



# USDA-APHIS-Animal Care



| ANIMAL WELFARE COMPLAINT   |   |   |                           |
|--|---|---|---------------------------|
| Complaint No.<br>AC19-450  | Date Entered:<br>27-Jun-19                | Processed By:<br>ASC                              |                           |
| Referred To:<br>Barksdale/Hovancsak  |   | Reply Due:<br>28-Jul-19                           |                           |
| <b>Facility or Person Complaint Filed Against</b>  |   |   |                           |
| Name:<br>Meidcal College of Wisconsin  |   | Customer No.:<br>634                              | License No.:<br>35-R-0029 |
| Address:<br>8701 Watertown Plank Rd  |   | Email Address:                                    |                           |
| City:<br>Milkwaukee  | State:<br>WI                              | Phone No.:<br>414-955-4209                        |                           |
| <b>Complainant Information</b>   |   |   |                           |
| Name:<br>(b) (6), (b) (7)(C), (b) (7)(D)   |   | Organization:<br>(b) (6), (b) (7)(D)              |                           |
| Address:<br>(b) (6), (b) (7)(C), (b) (7)(D)  |   | Email Address:<br>(b) (6), (b) (7)(C), (b) (7)(D) |                           |
| City:<br>(b) (6), (b) (7)(C), (b) (7)(D)   | State:<br>(b) (6), (b) (7)(C), (b) (7)(D) | Phone No.:<br>(b) (6), (b) (7)(C), (b) (7)(D)     |                           |
| How was the Complaint received?<br>Email   |   |   |                           |
| Details of Complaint:<br>SEE ATTACHED  |   |   |                           |
| <b>Results:</b><br>On June 01, 2019 a focused inspection was conducted that involved a review of records including IACUC minutes, protocols, semi annual inspections/review. While reviewing the October 2018 IACUC minutes the following was noted:<br><br>1. On September 6, 2018, the IACUC was notified by a Principal Investigator that several days prior (August 29, 2018), a cat was anesthetized using alpha-chloralose prior to being transported to a blood pressure recording room to record the effectson blood pressure and heart rate. A subcommitte was convened on September 24, 2018 to look into what took place in the lab. It was determined that the both the alpha cloralose used for anesthesia and room to measure blood pressure/heart rate had not been approved in the protocol. The protocol indicated the animal to be used for the procedure (cat) would be decerebrated, however, the cat involved had not been decerebrated.<br>2. Based on the findings the subcommittee determined the following:<br>a. The committee required the principal investigator to review the protocol to clarify if a new protocol was needed to include the correct anesthetic and room to be used for blood pressure and heart rate measurements or an amendment to the current approved protocol.<br>b. The principal investigator was required to develop a score sheet template to be used while monitoring the health of the animal before, during and post procedure.<br>c. Post approval monitoring will be used to assess the lab and principal investlgator's adherence to the IACUC's requirements. |   |   |                           |



## USDA-APHIS-Animal Care



|  |                    |
|--|--------------------|
| Application Kit Provided:<br>Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/> |                    |
| Inspector:<br>DAWN BARKSDALE, VMO  | Date:<br>27-Jun-19 |
| Reviewed By:<br>Cathy Hovancsak, SACS  | Date:<br>27-Jun-19 |



Animal and Plant  
Health Inspection  
Service

June 27, 2019

Animal Care  
4700 River Road  
Riverdale, MD 20737

(b) (6), (b) (7)(C), (b) (7)(D)

Dear Complainant,

Thank you for your correspondence dated 26-Jun-19. We are reviewing your concerns and assigned tracking number AC19-450. Please allow us enough time (30 to 60 days) to thoroughly look into your concerns. You may submit a request to the Animal and Plant Health Inspection Service (APHIS) Freedom of Information Act (FOIA) office to obtain any publically available information regarding our review.

FOIA Requests can be submitted three ways:

1. Web Request Form: <https://efoia-pal.usda.gov/App/Home.aspx>
2. Fax: 301-734-5941
3. US Mail:  
USDA- APHIS- FOIA  
4700 River Road, Unit 50  
Riverdale, MD 20737

Should you have any questions regarding the APHIS FOIA process or need assistance using the Web Request Form **please contact the APHIS FOIA office at 301-851-4102.**

Animal Care is a program within the U.S. Department of Agriculture (USDA) that directs activities to ensure compliance with and enforcement of the Animal Welfare Act and the Horse Protection Act. Animal Care establishes standards of humane treatment for regulated animals and monitors and achieves compliance through inspections, enforcement, education, and cooperative efforts under the Acts.

Please be assured that we will look into your concern(s) and take appropriate action(s).

Thank you for your interest into the humane treatment of these animals.

Sincerely,

Betty Goldentyer  
Associate Deputy Administrator  
Animal Care

From: (b) (6), (b) (7)(C), (b) (7)(D)  
To: Goldentyer Betty J - APHIS  
Cc: ACEAST  
Subject: Official Complaint -- Medical College of Wisconsin  
Date: Wednesday, June 26, 2019 5:37:43 PM

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(b) (6), (b) (7)(C), (b) (7)(D)

Dr. Elizabeth Goldentyer

6/26/19

USDA/APHIS/AC  
920 Main Campus Drive, Suite 2000  
Raleigh, NC 27606

Dr. Goldentyer,

I am writing to you today to file an Official Complaint against the Medical College of Wisconsin (35-R-0029), for what I believe are clear violations of the Animal Welfare Act which occurred recently.

I have obtained correspondence between the Medical College of Wisconsin, and the NIH which discusses clear AWA violations. Medical College of Wisconsin correspondence dated 9-25-18 states:

***"On Thursday, September 6, 2018, the IACUC Chair received word from a Principal Investigator (PI) that on August 29, 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."***

This incident clearly violates multiple sections of the Animal Welfare Act including, but not limited to, Sec. 2.31 Institutional Animal Care and Use Committee (IACUC) for performing unapproved procedures (an approved procedure would require that the animal had had the cerebrum removed), use of an unapproved anesthetic (alpha-chloralose), and performing the procedure in an unapproved location. Also, use of the unapproved anesthetic alpha-chloralose may also violate Sec. 2.33 Attending veterinarian and adequate veterinary care [(Lab Anim Sci. 1993 Jun;43(3):210-6. A review of laboratory animal anesthesia with chloral hydrate and chloralose) "CS should not be used as a sole anesthetic agent." (CS is the abbreviation used in this publication for alpha-chloralose)].

The violations which occurred at this institution clearly indicate a total disregard for federal regulations, as well as proper veterinary care.

I know that your office considers major violations of the Animal Welfare Act to be very serious in nature, especially when these violations have the potential to cause pain to animals. The treatment of animals at this facility illustrates attitudes of carelessness and negligence that must be punished so that meaningful changes can be made. Therefore, I also insist that you take the most severe action allowable under the Animal Welfare Act and immediately begin the process of issuing the maximum fine allowable against the Medical College of Wisconsin at the completion of your investigation.

I look forward to hearing from you in the near future about the fate of this facility.

Sincerely,

(b) (6), (b) (7)(C), (b) (7)(D)

(b) (6), (b) (7)(C), (b) (7)(D)

(b) (6), (b) (7)(C), (b) (7)(D)



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.

8701 Watertown Plank Road  
P.O. Box 26509  
Milwaukee, WI 53226-0509

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)

(b) (6), (b) (7)(C)

8701 Watertown Plank Road  
Milwaukee, WI 53226

O: (b) (6)

F:

Email: (b) (6), (b) (7)(C)

cc: (b) (6), (b) (7)(C)

(b) (6)

(b) (6), (b) (7)(C)

(b) (6)