

USDA-APHIS-Animal Care



ANIMAL WELFARE COMPLAINT						
Complaint No.	nplaint No. Date Entered:		Proces	Processed By:		
AC20-025	21-Oct-19		AVB			
Referred To:			Reply Due:			
Kent / Niemann			22-Nov-19			
	Facility or	Person Compla	int File	d Aga	inst	
Name:			Customer No.:).:	License No.:
Washington Universi	ty		1444	1444 43-R-0008		43-R-0008
Address:				En	nail Addr	ess:
660 S Euclid Campus	Box 8106					
City:		State:		Phone No.:		
Saint Louis		MO	(314) 362-3229			
	Co	omplainant Info	rmatio	n		
Name: (b) (6), (b) (7)(C), (b) (7)(D)			Organ	ization	1:	
Address: (b) (6), (b) (7)(C), (b)	(7)(D)				nail Addr 6), (b) (7)(C),	
City:		State:			e No.: (7)(C), (b) (7)(D	
How was the Complaint received?						
Email						
Details of Complaint:						
SEE ATTACHED						

Results:

On the days of November 4 through November 6 in 2019, Harvey Kent, VMO and I conducted a routine inspection at Washington University. We inspected the animals, facilities and paperwork. There were no noncompliant items documented on the inspection report. The project referred to in the complaint involving an experimental surgery, during which a pig developed ventricular fibrillation, was a procedure that was described in a written protocol which had been reviewed and approved by the IACUC. This was in compliance with the Animal Welfare Act. When unforeseen complications arose with the IACUC approved surgical procedure and during which a pig experienced ventricular fibrillation, it was explained to the inspectors that the veterinary staff had been involved in the care of the animal, which is also in accordance with AWA regulations. It was further explained that the IACUC, which provides institutional oversight for the animal care and use program, made the decision to suspend the protocol to allow time for supplemental training for staff who already had 25-30 years' experience with the procedure and species involved; an interventional cardiologist was also added to the protocol to help ensure success with subsequent procedures. The institution did report the suspension of the protocol to Animal Care's office.

The complaint also includes non-compliances that have previously been identified and documented on USDA inspection reports. Multiple non-compliances for the same issue are only cited when appropriate.



USDA-APHIS-Animal Care



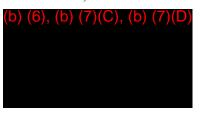
As a facility registered with the USDA, unannounced inspections will continue that the regulations and standards of the AWA are met, including the correct compliances.	·
Application Kit Provided:	
Yes: No: No:	
Inspector:	Date:
Erika Leisner	7-Nov-19
Reviewed By:	Date:
Jamilon Niemann, SACS	20-Nov-19

United States Department of Agriculture

October 21, 2019

Animal and Plant Health Inspection Service

Animal Care 4700 River Road Riverdale, MD 20737



Dear Complainant:

Thank you for your corresopondence dated 13-Oct-19. We are reviewing your concerns and assigned tracking number AC20-025. 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. U.S. Mail: USDA-APHIS-FOIA 4700 River Road, Unit 50 Riverdale, MD 20737

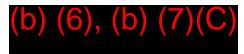
Should you have any questions regarding the APHIS FOIA process or need assistance using the Web Request Form please contact the APHIS FOIA office at 301-851-4102.

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

An Equal Opportunity Provider and Employer

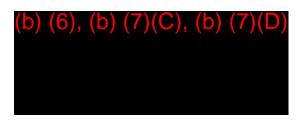
Benson, Amy V - APHIS

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

Sent: Sunday, October 13, 2019 1:31 PM

To: Gibbens, Robert - APHIS

Cc:APHIS-AnimalCare; acwest@aphis.usda.govSubject:Official Complaint Washington University



Dr. Robert Gibbens

10/12/19
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 a third Official Complaint against Washington University (43-R-0008), for clear violations of the Animal Welfare Act.

I am in possession of Washington University (WASHU) correspondence which discloses the suspension of a project which involves an experimental surgery, during which a pig developed ventricular fibrillation, and was euthanized. The initial report states: "Pig was euthanized due to ventricular fibrillation while performing surgery. IACUC determined training deficiency . . ." The final report states: "The IACUC suspended the protocol until additional training activities could be completed." The death of this animal is clearly due to the fact that the staff performing this procedure was untrained/unqualified. This is made obvious by the fact that the protocol was suspended 'until additional training activities could be completed.' Therefore this incident potentially violates Sec 2.31 Institutional Animal Care and Use Committee (IACUC) (d) IACUC review of activities involving animals (viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures

This incident also violates Sec. 2.32 Personnel qualifications. (a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.

The fact that this project was suspended to provide more training following an animal death, clearly indicates that the staff performing this surgical procedure was not adequately trained before the procedure, and therefore not only was the staff unqualified, this death was entirely preventable and unnecessary. Therefore this should constitute a serious violation of the Animal Welfare Act.

Additionally, the correspondence indicates that this incident was reported to AAALAC, however no indication exists that this incident was reported to the USDA. The IACUC regulation states: Sec. 2.31 Institutional Animal Care and Use Committee (IACUC) (7) If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity; Therefore, WASHU's failure to report this incident to the USDA/APHIS/AC is yet another failure to comply with federal regulations.

This incident demonstrates a continuing disregard for both the well-being of the animals at Washington University as well as the Animal Welfare Act and the authority of the USDA to enforce this act.

This facility has previously received three CRITICAL citations for three animal deaths in three inspections within 16 months, with the most recent one being in June of 2018. This latest death was reported at roughly the same time as another animal death, a dog who also died in connection to another surgical procedure.

This is clearly an extremely grave situation and must be dealt with accordingly to prevent even more negligent animal deaths at Washington University. This criminally negligent lab has now killed a pig, a dog, a monkey, and a rabbit within roughly two years. These incidents have now resulted in three CRITICAL violations of the same code section within the Animal Welfare Act Sec. 2.33 ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE, and a fourth violation of s separate code section should be issued. This law-breaking lab must be penalized before any more animals die. What is your office waiting for? How high must the death toll go?

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

As you know, Washington University was inspected on 6/27/17. This inspection contains yet another CRITICAL citation for failure to comply with 2.33 CRITICAL ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE. The report states: "The incident involved a dog recovering from anesthesia for a surgical procedure approved by the IACUC. The principal investigator's laboratory staff that was monitoring the dog's recovery communicated with the attending veterinarian about some concerns they had. The lab staff confirmed with the attending veterinarian by email that they would contact the on-call veterinarian if any complications occurred overnight as the animal continued to recover. When complications did arise, the lab staff failed to contact the on-call veterinarian. The laboratory staff attempted medical interventions, but the dog did not survive. At this time the lab staff contacted the on-call veterinarian to tell them what happened. The Director of the Division of Comparative Medicine confirmed that failure to communicate the complications with the veterinarian violated the research facility's policy. The director and attending veterinarian also stated that if the complications had been communicated to a veterinarian earlier, then the veterinarian would have suggested other interventions than what the lab staff provided." The failure of Washington University staff to provide adequate veterinary care for this animal caused this death.

As you also know, Washington University was inspected on 8/23/17. This inspection also contains a CRITICAL, citation for failure to comply with 2.33 ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE. This citation states: "On June 1, 2017 an adult male cynomolgus macaque died unexpectedly during transport... after the conclusion of a MRI and PET scan procedure. The IACUC self-identified that there was non-compliance with the facility's IACUC policies and a failure to follow the protocol.... the animal experienced ongoing complications such as hypothermia, hypotension, wet lung sounds and fluid in the endotracheal tube during the anesthetic procedure... Although interventional steps were taken, including assistance from the Division of Comparative Medicine's (DCM) veterinary technicians, and the laboratory staff felt the animal was stable, the animal's Sp02 values continued to be low and the animal died before the planned euthanasia. The IACUC also determined that the on-call veterinary staff should have been contacted prior to when a veterinarian had been called given the ongoing complications noted throughout the procedure." Again, the failure of Washington University staff to provide adequate veterinary care for this animal caused this death.

Another citation for violating 2.33 ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE was issued during the 3/7/17 USDA inspection:

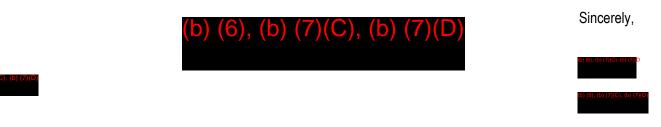
"In September 2016 the facility self-reported an incident to the Office of Laboratory Animal Welfare (OLAW) and USDA. The facility suspended a protocol as a result of inadequate intraoperative monitoring, as approved in the study protocol, and subsequent failure to identify a malfunctioning heating pad that may have contributed to the unexpected death of a rabbit undergoing a non-survival surgical procedure. According to anesthesia records, there was a period of approximately 4 hours in which no temperature was recorded while the animal was under anesthesia for this procedure. This is contrary to the approved protocol which states that a rectal temperature will be monitored and recorded every 15 minutes. Written records indicate that the animal died while under anesthesia and it is recorded that the animal's blood pressure dropped due to hypothermia and hemodilution. It was also noted in the records that the water-heated mat under the animal had turned off, leading to hypothermia." Again, the failure of Washington University to provide adequate veterinary care for this animal caused a death

I know that your office considers major violations of the Animal Welfare Act to be very serious in nature, especially when these violations unnecessarily kill animals. Since the Washington University has now committed three violations of exactly the same section of the Animal Welfare Act in three inspections within sixteen months and all three of these citations were CRITICAL, and all three of these citations were directly linked to the death of an animal, and another violation should be issued relevant to the death of a fourth animal, I must 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 Washington University at the completion of your investigation -- \$10,000 per infraction/per animal.

As long as your office continues to consider enforcement of the Animal Welfare Act a priority, you must take serious action against labs which repeatedly kill animals. You must make an example of Washington University.

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





Initial Report of Noncompliance

By: Maera Gagas

Date: 6-1-18	Time: 11:18 000	
Name of Person reporting: Telephone #: Fax #: Email:		
Name of Institution: Was Assurance number: A3	thington University St Lows	* * * * * * * * * * * * * * * * * * *
Did incident involve PHS fur Funding component: Was funding component co	ontacted (if necessary):	
What happened? Rig was authorized Surgers Tacuc Species involved: % y Personnel involved: Dates and times: Animal deaths:	TRUC Superbay Estilles	the surious broadure
		ac 95
Projected plan and schedule	for correction/prevention (if known):	
Projected submission to OL	AW of final report from Institutional Official:	
OFFICE USE ONLY Case #		
P q. S		

Washington University in St. Louis

Institutional Animal Care and Use Committee

Brent Morse, DVM, Acting 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 July 12, 2019 Assurance # D16-00245 (A3381-01)

Re: IACUC Protocol #20160210 "Antithrombotic and Cardioprotective Therapy with Minimal Bleeding Risk for PCI"

Dear Dr. Morse:

Washington University in St. Louis (WU), in accordance with Assurance D16-00245 (A3381-01) and PHS Policy IV.F.3., is providing a final report for a protocol suspension initially reported June 1, 2018.

A single pig experienced ventricular fibrillation during surgery and was euthanized. The IACUC determined that the length of the procedure and challenges with the surgical supplies may have contributed to the adverse event. The IACUC suspended the protocol until additional training activities could be completed. No non-compliance was associated with this suspension. The pause in activities was solely to allow sufficient time for supplemental training activities.

In response, the protocol was modified to include additional non-survival training animals and the investigator demonstrated a successful procedure in a training animal prior to the next survival surgery. In addition, an interventional cardiologist or other trained specialist was added to the protocol to provide support during subsequent procedures.

The IACUC reviewed and discussed the incident during the May 24, 2018 meeting and approved the proposed retraining plan. All activities were completed in June 2018 and the suspension lifted. Although the protocol is supported by NIH funds [R44HL135993], no direct costs were found to be associated with the suspension. If associated costs are identified, those funds will be returned.

Please let me know if you have questions or need additional information.

Sincerely,

(6)(6)

Johnsfer K. Lodge, Ph.D. Institutional Official Vice Chancellor for Research

C: AAALAC, International

Campus Box 1054, One Brookings Drive, St. Louis, Missouri 63130, (314)362-3229, Fax (314)747-6695, http://asc.wustl.edu



2016082569195950 Insp_id

Inspection Report

Washington University

660 S Euclid

Campus Box 8106

Saint Louis, MO 63110

Customer ID: 1444

Certificate: 43-R-0008

Site: 004

WASHINGTON UNIVERSITY

Type: FOCUSED INSPECTION

Date: 27-JUN-2018

2.33(b)(2) CRITICAL

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

In June of 2018 the facility self-reported an incident to USDA. The incident involved a dog recovering from anesthesia for a surgical procedure approved by the IACUC. The principal investigator's laboratory staff that was monitoring the dog's recovery communicated with the attending veterinarian about some concerns they had. The lab staff confirmed with the attending veterinarian by email that they would contact the on-call veterinarian if any complications occurred overnight as the animal continued to recover. When complications did arise, the lab staff failed to contact the on-call veterinarian. The laboratory staff attempted medical interventions, but the dog did not survive. At this time the lab staff contacted the on-call veterinarian to tell them what happened. The Director of the Division of Comparative Medicine confirmed that failure to communicate the complications with the veterinarian violated the research facility's policy. The director and attending veterinarian also stated that if the complications had been communicated to a veterinarian earlier, then the veterinarian would have suggested other interventions than what the lab staff provided. The facility shall establish and maintain programs of adequate veterinary care including the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care. Failure to do so can jeopardize the welfare of animals. This item has been corrected. The IACUC promptly investigated this incident and took corrective actions to prevent future occurrences.

This was a focused inspection limited to information pertaining to the self-reported incident.

This inspection on Jun 27, 2018 and exit interview on July 2, 2018 were conducted with facility representatives.

Prepared By: SNOW WILLIAM, D V M

SNOW WILLIAM, D V M USDA, APHIS, Animal Care

Date: 02-JUL-2018

Title: VETERINARY MEDICAL OFFICER 6125

Received By:

Title: Date: 02-JUL-2018

Page 1 of 1



2016082568759125 Insp_id

Inspection Report

Washington University

Saint Louis, MO 63110

660 S Euclid

Campus Box 8106

Customer ID: 1444

Certificate: 43-R-0008

Site: 004

WASHINGTON UNIVERSITY

Type: ROUTINE INSPECTION

Date: 23-AUG-2017

2.33(b)(4) CRITICAL REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

In August 2017 the facility self-reported the following incident to the USDA. On June 1, 2017 an adult male cynomolgus macaque died unexpectedly during transport to necropsy after the conclusion of a MRI and PET scan procedure. The IACUC self-identified that there was non-compliance with the facility's IACUC policies and a failure to follow the protocol. The animal was under anesthesia during the procedure and there were gaps in physiological monitoring (i.e. Sp02, PR, RR, EtCO2, body temperature and BP) based on the records, which should have occurred every 15 minutes. For example, there were no entries on anesthetic monitoring recorded between 3:47 am and 4:26 am (39 minutes); there were no entries for temperature or EtCO2 from 3:47 am to 8:20 am (4 hours, 33 minutes); and there was a lack of physiologic monitoring recorded between 7:00 am to 8:20 am (80 minutes). Also, the animal experienced ongoing complications such as hypothermia, hypotension, wet lung sounds and fluid in the endotracheal tube during the anesthetic procedure. The first documented rectal temperature near the start of the procedure at 3:47 am was recorded as 95.7 degrees F. Although a Bair Hugger had been placed on the animal around 4:25am, the next recorded temperature continued to be decreased at 94.8 degrees F at 8:20 am. Although the animal's temperature began to slowly increase after this time, the animal's recorded SpO2 dropped to 85% at 9:25 am (ranging 81%-91% from 9:25 am to 11:05 am) while previously being recorded mostly in the mid to upper 90's. Wet lung sounds and removal of some fluid from the endotracheal tube were first documented by the laboratory veterinary technician at 8:00 am. A veterinarian was contacted by phone by the PI approximately 6 hours into the approximately 8 hour procedure, at which time the veterinarian's suggestions were followed. Although interventional steps were taken, including assistance from the Division of Comparative Medicine's (DCM) veterinary technicians, and the laboratory staff felt the animal was stable, the animal's Sp02 values continued to be low and the animal died before the planned euthanasia. The IACUC also determined that the on-call veterinary staff should have been contacted prior to when a veterinarian had been called given the ongoing complications noted throughout the procedure.

By monitoring and recording physiologic parameters during anesthetic procedures at regular intervals, and as according to the protocol and facility's policies, changes in those parameters may be identified and addressed sooner. This can decrease possible negative effects on the health and well-being of the animal.

Prepared By: LEISNER ERIKA, D V M

LEISNER ERIKA, D V M USDA, APHIS, Animal Care

Date: 25-AUG-2017

Title: VETERINARY MEDICAL OFFICER 6037

Received By:

Date: 25-AUG-2017

Page 1

Title:



2016082568759125 Insp. id

Inspection Report

The research facility acted promptly to address this incident by conducting an investigation, reporting the incident to OLAW and USDA, and swiftly implementing appropriate corrective actions to prevent future occurrences. Corrective actions taken include, but are not limited to, retraining of the PI and laboratory staff, requiring use of DCM's anesthesia monitoring record and a period of increased monitoring of the laboratory's physiological records. This item has been corrected by the facility. The facility must ensure that it maintains programs of adequate veterinary care that include guidance to principal investigators and other personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia at all times.

The inspection was conducted on August 23-25, 2017 and an exit interview was conducted on August 25, 2017 with facility representatives.

Prepared By: LEISNER ERIKA, D V M Date: USDA, APHIS, Animal Care LEISNER ERIKA, D V M 25-AUG-2017 VETERINARY MEDICAL OFFICER 6037 Title: Received By: Date: 25-AUG-2017 Title: Page 2 of 2



ELEISNER

2016082568133941 Insp_id

Inspection Report

Washington University

660 S Euclid

Campus Box 8106

Saint Louis, MO 63110

Customer ID: 1444

Certificate: 43-R-0008

Site: 004

WASHINGTON UNIVERSITY

Type: ROUTINE INSPECTION

Date: 07-MAR-2017

2.33(b)(4) CRITICAL

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

***In September 2016 the facility self-reported an incident to the Office of Laboratory Animal Welfare (OLAW) and USDA. The facility suspended a protocol as a result of inadequate intraoperative monitoring, as approved in the study protocol, and subsequent failure to identify a malfunctioning heating pad that may have contributed to the unexpected death of a rabbit undergoing a non-survival surgical procedure. According to anesthesia records, there was a period of approximately 4 hours in which no temperature was recorded while the animal was under anesthesia for this procedure. This is contrary to the approved protocol which states that a rectal temperature will be monitored and recorded every 15 minutes. Written records indicate that the animal died while under anesthesia and it is recorded that the animal's blood pressure dropped due to hypothermia and hemodilution. It was also noted in the records that the water-heated mat under the animal had turned off, leading to hypothermia. The veterinary staff was not immediately notified of intraoperative problems or of the animal's death. A necropsy was not performed on the rabbit. By monitoring the temperature at more frequent intervals, changes in temperature may be identified and addressed sooner. The facility identified that proper steps to ensure the health and welfare of the animal may not have been taken because records to substantiate those efforts were inadequately maintained. The facility must ensure that proper guidance is provided to principal investigators and their personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization and euthanasia at all times. The research facility acted promptly to address this incident by conducting an investigation, reporting the incident to OLAW and USDA, and swiftly implementing appropriate corrective actions to prevent future occurrences. Corrective actions taken include, but are not limited to, retraining of all personnel involved, a submitted plan to ensure adequate expertise of the research team performing procedures and amending the protocol to include contacting veterinary staff immediately if complications occur. This item has been corrected by the facility.

The inspection was conducted on March 7-9, 2017 and an exit interview was conducted on March 9, 2017 with facility representatives.

Prepared By:	8.4	
	Date:	
	09-MAR-2017	
Title:		
Received By:		



2016082569645850 Insp_id

Inspection Report

Washington University

660 S Euclid Campus Box 8106

Saint Louis, MO 63110

Customer ID: 1444

Certificate: 43-R-0008

Site: 004

WASHINGTON UNIVERSITY

Type: ROUTINE INSPECTION

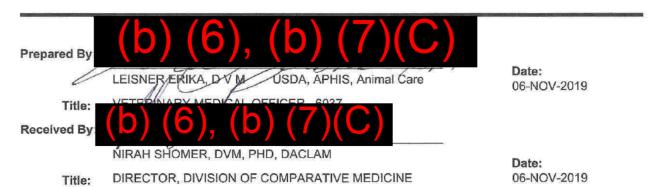
Date: 04-NOV-2019

No non-compliant items identified during this inspection.

This inspection was conducted November 4-6, 2019 with facility representatives. An exit interview was conducted on November 6, 2019 with facility representatives.

Additional Inspectors

Kent Harvey, Veterinary Medical Officer





Customer:

1444

Inspection Date: 04-NOV-19

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1444	43-R-0008	004	WASHINGTON UNIVERSITY	04-NOV-19
Count	Scientific Name		Common Name	
000007	Canis lupus familia	aris	DOG ADULT	
000102	Cavia porcellus		DOMESTIC GUINEA PIG	;
000007	Cricetulus migrato	rius	ARMENIAN HAMSTER /	MIGRATORY HAMSTER
000017	Macaca fascicular	ris	CRAB-EATING MACAQU	JE / CYNOMOLGUS MONKEY
000040	Macaca mulatta		RHESUS MACAQUE	
000030	Meriones unguicu	latus	MONGOLIAN GERBIL (C	COMMON PET / RESEARCH VARIETY)
000012	Mesocricetus aura	atus	SYRIAN / GOLDEN HAM	ISTER (COMMON PET/RESEARCH TYPE)
000034	Oryctolagus cunic	ulus	DOMESTIC RABBIT / EL	JROPEAN RABBIT
800000	Sus scrofa domes	tica	DOMESTIC PIG / POTBE	ELLY PIG / MICRO PIG
000257	Total			