



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) 402-7065

August 21, 2019

Re: Animal Welfare Assurance  
A3102-01 [OLAW Case 1W]

Dr. Ann B. Nattinger  
Senior Associate Dean for Research  
Medical College of Wisconsin  
8701 Watertown Plank Road  
Milwaukee, WI 53226

Dear Dr. Nattinger,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 15, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Medical College of Wisconsin. According to the information supplied OLAW understands that on July 31, 2019 a PI self-reported that on July 16, 17, or 30, 2019 five rats were administered an anti-inflammatory drug at doses greater than what were approved in the Animal Use Application (AUA). The animals showed no adverse effects. The related animal activity is funded by the PHS.

To address the issue, the PI submitted an Animal Amendment for IACUC review and submitted a written report to the IACUC detailing actions taken to correct the oversight and steps that would be taken to prevent a future similar recurrence.

The prompt consideration of this matter by the Medical College of Wisconsin was consistent with the philosophy of institutional self-regulation. Similarly, the corrective actions taken to resolve the issue and prevent recurrence are accepted by OLAW. This incident should be reported by your institution as subcontractor to the primary contractor who is responsible for conduct of the contract. We find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC Contact



August 15, 2019

Brent Morse, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare (OLAW)  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892

Re: Medical College of Wisconsin  
Assurance Number: D16-00064 (A3102-01)  
Animal Use Application: 246

Dear Dr. Morse,

We wish to report a noncompliant situation involving the administration of a drug at a dose not approved by the IACUC. This letter will describe the incident and our IACUC's response. We are also notifying AAALAC, International.

#### Incident

On Wednesday, July 31, 2019, immediately after discovering the error, a Principal Investigator informed our IACUC Chair and one of our veterinarians that a total of 5 rats had each received one dose of an anti-inflammatory drug on July 16, 17, or 30, 2019 at doses greater than what were approved in the Animal Use Application (AUA). The animals showed no adverse effects and an Animal Amendment was immediately submitted for IACUC review to correct the oversight. In addition to the Animal Amendment, the PI submitted a written report to the IACUC detailing the incident, the events that led up to it, actions taken to correct the oversight, and steps that would be taken to prevent a future similar recurrence.

#### IACUC Action

The IACUC discussed the self-report at a meeting on August 7, 2019. Because of the PI's proactive approach to the matter and because the animals showed no adverse effects, the IACUC decided not take any further disciplinary action.

Records indicate that funding for this study includes a grant from the National Institutes of Health (NIH), HHSN272201800012C (subcontracted from Innovation Pathways).

Please let me know if you have questions.

Respectfully,

(b) (6)

Ann B. Nattinger, MD, MPH  
Associate Provost for Research  
8701 Watertown Plank Road  
Milwaukee, WI 53226

O: (b) (6)

F: (b) (6)

Email: [anatting@mcw.edu](mailto:anatting@mcw.edu)

cc: John D. Imig, PhD, MCW IACUC Chair

(b) (6)

Joseph Thulin, DVM, DACLAM, MCW Attending Veterinarian

(b) (6)

**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, August 20, 2019 7:29 AM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Imig, John; Thulin, Joseph; (b) (6) Nattinger, Ann  
**Subject:** RE: Reportable Event - Medical College of Wisconsin, Assurance Number D16-00064 (A3102-01)

Thank you for providing this report (b) (6) We will send an official response soon.

Best regards, Brent Morse

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

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**From:** (b) (6)  
**Sent:** Monday, August 19, 2019 5:33 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Imig, John <jdimig@mcw.edu>; Thulin, Joseph <jthulin@mcw.edu>; (b) (6)  
Nattinger, Ann <anatting@mcw.edu>  
**Subject:** Reportable Event - Medical College of Wisconsin, Assurance Number D16-00064 (A3102-01)

Hello,

Attached please find a written report of a reportable situation from the Medical College of Wisconsin, Assurance Number D16-00064 (A3102-01).

Respectfully,

(b) (6)

(b) (6)