

|   |          |   |                                       |
|---|----------|---|---------------------------------------|
| Every research facility, exhibitor, carrier, and intermediate handler not required to be licensed under Section 3 of the Animal Welfare Act, shall register with the USDA (7 USC 2136). This application provides information for such registration.  |          | OMB No. 0579-0036<br>FORM APPROVED  |                                       |
| <b>U.S. DEPARTMENT OF AGRICULTURE</b><br><b>ANIMAL AND PLANT HEALTH INSPECTION SERVICE</b><br><b>APPLICATION FOR REGISTRATION</b><br>(TYPE OR PRINT)  |          | <b>USDA USE ONLY</b><br>Applicant should send completed form to this address.<br>USDA APHIS ANIMAL CARE<br>WESTERN<br>2150 Centre Ave.<br>Building B, Mailstop 3W11<br>Fort Collins, CO 80526-8117<br>(970) 494-7478                            |                                       |
| <b>REGISTRATION UPDATE</b>  |          | <b>CERTIFICATE NO./CUST NO:</b><br>43-R-0008<br><br>1444  | <b>RENEWAL DATE</b><br><br>4-May-2019 |
| 1. REGISTRANT (Name and permanent mailing address, including Zip Code)<br><br>Washington University<br>660 S Euclid Campus Box 8106<br>Saint Louis, MO 63110<br><i>St. Louis</i><br>COUNTY: <u>JACKSON</u> TELEPHONE (314) 362 - 3229   |          | 2. LOCATION (S) OF BUSINESS, EXHIBITION SITE(S), OR RESEARCH FACILITIES<br><i>(Use additional sheets if necessary)</i><br><div style="background-color: black; color: red; font-size: 2em; text-align: center; padding: 10px;">(b) (7)(F)</div> |                                       |
| 3. (A) PREVIOUS USDA REGISTRATION NUMBER (IF ANY)   |          | 4. (B) ACTIVE USDA CERTIFICATE NUMBER(S) IN WHICH YOU HAVE AN INTEREST:   |                                       |
| 5. ARE YOU USING FEDERAL FUNDS TO CARRY OUT RESEARCH, TESTS, OR EXPERIMENTS<br><br><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No  |          | 6. TYPE OF REGISTRATION:<br><input type="checkbox"/> Class E – Exhibitor <input type="checkbox"/> Class H – Intermediate Handler<br><br><input type="checkbox"/> Class R – Research Facility <input type="checkbox"/> Class T – Carrier         |                                       |
| 7. FEDERAL FUND TYPES:<br><br><input checked="" type="checkbox"/> Award <input type="checkbox"/> Contract <input checked="" type="checkbox"/> Grant <input type="checkbox"/> Loan   |          | 8. TYPE OF ORGANIZATION:<br><br><input type="checkbox"/> Partnership <input type="checkbox"/> Corporation <input type="checkbox"/> Individual<br><br><input checked="" type="checkbox"/> Other (Specify) <u>University</u>                      |                                       |
| 9. IF INDIVIDUAL IDENTIFY EACH OWNER, IF PARTNERSHIP IDENTIFY EACH PARTNER OR OFFICER, IF CORPORATION, IDENTIFY PRINCIPAL OFFICERS FOR RESEARCH FACILITIES INCLUDE THE INSTITUTIONAL OFFICIAL (Use separate sheet if needed)  |          |   |                                       |
| A. NAME   | B. TITLE | C. ADDRESS (full address, including ZIP Code)   |                                       |
| (b) (6), (b) (7)(C)   |          | 660 South Euclid Ave, Campus Box 8106<br>St. Louis, MO 63110  |                                       |
|   |          | 660 South Euclid Ave, Campus Box 1054<br>St. Louis, MO 63110  |                                       |
|   |          | 660 South Euclid Ave, Campus Box 8061<br>St. Louis, MO 63110  |                                       |
|   |          | 660 South Euclid Ave, Campus Box 8031<br>St. Louis, MO 63110  |                                       |
|   |          | 660 South Euclid Ave, Campus Box 1054<br>St. Louis, MO 63110  |                                       |
|   |          | 660 South Euclid Ave, Campus Box 1054<br>St. Louis, MO 63110  |                                       |
| <b>CERTIFICATION</b><br>I hereby register as a Research Facility, Exhibitor, Carrier, or Intermediate Handler under the Animal Welfare Act, 7 U.S.C. 2131 et seq. and I certify that the information provided herein is true and correct to the best of my knowledge. I hereby acknowledge receipt of and agree to comply with all the regulations and standards contained in 9 CFR, Subpart A, parts 1, 2 and 3. I certify that all listed persons are 18 years of age or older. |          |   |                                       |
| 10. SIGNATURE<br><div style="background-color: black; color: red; font-size: 2em; text-align: center; padding: 10px;">(b) (6), (b) (7)(C)</div>   |          | 11. NAME AND TITLE (Type or Print)<br><div style="background-color: black; color: red; font-size: 2em; text-align: center; padding: 10px;">(b) (6), (b) (7)(C)</div>  |                                       |
|   |          | 12. DATE SIGNED<br>4/15/19  |                                       |



Animal and Plant  
Health Inspection  
Service

September 27, 2017

Certified Mail Return Receipt:  
7016 3010 0001 0727 8423

Animal Care  
4700 River Road  
Riverdale, MD 20737

Washington University  
660 S. Euclid Campus Box 8106  
Saint Louis, MO 63110  
Attn: Jennifer Lodge, Ph.D.

Customer No.: 1444  
Registration No.: 43-R-0008

**RE: Official Warning; Notice of Alleged Violation**

Dear Registrant:

Our agency, the Animal and Plant Health Inspection Service, is responsible for enforcing the Animal Welfare Act (7 U.S.C. § 2131 *et seq.*) (AWA), and other agricultural laws that help prevent the spread of animal and plant pests and diseases and ensure the welfare of animals. We have reason to believe that you failed to comply with the regulations issued under the AWA, as described in the enclosed attachments. Noncompliance with the regulations can have serious and costly impacts that are detrimental to animals and the public interest. You should take prompt action to correct noncompliances and establish procedures so they do not recur.

Please know that after providing you with an opportunity for a hearing, our agency may pursue civil penalties and other sanctions for each alleged violation of the AWA and regulations. Although we have authority to pursue penalties for the allegations in the attachment, we have decided not to do so in this instance, so long as you comply with the AWA and regulations in the future.

If you have any questions concerning this letter, please contact 970-494-7478.

Sincerely,

Gerald Rushin  
Assistant Deputy Administrator  
Animal Care

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

USDA

**OFFICIAL WARNING**  
**NOTICE OF ALLEGED VIOLATION**

CASE NUMBER:  
**MO170033**

VIOLATOR:  
Washington University

Customer# 1444  
Registration # 43-R-0008

ADDRESS (City, State):  
Saint Louis, MO

The Animal and Plant Health Inspection Service (APHIS) has evidence that on or about March 7, 2017, August 23, 2017, you failed to comply with the regulations issued under the Animal Welfare Act (7 U.S.C. § 2131 *et seq.*) (AWA), as documented in the attached inspection report(s).

APHIS published Federal regulations to ensure the welfare of animals and help prevent the spread of animal and plant pests and diseases. Since violations of the regulations can have serious and costly impacts that are detrimental to animals and the public interest, APHIS is providing you with this Official Warning. This Official Warning is not to be construed as a final agency action or an adjudicated finding of a violation. If APHIS obtains evidence of any violation of these Federal regulations in the future, APHIS may pursue civil penalties and other sanctions for these alleged violations and for any future violations. If you have any questions concerning this Official Warning, please contact the APHIS office telephone number listed in this notice.

APHIS OFFICIAL (Name):  
Gerald Rushin

OFFICE ADDRESS:  
4700 River Road  
Riverdale, MD 30737

APHIS OFFICIAL (TITLE):  
Assistant Deputy Administrator  
Animal Care

DATE ISSUED: Sept. 27, 2017  
TELEPHONE NO: (970) 494-7478

CERTIFIED MAIL RECEIPT NO:  
7016 3010 0001 0727 8423



## Inspection Report

Washington University  
660 S Euclid  
Campus Box 8106  
Saint Louis, MO 63110

Customer ID: **1444**

Certificate: **43-R-0008**

Site: 001

WASHINGTON UNIVERSITY

Type: ROUTINE INSPECTION

Date: 07-MAR-2017

No non-compliant items identified during this inspection.

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

**Prepared By:**

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

**Date:**

09-MAR-2017

**Title:** VETERINARY MEDICAL OFFICER 6037

**Received By:**

Obtained by Rise for Animals. Uploaded 07/07/2020

**Title:**  
19-04266\_000004

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

**Date:**

09-MAR-2017



| Cust No | Cert No   | Site | Site Name             | Inspection |
|---------|-----------|------|-----------------------|------------|
| 1444    | 43-R-0008 | 001  | WASHINGTON UNIVERSITY | 07-MAR-17  |

No Animals were Inspected.

| Count  | Species |
|--------|---------|
| 000000 | NONE    |
| 000000 | Total   |





## 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:

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

Date:  
09-MAR-2017

Title: VETERINARY MEDICAL OFFICER 6037

#### Received By:

Obtained by Rise for Animals. Uploaded 07/07/2020

Title:  
19-04266\_000006

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

Date:  
09-MAR-2017



United States Department of Agriculture  
Animal and Plant Health Inspection Service

**Inspection Report**

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**Prepared By:**

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

**Date:**  
09-MAR-2017

**Title:**      VETERINARY MEDICAL OFFICER    6037

**Received By:**

**Obtained by Rise for Animals. Uploaded 07/07/2020**

**Title:**  
19-04266\_000007

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

**Date:**  
09-MAR-2017



| Cust No | Cert No   | Site | Site Name             | Inspection |
|---------|-----------|------|-----------------------|------------|
| 1444    | 43-R-0008 | 004  | WASHINGTON UNIVERSITY | 07-MAR-17  |

| Count         | Species   |
|---------------|---|
| 000002        | ARMENIAN HAMSTER / MIGRATORY HAMSTER  |
| 000007        | CRAB-EATING MACAQUE / LONG-TAILED MACAQUE / CYNOMOLGUS MONKEY                   |
| 000012        | DOMESTIC PIG / POTBELLY PIG / MICRO PIG   |
| 000013        | SYRIAN HAMSTER / GOLDEN HAMSTER (INCLUDES COMMON NON-DWARF PET STORE VARIETIES) |
| 000014        | DOG ADULT   |
| 000024        | MONGOLIAN GERBIL (INCLUDING MOST COMMON US PET AND RESEARCH VARIETIES)          |
| 000027        | EUROPEAN RABBIT   |
| 000049        | RHESUS MACAQUE *MALE  |
| 000070        | DOMESTIC GUINEA PIG   |
| <b>000218</b> | <b>Total</b>  |





United States Department of Agriculture  
Animal and Plant Health Inspection Service  
Teachable Moments

Legal Name: WASHINGTON UNIVERSITY

Customer Number: 1444 Certificate Number: 43-R-0008

Inspection Date: 07-MAR-17 Site Number: 004

Inspector: ERIKA LEISNER, D V M

Section: \_\_\_\_\_

**2.31(c)(2) INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

A surgical area was inspected approximately one month later than the required 6 month IACUC facility inspection cycle. There were no negative impacts on animals.

## Research Facility Protocol Selection Worksheet\*

Legal Name : Washington University

Customer Number: 1444

Certificate Number: 43-R-0008

Inspection Date: March 7-9, 2017

Site Number: 004

Inspector: Erika Leisner

| Reasons Protocols Were Selected for Review :   | How Many Protocols Were Selected |
|--|----------------------------------|
| 1. Protocols identified during inspection of concern (select all)  | 2                                |
| 2. Column E protocols ( select all)  | 0                                |
| 3. Protocols with IACUC-approved exemptions/exceptions (select all)  | 1                                |
| 4. Protocols cited as noncompliant and not corrected during the last inspection (select all)   | 0                                |
| 5. Additional Protocols Selected:<br>a. If <5 remaining protocols, select all remaining:<br><br>b. If >5 remaining protocols, select 5 additional protocols:<br>1) Protocol for each regulated species and/or,<br>2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance): | 5                                |
| <b>Total Protocols Selected and Reviewed</b>   | 8                                |

\*Note: Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.

MAR 14 2017  
MAR 15 2017



## 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: 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. SpO2, 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 SpO2 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 USDA, APHIS, Animal Care

Date:  
25-AUG-2017

Title: VETERINARY MEDICAL OFFICER 6037

#### Received By:

Obtained by Rise for Animals. Uploaded 07/07/2020

Title:  
19-04266\_000011

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

Date:  
25-AUG-2017



## Inspection Report

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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.

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**Prepared By:**

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

**Date:**  
25-AUG-2017

**Title:**      VETERINARY MEDICAL OFFICER    6037

**Received By:**

**Obtained by Rise for Animals. Uploaded 07/07/2020**

**Title:**  
19-04266\_000012

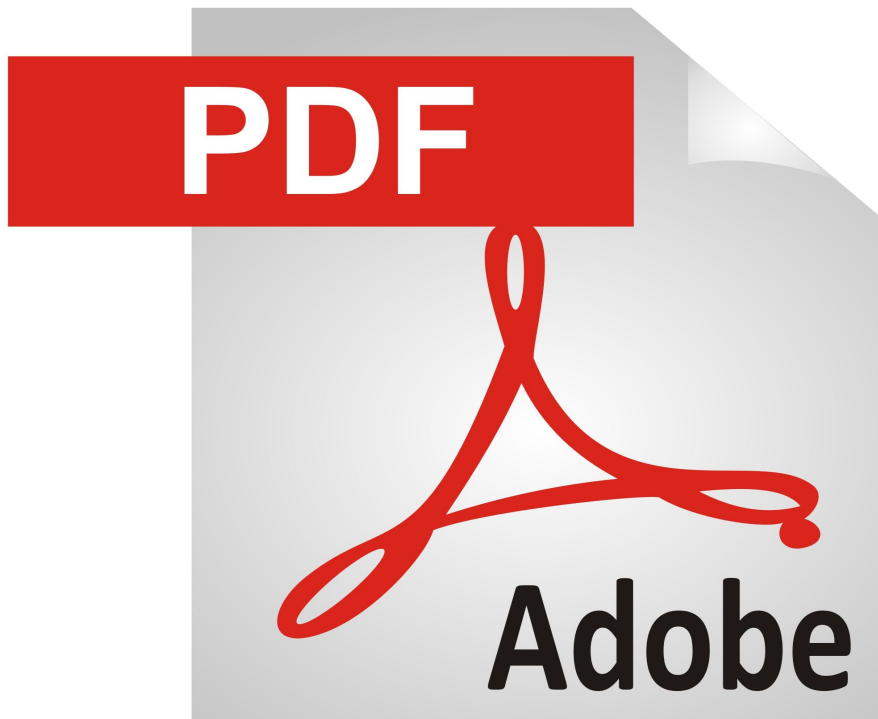
(b) (6), (b) (7)(C)

**Date:**  
25-AUG-2017



| Cust No | Cert No   | Site | Site Name             | Inspection |
|---------|-----------|------|-----------------------|------------|
| 1444    | 43-R-0008 | 004  | WASHINGTON UNIVERSITY | 23-AUG-17  |

| Count         | Species   |
|---------------|---|
| 000002        | DOG ADULT   |
| 000004        | DOMESTIC PIG / POTBELLY PIG / MICRO PIG   |
| 000005        | CRAB-EATING MACAQUE / LONG-TAILED MACAQUE / CYNOMOLGUS MONKEY                   |
| 000011        | DOMESTIC FERRET   |
| 000016        | ARMENIAN HAMSTER / MIGRATORY HAMSTER  |
| 000017        | DOMESTIC RABBIT / EUROPEAN RABBIT   |
| 000027        | SYRIAN HAMSTER / GOLDEN HAMSTER (INCLUDES COMMON NON-DWARF PET STORE VARIETIES) |
| 000050        | RHESUS MACAQUE  |
| 000053        | MONGOLIAN GERBIL (INCLUDING MOST COMMON US PET AND RESEARCH VARIETIES)          |
| 000063        | DOMESTIC GUINEA PIG   |
| <b>000248</b> | <b>Total</b>  |



CFR : 2.33(b)(4)

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**Photographer:** SCANNED INTO ACIS BY ERIKA LEISNER ON 8/28/17

**Date and Time:** 28-AUG-17

**Inspection No:** 2016082568759125

**Description:**

Washington University's self report letter to USDA regarding the June 1, 2017 incident. \*\*\*May contain PII and/or proprietary information\*\*\*

**Certificate:** 43-R-0008

**Legal Name:**

**WASHINGTON  
UNIVERSITY**

Obtained by Rise for Animals. Uploaded 07/07/2020





# Washington University in St. Louis

## Institutional Animal Care and Use Committee

August 7, 2017

Robert M. Gibbens, DVM  
Regional Director - Animal Care  
Western Regional Office, USDA/APHIS/AC  
2150 Centre Avenue, Building B  
Mail Stop 3W11  
Fort Collins, CO 80526

Re: Protocol title: "Validation of Neuroimaging Biomarkers"; supported by PHS/NIH fund #RO1 NS058714

Dear Dr. Gibbens:

Washington University in St. Louis (WU), certificate #43-R-008, is hereby reporting serious noncompliance.

On June 1, 2017, a non-human primate died unexpectedly during transport to be euthanized after a MRI and PET scan procedure. It was identified there was non-compliance with IACUC policies and a failure to follow the protocol, which consisted of: a) there were gaps in the physiological records, which called into question whether the animal was monitored appropriately (every 15 minutes) during the procedure; b) Due to ongoing complications (e.g. hypothermia and hypertension), the on-call veterinarian should have been contacted earlier in the procedure to help address the complications; c) The Division of Comparative Medicine (DCM) was not properly contacted when the animal died unexpectedly to allow for a gross necropsy to be performed. The IACUC chair convened an IACUC subcommittee on June 23, 2017 to review the medical records and discuss the issues; its assessment was discussed at the next full IACUC meeting on July 21, 2017.

### Immediate corrective actions implemented:

- 1) A qualified DCM vet tech was present during the next four scans performed during June 20-29, 2017, which included the hands on training noted under item #3 below
- 2) DCM's anesthesia record form is required to be used, in addition to the PI's own forms, to assist in ensuring properly physiological monitoring is completed and documented every 15 minutes.
- 3) In person training was provided to the PI and lab staff regarding proper monitoring and documentation; identifying complications; when to contact DCM a) for assistance in addressing complications and b) when an animal dies unexpectedly or is electively euthanized before the planned experimental endpoint.

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

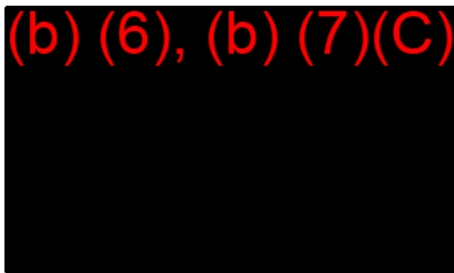
In addition to approving the above corrective actions, the full IACUC imposed additional corrective actions on July 25, 2017, after it reviewed and discussed the incident at its next scheduled meeting, which included:

- PI and his lab staff will receive in person training on federal regulations, the Guide, and IACUC policies within 30 days.
- The IACUC imposed a 3-month probation period, with monthly follow-up re-inspections during the probationary period, which includes increased monitoring of physiological records.

Additional details regarding the situation are summarized in the enclosed attachment. Please let me know if you have questions or need additional information.

Sincerely,

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

A large black rectangular redaction box covers the signature area. The text "(b) (6), (b) (7)(C)" is printed in red at the top left of the redacted area.

enclosure

Summary of events - USDA report  
Protocol title: "Validation of Neuroimaging Biomarkers"

The IACUC was notified on June 15, 2017 of the unanticipated death of a NHP that occurred on June 1, 2017. The animal died unexpectedly at the conclusion of a MRI and PET brain scan. The procedure began at approximately 3:30am on June 1<sup>st</sup>. The animal died at approximately 11:30am after the scans had been completed while being transported to a necropsy room. The animal experienced complications (hypothermia and hypertension and fluid in the lungs) while under anesthesia. Interventional steps were taken, and the animal was believed to be stable, but died just before the planned euthanasia.

The PI met with veterinary staff, which included the IACUC chair, on June 19, 2017 as part of a veterinary consultation to discuss the sequence of events and the complication that occurred during the procedure.

On June 23, 2017, the IACUC chair convened an IACUC subcommittee to review the medical records and discuss the issues. The subcommittee determined the following:

1. There were gaps in physiological monitoring ( SpO<sub>2</sub>, PR, RR, EtCO<sub>2</sub>, Temp., BP, Isoflurane concentration) based on the records, which should have occurred every 15 minutes; examples include:
  - No entries on anesthetic monitoring record between 03:47am and 04:26am (39 minutes)
  - No entries for temperature or EtCO<sub>2</sub> from 03:47am – 8:20am (4 hrs, 33 minutes)
  - There were no physiologic monitoring recorded between 07:00 to 08:20 (80 minutes)
2. The on-call Vet staff should have been contacted prior than 9:45am to help address the ongoing complications. Given the varying hypothermia and hypertension noted throughout the procedure, ideally the vet staff should have been contacted at 8:00am or shortly thereafter when the wet lungs sounds and fluid in the endotracheal tube were first identified because the BP continued to be depressed and SpO<sub>2</sub> values continued to be low after the PI's vet tech thought the fluid in the lungs had been addressed.
3. The Division of Comparative Medicine (DCM) was not properly contacted when the animal died, which would have enabled a gross necropsy to be performed.

The PI was formally notified on July 10, 2017 of the IACUC subcommittee's determinations. The PI promptly provided a written response to the IACUC to outline the steps he had already taken to help address the issues.

The IACUC issued its final determination and additional corrective actions on July 25, 2017, based on its review at the July 21, 2017 IACUC meeting.



CFR : 2.33(b)(4)

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**Photographer:** SCANNED INTO ACIS BY ERIKA LEISNER ON 8/28/17

**Date and Time:** 28-AUG-17

**Certificate:** 43-R-0008

**Inspection No:** 2016082568759125

**Legal Name:**

**Description:**

The laboratory veterinary technician's anesthesia record for the procedure conducted during the June 1, 2017 incident at Washington University. The facility blocked out some PII on the record. \*\*\*May contain PII and/or proprietary information\*\*\*

**WASHINGTON  
UNIVERSITY**

Obtained by Rise for Animals. Uploaded 07/07/2020



## Inspection Report

Washington University  
660 S Euclid  
Campus Box 8106  
Saint Louis, MO 63110

Customer ID: **1444**  
Certificate: **43-R-0008**  
Site: 001  
WASHINGTON UNIVERSITY

Type: --RESCINDED--  
Date: 07-FEB-2018

No non-compliant items identified during this inspection. This was a focused inspection limited to paperwork.

This inspection and exit interview were conducted with facility representatives. An exit interview was completed on February 8, 2018.

### Additional Inspectors

Snow William, Veterinary Medical Officer

### Prepared By:

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

Date:  
08-FEB-2018

Title: VETERINARY MEDICAL OFFICER 6037

### Received By:

Obtained by Rise for Animals. Uploaded 07/07/2020

Title:  
19-04266\_000023

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

Date:  
08-FEB-2018



| Cust No | Cert No   | Site | Site Name             | Inspection |
|---------|-----------|------|-----------------------|------------|
| 1444    | 43-R-0008 | 001  | WASHINGTON UNIVERSITY | 07-FEB-18  |

No Animals were Inspected.

| Count  | Species |
|--------|---------|
| 000000 | NONE    |
| 000000 | Total   |





## 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: 07-FEB-2018

No non-compliant items identified during this inspection. This was a focused inspection limited to paperwork.

This inspection and exit interview were conducted with facility representatives. An exit interview was completed on February 8, 2018.

### Additional Inspectors

Snow William, Veterinary Medical Officer

### Prepared By:

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

Date:

27-FEB-2018

Title: VETERINARY MEDICAL OFFICER 6037

### Received By:

Obtained by Rise for Animals. Uploaded 07/07/2020

(b) (6), (b) (7)(C)  
Title: SENT VIA EMAIL  
19-04266\_000025

Date:

27-FEB-2018



| Cust No | Cert No   | Site | Site Name             | Inspection |
|---------|-----------|------|-----------------------|------------|
| 1444    | 43-R-0008 | 004  | WASHINGTON UNIVERSITY | 07-FEB-18  |

No Animals were Inspected.

| Count  | Species |
|--------|---------|
| 000000 | NONE    |
| 000000 | Total   |

## Fausch, Emily R - APHIS

---

**From:** Leisner, Erika L - APHIS  
**Sent:** Wednesday, February 28, 2018 2:33 PM  
**To:** AC West  
**Subject:** FW: USDA Inspection Report for site 004 on 2/7/18 - \*Reply Requested\*  
**Attachments:** Wash U (2-7-18).pdf

**From:** (b) (6), (b) (7)(C) @wustl.edu]  
**Sent:** Wednesday, February 28, 2018 8:25 AM  
**To:** Leisner, Erika L - APHIS <Erika.L.Leisner@aphis.usda.gov>  
**Subject:** RE: USDA Inspection Report for site 004 on 2/7/18 - \*Reply Requested\*

Erika:

I have received the report. Thanks for the update.

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

Washington University  
Division of Comparative Medicine  
Box 8061, 660 S. Euclid Ave.  
St. Louis, MO 63110  
Phone: (b) (6), (b) (7)(C)  
Fax: (b) (6), (b) (7)(C)  
Email: (b) (6), (b) (7)(C)@wustl.edu

**From:** Leisner, Erika L - APHIS [mailto:Erika.L.Leisner@aphis.usda.gov]  
**Sent:** Tuesday, February 27, 2018 5:33 PM  
**To:** (b) (6), (b) (7)(C)  
**Subject:** USDA Inspection Report for site 004 on 2/7/18 - \*Reply Requested\*

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

As we discussed on the phone, this amended inspection report attached to this email and dated 2/27/18 by the signature block replaces the previous inspection report dated 2/8/18 by the signature block. The previous inspection report is no longer valid. Please be sure to check and see that you can open the file and view it before responding. Please reply by indicating that you have received the inspection report. As always, please let me know if you have any questions. Thank you!

Very Respectfully,  
Erika Leisner, DVM, MS  
Veterinary Medical Officer  
USDA/APHIS/Animal Care  
Mobile: (b) (6), (b) (7)(C)

[erika.leisner@aphis.usda.gov](mailto:erika.leisner@aphis.usda.gov)



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## 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 USDA, APHIS, Animal Care

Date:  
02-JUL-2018

Title: VETERINARY MEDICAL OFFICER 6125

#### Received By:

Obtained by Rise for Animals. Uploaded 07/07/2020

Title:  
19-04266\_000029

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

Date:  
02-JUL-2018



## Species Inspected

| Cust No | Cert No   | Site | Site Name             | Inspection |
|---------|-----------|------|-----------------------|------------|
| 1444    | 43-R-0008 | 004  | WASHINGTON UNIVERSITY | 27-JUN-18  |

No Animals were Inspected.

| Count  | Scientific Name | Common Name |
|--------|-----------------|-------------|
| 000000 | NONE            | NONE        |
| 000000 | Total           |             |





## Inspection Report

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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: 20-AUG-2018

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No non-compliant items identified during this inspection.

This inspection (08/20/2018) and exit interview (08/21/2018) were conducted with facility representatives.

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**Prepared By:**

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

**Date:**  
21-AUG-2018

**Title:** VETERINARY MEDICAL OFFICER 6125

**Received By:**

Obtained by Rise for Animals. Uploaded 07/07/2020

**Title:**  
19-04266\_000031

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

**Date:**  
21-AUG-2018



## Species Inspected

| Cust No | Cert No   | Site | Site Name             | Inspection |
|---------|-----------|------|-----------------------|------------|
| 1444    | 43-R-0008 | 004  | WASHINGTON UNIVERSITY | 20-AUG-18  |

| Count         | Scientific Name               | Common Name  |
|---------------|-------------------------------|--|
| 000006        | <i>Canis lupus familiaris</i> | DOG ADULT  |
| 000084        | <i>Cavia porcellus</i>        | DOMESTIC GUINEA PIG                                |
| 000012        | <i>Macaca fascicularis</i>    | CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY            |
| 000042        | <i>Macaca mulatta</i>         | RHESUS MACAQUE                                     |
| 000044        | <i>Meriones unguiculatus</i>  | MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)   |
| 000051        | <i>Mesocricetus auratus</i>   | SYRIAN / GOLDEN HAMSTER (COMMON PET/RESEARCH TYPE) |
| 000010        | <i>Mustela putorius furo</i>  | DOMESTIC FERRET                                    |
| 000016        | <i>Oryctolagus cuniculus</i>  | DOMESTIC RABBIT / EUROPEAN RABBIT                  |
| 000006        | <i>Sus scrofa domestica</i>   | DOMESTIC PIG / POTBELLY PIG / MICRO PIG            |
| <b>000271</b> | <b>Total</b>                  |  |



## Inspection Report

Washington University  
660 S Euclid Campus Box 8106  
Saint Louis, MO 63110

Customer ID: **1444**

Certificate: **43-R-0008**

Site: 001

WASHINGTON UNIVERSITY

Type: ROUTINE INSPECTION

Date: 20-AUG-2018

No regulated activities.

**Prepared By:**

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

**Date:**

21-AUG-2018

**Title:** VETERINARY MEDICAL OFFICER 6125

**Received By:**

Obtained by Rise for Animals. Uploaded 07/07/2020

**Title:**  
19-04266\_000033

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

**Date:**

21-AUG-2018



## Species Inspected

| Cust No | Cert No   | Site | Site Name             | Inspection |
|---------|-----------|------|-----------------------|------------|
| 1444    | 43-R-0008 | 001  | WASHINGTON UNIVERSITY | 20-AUG-18  |

No Animals were Inspected.

| Count  | Scientific Name | Common Name |
|--------|-----------------|-------------|
| 000000 | NONE            | NONE        |
| 000000 | Total           |             |



## 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: 11-FEB-2019

No non-compliant items identified during this inspection.

This inspection was conducted February 11 -13, 2019 and an exit interview was conducted on February 13, 2019 with facility representatives.

**Prepared By:**

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

**Date:**  
13-FEB-2019

**Title:** VETERINARY MEDICAL OFFICER 6037

**Received By:**

**Obtained by Rise for Animals. Uploaded 07/07/2020**

**Title:**  
19-04266\_000035

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

**Date:**  
13-FEB-2019



## Species Inspected

| Cust No | Cert No   | Site | Site Name             | Inspection |
|---------|-----------|------|-----------------------|------------|
| 1444    | 43-R-0008 | 004  | WASHINGTON UNIVERSITY | 11-FEB-19  |

| Count         | Scientific Name               | Common Name                                      |
|---------------|-------------------------------|--|
| 000011        | <i>Canis lupus familiaris</i> | DOG ADULT  |
| 000080        | <i>Cavia porcellus</i>        | DOMESTIC GUINEA PIG                              |
| 000017        | <i>Cricetulus migratorius</i> | ARMENIAN HAMSTER / MIGRATORY HAMSTER             |
| 000005        | <i>Macaca fascicularis</i>    | CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY          |
| 000046        | <i>Macaca mulatta</i>         | RHESUS MACAQUE                                   |
| 000040        | <i>Meriones unguiculatus</i>  | MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY) |
| 000022        | <i>Oryctolagus cuniculus</i>  | DOMESTIC RABBIT / EUROPEAN RABBIT                |
| 000017        | <i>Sus scrofa domestica</i>   | DOMESTIC PIG / POTBELLY PIG / MICRO PIG          |
| <b>000238</b> | <b>Total</b>                  |  |



# Research Facility Protocol Selection Worksheet <sup>\*</sup>

Legal Name : Washington University

Customer Number: 1444

Certificate Number: 43-R-0008

Inspection Date: 2/11-2/13/2018

Site Number: 001

Inspector: Erika Leisner

| Reasons Protocols Were Selected for Review :   | How Many Protocols Were Selected |
|--|----------------------------------|
| 1. Protocols identified during inspection of concern (select all)  | 0                                |
| 2. Column E protocols ( select all)  | 0                                |
| 3. Protocols with IACUC-approved exemptions/exceptions (select all)  | 0                                |
| 4. Protocols cited as noncompliant and not corrected during the last inspection (select all)   | 0                                |
| 5. Additional Protocols Selected:<br>a. If <5 remaining protocols, select all remaining:<br><br>b. If >5 remaining protocols, select 5 additional protocols:<br>1) Protocol for each regulated species and/or,<br>2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance): | 0                                |
| <b>Total Protocols Selected and Reviewed</b>   | 0                                |

\*Note: Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.



## Inspection Report

Washington University  
660 S Euclid Campus Box 8106  
Saint Louis, MO 63110

Customer ID: **1444**  
Certificate: **43-R-0008**  
Site: 001  
WASHINGTON UNIVERSITY

Type: ROUTINE INSPECTION  
Date: 11-FEB-2019

No non-compliant items identified during this inspection. No regulated animals were present during the inspection.

The inspection was conducted along with another site during February 11-13, 2019 and an exit interview was conducted on February 13, 2019 with facility representatives.

**Prepared By:**

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

**Date:**  
13-FEB-2019

**Title:** VETERINARY MEDICAL OFFICER 6037

**Received By:**

**Obtained by Rise for Animals. Uploaded 07/07/2020**

**Title:**  
19-04266\_000038

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

**Date:**  
13-FEB-2019



## Species Inspected

| Cust No | Cert No   | Site | Site Name             | Inspection |
|---------|-----------|------|-----------------------|------------|
| 1444    | 43-R-0008 | 001  | WASHINGTON UNIVERSITY | 11-FEB-19  |

No Animals were Inspected.

| Count  | Scientific Name | Common Name |
|--------|-----------------|-------------|
| 000000 | NONE            | NONE        |
| 000000 | Total           |             |

# Research Facility Protocol Selection Worksheet <sup>\*</sup>

Legal Name : Washington University

Customer Number: 1444

Certificate Number: 43-R-0008

Inspection Date: 2/11-2/13/2018

Site Number: 004

Inspector: Erika Leisner

| Reasons Protocols Were Selected for Review :   | How Many Protocols Were Selected |
|--|----------------------------------|
| 1. Protocols identified during inspection of concern (select all)  | 2                                |
| 2. Column E protocols ( select all)  | N/A                              |
| 3. Protocols with IACUC-approved exemptions/exceptions (select all)  | 1                                |
| 4. Protocols cited as noncompliant and not corrected during the last inspection (select all)   | 0                                |
| 5. Additional Protocols Selected:<br>a. If <5 remaining protocols, select all remaining:<br><br>b. If >5 remaining protocols, select 5 additional protocols:<br>1) Protocol for each regulated species and/or,<br>2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance): | 5                                |
| <b>Total Protocols Selected and Reviewed</b>   | <b>8</b>                         |

\*Note: Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.