



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, 2021

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

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) receipt of your October 14, 2021 letter in response to OLAW's September 23, 2021 request for information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Wisconsin-Madison. According to the information provided, OLAW understands that training is provided to research personnel when they first join the animal program. In addition, reminders about protocol compliance are provided at various timepoints such as semi-annual inspections of laboratories, preparation for regulatory inspection, directed or routine post-approval monitoring and both online and in-person classes. Retraining is also provided when non-compliance events occur.

OLAW appreciates the prompt consideration of this matter by University of Wisconsin-Madison which is consistent with the philosophy of institutional self-regulation. OLAW expects continuing post-approval monitoring to prevent recurrence of this non-compliance and potential associated animal welfare concerns. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence.

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

CC: IACUC contact

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



Office of the Vice Chancellor for  
Research and Graduate Education  
UNIVERSITY OF WISCONSIN-MADISON

October, 14, 2021

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910

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

Dear Dr. Lukovsky-Akhsanov:

This letter replies to your request for more information regarding A3368-01 OLAW Case 11M:

"Please provide details regarding any training conducted for research personnel on the topic of protocol compliance."

Research personnel at UW-Madison receive training in protocol compliance when they first join the animal program (Animal User Orientation; Figure 1), and this training is refreshed every five years via an Animal User Recertification module. Through these modules, personnel are taught:

- that a protocol is a contract between the research team and the IACUC that approved the protocol,
- to know and understand the contents of their protocol (Figure 2),
- they cannot perform a procedure on an animal if the procedure is not listed in an approved protocol (Figure 3),
- they cannot deviate from procedures and care defined within the protocol (Figure 4), and
- that deviations from a protocol can have serious consequences on, among other things, animal welfare, research quality and public trust (Figure 5).

During these trainings, researchers are provided contact information if they have questions, concerns or need to amend their protocol.

We continue to reinforce this training throughout a researcher's tenure in the animal program, providing them with reminders about protocol compliance:

- at the end of every email sent to people required to take species-specific training,
- at the end of every species-specific online module,
- during every hands-on class taught by the University's animal program trainers (Figure 6),
- during every class on Surgery Fundamentals,
- at semi-annual IACUC inspections of laboratories,
- during the preparation for every AAALAC site visit, and
- during every directed or routine post-approval monitoring exercise.

Office of the Vice Chancellor for Research and Graduate Education  
333 Bascom Hall 500 Lincoln Drive Madison, Wisconsin 53706 608-262-1044

During on-boarding sessions and regular ongoing interactions, veterinarians develop rapport with research staff and teach the importance of communication. It is worth noting that the event that prompted this correspondence was self-reported by the PI.

Finally, when non-compliance events occur, retraining is provided as described in the original letter.

If you have any questions, please contact either of us.

Sincerely,

(b) (6)

Daniel Uhlrich, PhD  
SMPH ACUC Chair

(b) (6)

Nadine Connor, PhD  
Institutional Official

## Menu

### ▼ Course Outline

#### Introduction

- Wisconsin Discoveries
- Protocols Are Contracts
- The 3 Rs
- AWA, PHS
- ACUC Policies
- The Guide
- AAALAC
- Inspections
- RARC
- Safety
- Whistleblower Law
- Know Your Species
- Next Steps
- Record Course Completion

## Animal User Orientation

Figure 1



Thank you for joining the ranks of University of Wisconsin researchers who study animals to better understand health, basic biology, and social issues.

Your role comes with obligations to animals, UW-Madison, the public, and federal, state, and local regulations.

This module introduces the concepts and regulations that you need to know.

# ANIMAL USER ORIENTATION



BEGIN

Figure 2

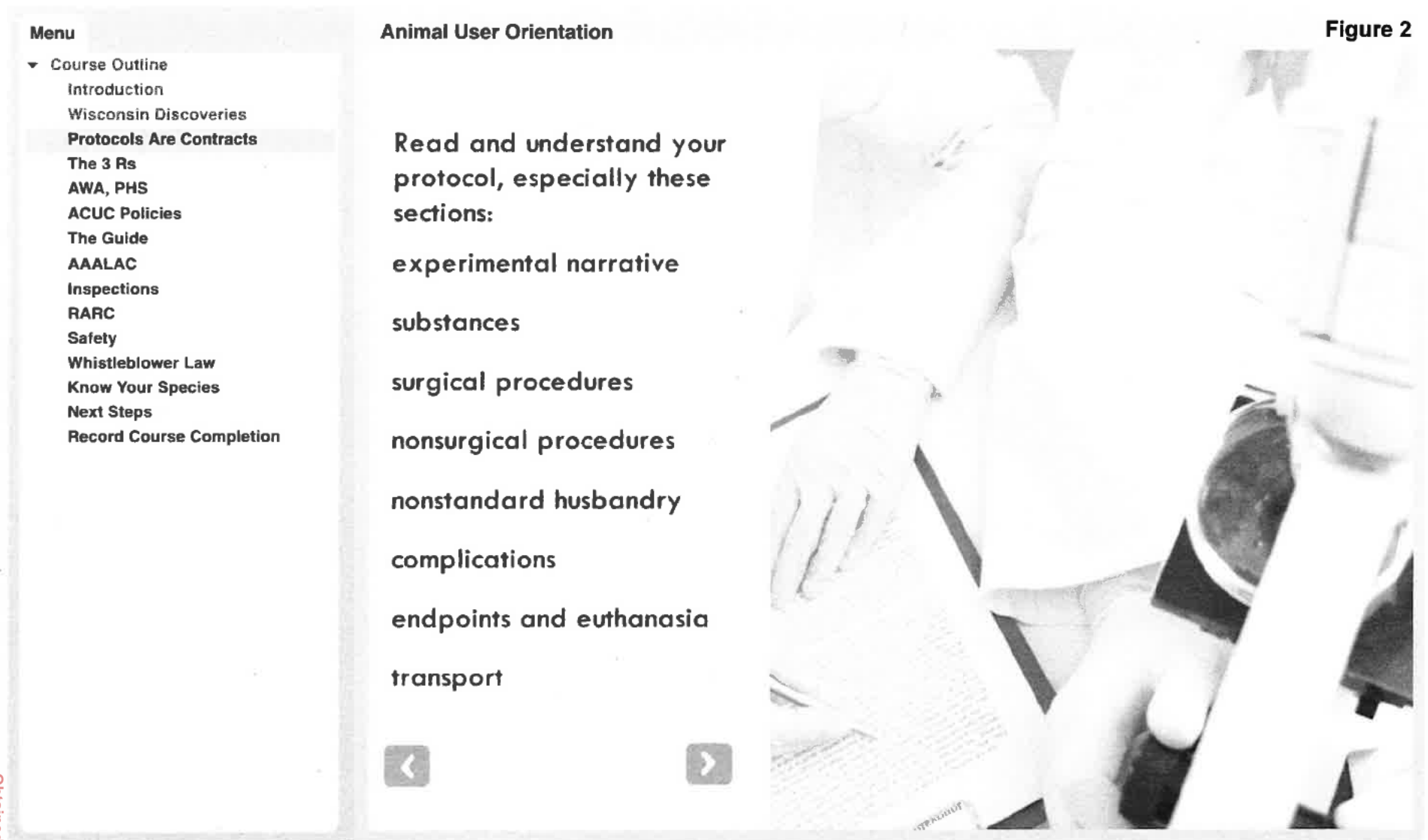


Figure 3

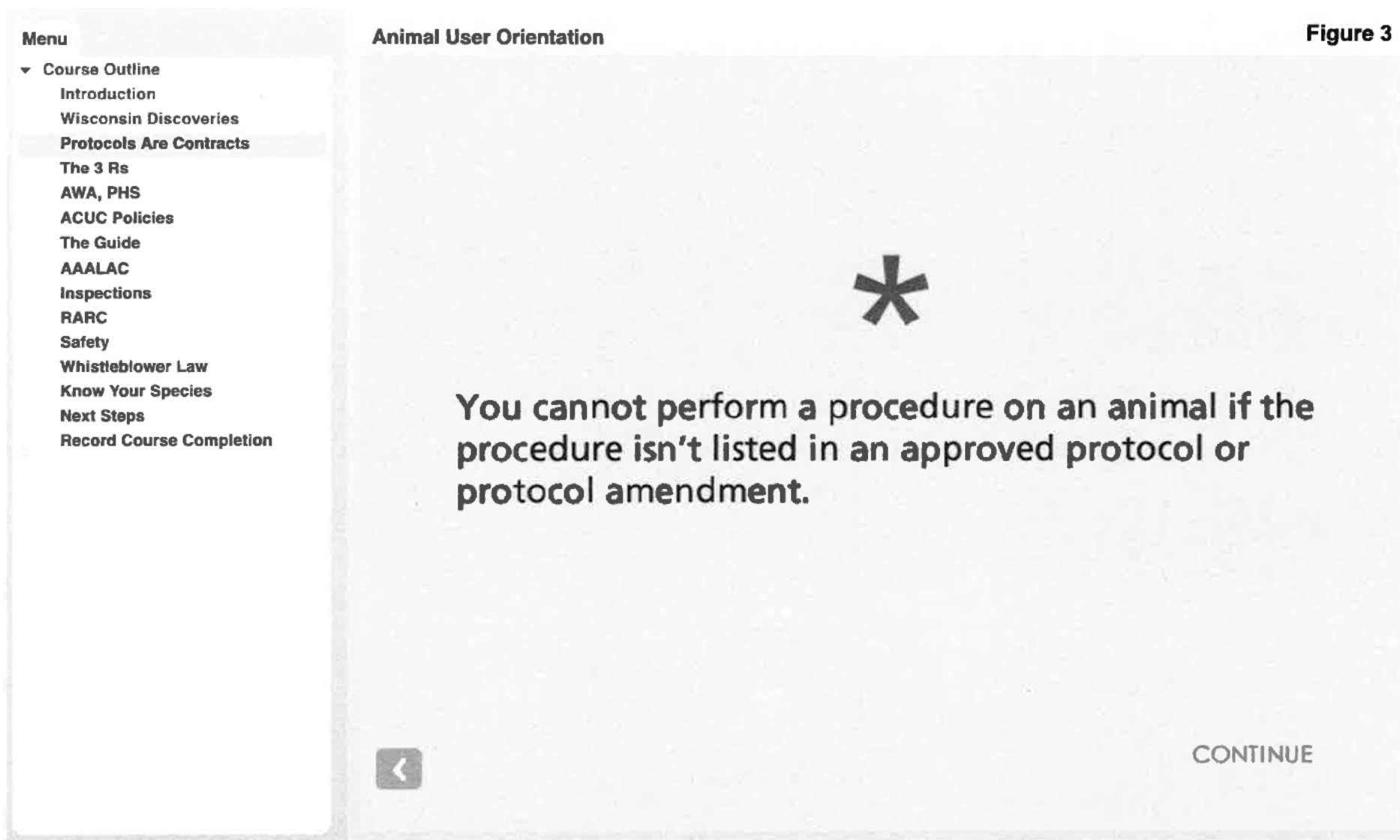



Figure 4

<b>If you are named on an IACUC-approved protocol,</b>	<b>If you are not named on an IACUC-approved protocol,</b>
read and understand the parameters of your work with animals. You can find your protocol at <a href="http://arrow.wisc.edu">arrow.wisc.edu</a>	understand that the rules you are following are based on federal regulations and campus policies.
You cannot deviate from procedures and care defined within the protocol.	You cannot deviate from these rules.
<b>Check the appropriate box and then initial below.</b>	
I am named on an IACUC-approved protocol. I have read the protocol and agree to continue to abide by what is described within. <input type="checkbox"/>	I am <u>not</u> named on an IACUC-approved protocol, but I understand that I must follow rules as described in all SOPS, UW Madison policies, and federal regulations for animal care. <input type="checkbox"/>
<i>initial below</i>	
<div> <span>◀ PREV</span> <span>SUBMIT</span></div>	

## Protocol and policy violations have consequences.

You can impact animal welfare, research and reputations if you deviate from the IACUC-approved protocol or campus policies. When you don't follow your protocol and policies -

- you can harm animals
- your collected data cannot be used for journal manuscripts or grant applications
- the IACUC can revoke your animal-use privileges or access to animal facilities
- federal agencies can demand the return of grant funds or assess fines
- you violate public trust
- you can damage the reputation of your lab and UW-Madison

☐

I understand that protocol or policy violations have serious repercussions.

*initial below to acknowledge*



← PREV

SUBMIT →

Figure 5

# Mouse Training

Figure 6

**Prerequisites:** ( *Animal User Orientation* or *RARC Animal User Recertification* )

This training consists of two sections: an online module, followed by a hands-on training. You must finish both sections to complete the training.

Related Information ▾

Contacts ▾

**You completed this course:** 11/03/09

We are happy to help! If you would like additional training, please put a check mark next to the procedures that are listed in your protocol that you are required to know. Then click the 'Request training' button to email a training session request to the trainers.

**Handling**

☐ General handling

☐ Restraint

**Injections**

☐ IM (Intramuscular)

☐ IP (Intraperitoneal)

☐ IV - Retro-orbital

☐ IV - Tail vein

☐ SQ (Subcutaneous)

**Blood collection**

☐ Aorta

☐ Brachial artery

☐ Cardiac

☐ Maxillary

☐ Pedal vein

☐ Retro-orbital

☐ Saphenous vein

☐ tail nick or tail vein

**Genotyping and Identification**

☐ Ear tag/notch

☐ Tail snip

**Anesthesia and Euthanasia**

☐ Cervical dislocation

☐ CO2

☐ Isoflurane

**Other**

☐ Oral gavage

☐ Other Techniques

☐ Pathology

Request training

Reset



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September 23, 2021

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

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 August 12, 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. According to the information provided, OLAW understands that a laboratory was performing a non-surgical procedure on rabbits which called for a topical anesthetic however the anesthetic was found to be expired. The lab withheld use of the expired agent as the experiments were already in-progress. The animals were heavily sedated with ketamine/xylazine during the procedure and monitored post-procedure by staff including veterinary staff. No adverse effect on animal well-being was noted. This study was supported by PHS funding.

As a corrective measure, lab members were retrained to ensure that all supplies are on hand prior to the start of experiments. The Principal Investigator (PI) has also been instructed to inventory medications on a regular basis to ensure fresh stock is ordered in a timely manner.

OLAW appreciates the prompt consideration of this matter by University of Wisconsin-Madison which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW requests the following information:

- Please provide details regarding any training conducted for research personnel on the topic of protocol compliance.

We look forward to your responses to the to the additional information request by **October 15, 2021** to [Nicole.Lukovsky@NIH.gov](mailto:Nicole.Lukovsky@NIH.gov). We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

CC: IACUC contact  
Dr. Robert M. Gibbens, USDA, APHIS, AC



A3368-11M

**Office of the Vice Chancellor for  
Research and Graduate Education**  
UNIVERSITY OF WISCONSIN-MADISON

August 12, 2021

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

Dear Dr. Morse:

This letter is to report a June event that occurred in the UW School of Medicine and Public Health (SMPH). This research is supported by NIH.

A laboratory was performing a non-surgical procedure on rabbits to infect their eyes with an experimental agent. The protocol calls for use of topical anesthetic drops on the eyes. However, the team discovered that their topical anesthetic had expired. Since the experiments were in-progress, the lab decided to withhold the topical anesthetic rather than use the expired drug.

The PI reports that the rabbits were sedated heavily with a ketamine/xylazine mixture during the procedure, and staff closely observed the animals for several hours afterwards. Veterinary staff also assessed the animals. No adverse effect on animal well-being was detected.

To avoid future such incidences, lab members were retrained on the importance of ensuring that all supplies are on-hand before they begin experiments. The PI has also been instructed to inventory medications on a regular basis to make certain fresh stock is always ordered in a timely manner when needed.

The SMPH ACUC discussed the event and corrective actions at their July 12, 2021 meeting. The Committee approved the assessment report and the corrective actions.

If you have any questions, please contact Dr. Janet Welter or either of us.

(b) (6)

Daniel Uhlrich, PhD  
SMPH IACUC Chair

(b) (6)

Nadine Connor, PhD  
Institutional Official

**Office of the Vice Chancellor for Research and Graduate Education**  
333 Bascom Hall 500 Lincoln Drive Madison, Wisconsin 53706 608-262-1044

## Wolff, Axel (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, August 16, 2021 7:08 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Incident Report from Nadine Connor @ UW-Madison

Thank you for this report. We will send a response soon.

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

**From:** (b) (6)  
**Sent:** Friday, August 13, 2021 11:16 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) Janet Welter <welter@rarc.wisc.edu>; Dan Uhlrich <dan.uhlrich@wisc.edu>  
**Subject:** Incident Report from Nadine Connor @ UW-Madison

Dr. Morse:

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

(b) (6)