person Reporting: Janet Welter, AV Telephone #: Fax #: Email:	
Name Assu	of Institution:Univ. of Wisconsin (Madison)_W rance number:A3368	NPRC
Fund	cident involve PHS funded activity?? ling component: funding component contacted (if necessary):	
	rmosets had blood taken for blood glucose test validated but within recommended volumes. No negative of	
Per Dat	cies involved: Marmoset sonnel involved: PI es and times: ? mal deaths: no	
Projec	eted plan and schedule for correction/prevention (if k	nown):
Projec	ted submission to OLAW of final report from Institu	tional Official:
< 60 d	ays	
	CE USE ONLY #	