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

December 17, 2018

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

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 December 4, 2018 letter reporting a series of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Medical College of Wisconsin, following up on an initial September 25, 2018 email notification. According to the information provided, OLAW understands that a cat was anesthetized with an unapproved anesthetic and transported to an unauthorized location where an decerebration procedure was performed without prior IACUC approval. The animal activities in question were PHS-funded.

The corrective actions consisted of Principal Investigator implementing an action plan which included discussing all prior and proposed studies at biweekly meetings to ensure all laboratory personnel understand procedures approved under each protocol and developing score sheets for each animal use protocol to document all activities for each experiment upon completion.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. Your prompt and thorough resolution of this matter is commendable and consistent with the PHS Policy philosophy of monitored self-regulation. We appreciate having been informed of this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair
Dr. Robert M. Gibbens, Director Western Sector, USDA, APHIS, AC

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MEDICAL COLLEGE OF WISCONSIN

December 4, 2018

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 Applications: 2972 and 3388

Dear Dr. Morse,

We wish to provide an update as to the resolution of the 2 noncompliant situations initially reported on September 25, 2018, one involving the use of an unapproved anesthetic and both involving the conduct of procedures in a location not approved by the IACUC. We are also notifying AAALAC, International.

The IACUC initially discussed these 2 incidents at a meeting on September 19, 2018. Because the Committee was unable to determine a course of action based on the information originally provided by the Principal Investigators (PIs), a subcommittee was formed to further investigate and report back to the IACUC on October 3, 2018.

With regards to AUA 3388 (conduct of procedures in a location not approved by the IACUC), the subcommittee confirmed that IACUC approval was in place for all the procedures which were performed on the rats and that the only noncompliance was in fact the conduct of procedures in a room not approved by the IACUC. The PI submitted an Amendment to add the room. The IACUC agreed that the initial self-report and subsequent amendment were sufficient to address the noncompliance; no further action was required.

With regards to AUA 2972 (use of an unapproved anesthetic and conduct of procedures in a location not approved by the IACUC), based on additional information obtained by the subcommittee, the IACUC determined that all procedures and anesthetics used on the cats were approved under a different AUA. The PI was required to provide an Action Plan describing the steps he planned to take to improve recordkeeping and prevent recurrence of similar situations. The Committee found the initial Action Plan

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unclear, and the subcommittee met with the PI to obtain the necessary clarification. The results of that meeting were presented to the IACUC on November 21, 2018. The IACUC accepted the PI's revised Action Plan which included the following:

1. Conduct of lab meetings every 2 weeks to fully discuss all prior and proposed studies so that all lab members understand which procedures are approved under which AUAs.
2. Creation of score sheets for each AUA so that all actions of every experiment are recorded at the time they are completed. (The IACUC reviewed the score sheets and found them acceptable.)

The IACUC agreed that no further information was necessary from the PI.

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:
Email: anatting@mcw.edu

cc: John D. Imig, PhD, MCW IACUC Chair
(b) (6)
Joseph Thulin, DVM, DACLAM, MCW Attending Veterinarian
(b) (6)

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Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, December 06, 2018 3:15 PM
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. Doctor Gopee 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: Thursday, December 06, 2018 2:15 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: RE: Reportable Event - Medical College of Wisconsin, Assurance Number D16-00064 (A3102-01)

Hello,

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

Respectfully,

(b) (6)

(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Wednesday, September 26, 2018 8:41 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Reportable Event - Medical College of Wisconsin, Assurance Number D16-00064 (A3102-01)

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Good morning and thank you Sandra for these reports. We will open two case files and await your Oct. final reports.

Regards,
Joan

From: (b) (6)
Sent: Wednesday, September 26, 2018 9:30 AM
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)

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MEDICAL COLLEGE OF WISCONSIN

September 25, 2018

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 Applications: 2972 and 3388

Dear Dr. Morse,

We wish to report 2 noncompliant situations, one involving the use of an unapproved anesthetic and both involving the conduct of procedures in a location not approved by the IACUC. This letter will detail the incident and the actions taken by our IACUC. The incidents are under further investigation; we will send an additional letter once the investigation is complete. At that time, we will also notify AAALAC, International.

Incident

On Thursday, September 6, 2018, the IACUC Chair received word from a Principal Investigator (PI) that on August 28, 2018, a cat was anesthetized using alpha-chloralose prior to being transported to a blood pressure recording room in order to record the effects of a treatment on blood pressure and heart rate. According to the animal record, the animal apparently was not decerebrated as described in the AUA. In addition, the AUA did not include approval to use either alpha-chloralose or the room in which blood pressure recordings were taken.

Records indicate that funding for this study, AUA 2972, includes a grant from the National Institutes of Health (NIH), 2P01 DK068051.

Also on Thursday, September 6, 2018, the IACUC Chair received an email from another PI who works closely with the first PI, stating that his lab also conducted blood pressure recordings on rats in the same blood pressure recording room without having prior IACUC approval to use that room.

Records indicate that funding for this study, AUA 3388, includes a grant from the National Institutes of Health (NIH), 2R01 DK025731.

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IACUC Action

The IACUC discussed these self-reports at a meeting on September 19, 2018. The Committee was unable to determine a course of action based on the information originally provided by the PIs. A subcommittee was formed to further investigate by comparing the written self-report(s) with the animal record(s) and the approved AUAs. The subcommittee will report back to the IACUC on October 3, 2018. At that time, the Committee will determine an Action Plan to address the situation(s).

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:
Email: anatting@mcw.edu

cc: John D. Imig, PhD, MCW IACUC Chair
(b) (6)
Joseph Thulin, DVM, DACLAM, MCW Attending Veterinarian
(b) (6)

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Ward, Joan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, September 26, 2018 9:41 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Event - Medical College of Wisconsin, Assurance Number D16-00064 (A3102-01)

Good morning and thank you (b) (6) for these reports. We will open two case files and await your Oct. final reports.

Regards,
Joan

From: (b) (6)
Sent: Wednesday, September 26, 2018 9:30 AM
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)

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