



# ANIMAL WELFARE COMPLAINT

Complaint No.						
Complaint No.	Date Entered:	Processed By: SSE				
AC19-172 15-Mar-19 Referred To:						
Moore/Yager			Reply Due:			
Moore/Yager 16-Apr-19 Facility or Person Complaint Filed Against						
Name: Customer No.: License No.:						
University of Houston			1458		74-R-0020	
Address:			Email Address:			
RM 10 SCIENCE & RESEARCH 2 BLDG						
City: State:		Phone No.:				
Houston TX						
Complainant Information						
Name: Organization:						
(b) (6), (b) (7)(C), (b) (7)(D)			(b) (6), (b) (7)(			
Address:			Email Address:			
(b) (6), (b) (7)(C), (b) (7)(D)			(b) (6), (b) (7)(C), (b) (7)(D)			
City:		State:	Pł	none No.:		
How was the Complaint received?						
Email						
Details of Complaint:						
SEE ATTACHED						
Results:						
Full routine Inspection	Full routine Inspection conducted on April 24, 2019 with no non-compliances identified.					
In February 2018 su	In February 2018 surgical procedure resulted in rhabdomylosis, subsequent renal failure and death					
of a primate. IACUC and inspector review indicated there was adequate care before, during and after						
surgical procedure. Identical procedures previously and subsequesntly performed without						
complications. Additional precautions were implemeted to prevent recurrances.						
In September/October 2017 an adult macaque was unintentionally placed on a restricted diet for 17						
days over a 23 day period. Normal feeding was conducted on weekends with biscuit restriction on						
weekdays. Food enrichment items were provided twice daily on weekdays. The animal demonstrated						
normal behavior and physical appearance during all daily observations. The diet restriction error was						
discovered during routine physical exam/testing under sedation. Weight loss may have been up to						
18.6 %, body condition score deviated from 2.5 to 2/5. Appropriate corrective actions were taken and						
changes were initiated to prevent recurrances. There appeared to be no severe or serious impact on animal welfare.						
Application Kit Provided:						
Yes:	No: 🕅					
Inspector:					Date:	
Mary Moore					29-May-19	
Reviewed By:					Date:	
Cody Yager					29-May-19	



**USDA-APHIS-Animal Care** 





Animal and Plant Health Inspection Service

Animal Care Western Region

March 15, 2019

Dear Complainant:

Thank you for your correspondence dated 5-Mar-19 concerning University of Houston. Your complaint has been issued number AC19-172. Depending on the circumstances of the situation, please allow us enough time (30 to 60 days) to thoroughly look into your concerns. After that time, the status of our findings may be requested through the Freedom of Information Act (FOIA) office.

### FOIA Requests can be submitted three ways:

- 1. Web Request Form: <u>https://efoia-pal.usda.gov/App/Home.aspx</u>
- 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 the division of the U.S. Department of Agriculture (USDA) that is responsible for the enforcement of the Animal Welfare Act. The Act provides minimum standards for the humane care and use of animals at USDA licensed or registered facilities.

Animal Care inspectors conduct routine unannounced inspections at all USDA licensed and registered facilities to ensure that they are meeting or exceeding these minimum standards. Our inspectors also conduct searches when necessary in response to valid concerns and complaints received from the public to ensure the well-being of the animals and compliance with the law. If violations are found enforcement action appropriate for the circumstances will be initiated.

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

Thank you for your interest into the welfare of these animals.

Sincerely,

Bernadette Juarez Deputy Administrator USDA APHIS Animal Care

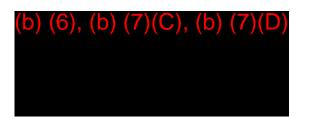
An Equal Opportunity Provider and Employer

### Ennis, Sari - APHIS

From:
Sent:
To:
Cc:
Subject:

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

Tuesday, March 5, 2019 3:32 PM Gibbens, Robert - APHIS AC West Official Complaint -- University of Houston



Dr. Robert Gibbens 3/5/19 Director, Western Region, USDA/APHIS/AC, 2150 Center Ave. Building B, Mailstop 3W11 Fort Collins, CO 80526-8117

Dr. Gibbens,

I am writing to you today to file an Official Complaint against the University of Houston (74-R-0020 UH) for clear violations of the Animal Welfare Act.

University of Houston correspondence dated 7/31/18 contains the following statement which discloses an animal death caused by negligence:

"An adult rhesus macaque recently underwent an IACUC-approved procedure, during which the upper body was placed in ventral recumbency while the lower body was place on its right side; this is the routine positioning for animals undergoing this procedure. Upon recovery from anesthesia, the right rear limb was swollen and the animal was unwilling to move the limb; veterinary staff suspected something wrong with the leg itself and/or neurological deficits related to manipulations conducted as part of the surgery. Veterinary care and treatment were provided, including the administration of dexamethasone, meloxicam, and antibiotics. Despite careful monitoring and continued treatment (including the above plus IV fluids for mild dehydration, vitamin B12 and buprenorphine), the primate's condition unfortunately declined and she died several days later."

It is eminently clear that this monkey was severely injured during the surgery, which was clearly not performed as designed. Therefore, this is an obvious violation of Sec. 2.38 Misc. (f)(1) Animal Handling. This incident should be considered critical because it took the life of the animal in question, and if procedures such as this are similarly botched in the future more monkeys will die.

Additional UH correspondence dated 3/6/18 states:

"One nonhuman primate (NHP) did not receive adequate food over a 23 -day period. NHPs must be fed at least once each day except as otherwise might be required to provide adequate veterinary care . . . In this situation, the primate was placed on food restriction by Animal Care Operations (ACO) staff prior to notification from the research laboratory. The animal was then partially restricted for approximately 23 days, not including weekends. The animal subsequently lost 20% of its body weight."

This is a clear violation of Sec. 3.82 Feeding

These violations indicate clear negligence which in one incident took the life of an animal, and in another case caused the animal to lose 20% of his/her body weight in the course of approximately 3 weeks.

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

I know that your office considers major violations of the Animal Welfare Act to be very serious in nature, especially when these violations kill or seriously injure animals. Since the University of Houston has now demonstrated a pattern of serious violations, this facility must be severely penalized to avoid further non-compliances which will endanger even more animals. Therefore, I must insist that you take the most severe action allowable under the Animal Welfare Act and immediately begin the process of launching a full investigation of this facility, and at the completion of the investigation, issuing the maximum fine allowable against the University of Houston at the completion of your investigation -- \$10,000 per infraction/per animal.

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



Attachments: 2 NIH Reports

Sincerely,

#### Date: July 31, 2018

To: Brent Morse, DVM, DACLAM Director, Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health Rockledge 1, Suite 360, MSC 7982 6705 Rockledge Drive Bethesda, MD 20892-7982 olawdco@mail.nih.gov

Re: University of Houston, Reportable Event (Assurance A3136-01) Funding: National Eye Institute: R01 EY026568

Dear Dr. Morse,

As Institutional Official for the University of Houston, I have the duty to inform you of a reportable event having occurred in the abovementioned federally funded research project.

HOUSTON

**Division of Research** 

#### Unanticipated Event:

An adult rhesus macaque recently underwent an IACUC-approved surgical procedure, during which the upper body was placed in ventral recumbency while the lower body was place on its right side; this is the routine positioning for animals undergoing this procedure. Upon recovery from anesthesia, the right rear limb was swollen and the animal was unwilling to move the limb; veterinary staff suspected something wrong with the leg itself and/or neurological deficits related to manipulations conducted as part of the surgery. Veterinary care and treatment were provided, including the administration of dexamethasone, meloxicam, and antibiotics. Despite careful monitoring and continued treatment (including the above plus IV fluids for mild dehydration, vitamin B12 and buprenorphine), the primate's condition unfortunately declined and she died several days later.

The IACUC worked closely with Animal Care Operations (ACO) and the Principal Investigator (PI) to review all related surgery, anesthesia, and medical records, as well as histopathology/necropsy reports in detail. The necropsy report ultimately indicated extensive necrosis of the muscle of the right rear limb due to ischemia during surgery, leading to infiltration of the blood with myoglobin. The level of myoglobin subsequently led to acute renal necrosis/failure, causing death. Per the PI, brain tissue was sent for histopathological analysis as part of standard research procedures. No abnormal findings were noted, therefore it is believed that the outcome relates directly to the positioning of the animal during a long surgical procedure, and not to the IACUC-approved surgery outlined in the protocol. The IACUC also agreed that adequate veterinary judgment was utilized throughout the short course of the animals' decline.

#### Resulting institutional action:

Although this issue has not occurred in previous nor subsequent surgeries, the Attending Veterinarian immediately drafted written recommendations to further advise and retrain ACO surgical staff on the prevention of pressure, ischemic, and nerve injuries, including the placement of padding and positioning during surgery.

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A3136-Z

Additional padding was ordered for the surgical table and is now being utilized. The Pi stated that additional surgical procedures on other protocols have been conducted utilizing the padding and additional turning of the animal to avoid pressure injuries; he was complimentary of staff and felt these changes had positive impact. The IACUC accepted these actions and will be notified (and will initiate further investigation) should additional events occur.

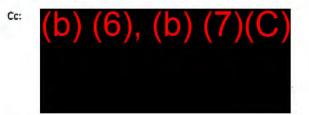
If you have any questions, please do not hesitate to contact me.

(b) (6)

Sincerely,

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A3136-W

# UNIVERSITY of HOUSTON Division of Research

Date: March 6, 2018

To: Axel Wolff, MS, DVM Director, Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health Rockledge 1, Suite 360, MSC 7982 6705 Rockledge Drive Bethesda, MD 20892-7982 <u>olawdco@mail.nih.gov</u>

Re: University of Houston, Reportable Event (Assurance A3136-01) Funding: National Eye Institute: R01 EY026568

Dear Dr. Wolff,

As Institutional Official for the University of Houston, I have the duty to inform you of an incident of serious noncompliance regarding the unintentional partial fasting of research animal by husbandry staff, inconsistent with the approved research protocol. The animal in question is an adult rhesus macaque taking part in a research study funded by the National Institutes of Health.

At its February 2018 fully convened meeting, the University of Houston IACUC determined the following finding to be substantiated:

 One nonhuman primate (NHP) did not receive adequate food over a 23-day period. NHPs must be fed at least once each day except as otherwise might be required to provide adequate veterinary care [*The Guide*, 8<sup>th</sup> Edition, p 31<sup>1</sup>, p 56<sup>2</sup>]

In this situation, the primate was placed on food restriction by Animal Care Operations (ACO) staff prior to notification from the research laboratory. The animal was then partially restricted for approximately 23 days, not including weekends. The animal subsequently lost 20% of its body weight.

Following sedation for routine TB and B-virus testing, an ACO clinical veterinarian found the animal to be thin. When preliminary discussion with the laboratory research technician and husbandry staff revealed that the animal had been erroneously fasted, this issue was self-reported to the IACUC for further investigation.

Key information:

The animal was participating in a research protocol that involved a surgical procedure; the completion of this
surgical procedure is typically followed by behavioral training, which involves IACUC-approved restricted
access to food.

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<sup>&</sup>lt;sup>3</sup> The Guide, page 31: "The animals should be closely monitored to ensure that food and fluid intake meets their nutritional needs [Toth and Gardiner 2000]."

<sup>&</sup>lt;sup>2</sup> The Guide, page 56: "At a minimum, animals must have enough space to express their natural postures and postural adjustments without touching the enclosure walls or ceiling, be able to turn around, and have ready access to food and water."

- Based on the surgical date and previous experience with this particular research protocol, the current standing work order for this protocol<sup>3</sup> was preemptively edited by an ACO supervisor to add this primate; the order was posted prior to receiving a formal request from the Principal Investigator (PI) to add the animal to the behavioral training group. The behavioral training was not initiated by the research team for this animal during this time frame.
- During the time period the animal was fasted:
  - o The animal had restricted access to food and received water ad libitum.
  - During the work week (Monday Friday), the NHP received a novelty and occupational enrichment food items per standard operations, but was not fed any biscuits.
  - o On Saturdays and Sundays, the animal was fed a standard ration of biscuits.
  - The animal was observed daily, in its cage, by members of the animal care staff (clinical veterinarians, veterinary technicians, supervisors); no abnormal behaviors were observed and/or noted during this time.
- Once the animal recovered from anesthesia (following the routine testing procedure during which the weight loss was dis Fcovered), fluids and vitamin supplementation were administered subcutaneously, and fruit and biscuits were offered. The vet reported that following anesthesia, the NHP appeared bright and alert, with a healthy appetite. The animal has since regained and continues to maintain a healthy body weight.

### Corrective action:

As part of disciplinary action, the supervisor responsible for the error was immediately instructed by the attending vet to hold a meeting with the husbandry staff and ACO veterinarians to discuss the issues involved in the work order process. During this time, the work order process underwent structured analysis, resulting in significant improvements specifically aimed toward avoiding a similar unintended fasting situation in the future, including:

- The submission of separate work orders for each individual procedure; if procedures and/or restrictions
  for the weekends do not match those for the work week, separate work orders must be submitted.
- Visual Cues: additional visual cues (e.g., color-coded acetates specific to type of restriction, removal of feeders from cages, visual (magnetic) notation of completion) have been added.
- Daily communication processes regarding work orders have been more clearly defined.

Investigators were notified regarding the changes to the work order process .

In addition to the ACO-initiated changes, the IACUC also requires:

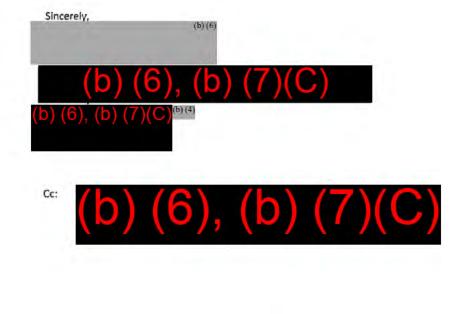
- The creation of a long-term (~6-9 month) training and/or mentoring plan must for the responsible supervisor. The plan should provide a generous amount of various opportunities for:
  - Additional NHP training focused on species-specific details and related regulatory requirements
  - Hands-on NHP training
  - Shadowing/mentoring opportunities in the area of NHPs

The IACUC will review this plan concurrent with initiation.

<sup>3</sup> When a research animal has been placed on restricted access to food, the ACO husbandry team does not provide the animal with food except on the weekends; the research staff provides the animal with food as part of the behavioral training in accordance with the IACUC-approved procedures.

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If you have any questions, please do not hesitate to contact me.



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