

#### DEPARTMENT OF HEALTH & HUMAN SERVICES

#### PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY

Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, Maryland 20892-6910

Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500

Bethesda, Maryland 20817 Telephone: (301) 496-7163 Facsimile: (301) 480-3387

April 18, 2022

Re: Animal Welfare Assurance A3031-01 [OLAW Case 1L]

Dr. Erin Rothwell Interim Vice President for Research The University of Utah (b) (4) Park Building Salt Lake City, UT 84112

Dear Dr. Rothwell,

The Office of Laboratory Animal Welfare (OLAW) acknowledged receipt of your April 4, 2022, letter in response to allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Utah (UU). These allegations were received from People for the Ethical Treatment of Animals (PETA) regarding USDA APHIS Inspection Reports dated October 22, 2020 and September 7, 2021.

This Office requested additional information regarding three events described in the Inspection Report dated October 22, 2020. One event involved a marmoset that underwent a surgical procedure and multiple attempts at IV catheterization were performed. Necropsy findings confirmed the presence of deep vein thrombosis. OLAW requested the corrective actions taken in response to this incident and verification that personnel were properly trained. It is understood the Office of Comparative Medicine hired an American College of Laboratory Animal Medicine (ACLAM) boarded Senior Clinical Veterinarian in response to incidents involving marmosets. She has more than 10yr of experience using common marmosets for preclinical research and provides specialized training to personnel and experimental support to investigators including advanced clinical care and colony management.

The ACLAM-boarded veterinarian will work directly with the Principal Investigator (PI) who utilizes marmosets to oversee and conduct all experiments that require animals to be anesthetized for advanced imaging alone or in combination with a major or minor operating procedure. She has trained and evaluated the proficiency of the PI and laboratory manager and verified they are both capable of successfully performing the procedures that previously resulted in reportable incidents to OLAW. It is also understood she and/or another Clinical Veterinarian will frequently be present when these procedures are performed. Also, the IACUC has verified study personnel capabilities and training by post-approval monitoring and a review of surgical progress reports.

OLAW acknowledges the incident involving the multiple attempts at IV catheterization was reported to this Office due to the research being supported by NSF funding. OLAW required no additional corrective actions regarding the incident and the case was closed.

Page 2 = Dr. Rothwell April 18, 2022 OLAW Case A3031-3L

The second incident involved an anesthetized male marmoset that developed respiratory difficulties resulting in euthanasia. Necropsy findings revealed acute laryngitis/pharyngitis due to trauma from intubation as the cause of death. OLAW requested details of the corrective action plan, verification of properly trained personnel and verification by the IACUC that a noncompliance was not identified. The letter reiterates the hiring of the ACLAM-boarded veterinarian in response to incidents involving marmosets. As previously stated, she has trained and evaluated the PI and laboratory manger's proficiency and confirmed their capability to perform procedures, including endotracheal intubation and peripheral vein catheter placement. It is emphasized that she and/or another Clinical Veterinarian will frequently be present when these procedures are performed. Also, the IACUC confirmed study personnel capabilities and training through post-approval monitoring and a review of surgical progress reports. OLAW acknowledges that a final report regarding the incident was submitted to this Office due to the research being supported by NFS funding. Our official response did not require the institution to take any additional corrective actions.

The third event involved 8 rabbits that underwent a 2<sup>nd</sup> surgery to implant a supplemental lens which occurred 14d after the first surgery. The second surgery was not approved in the protocol. The protocol was amended to include the second surgery. The IACUC reviewed the matter and determined it to be a protocol noncompliance. OLAW acknowledges the incident was not reported to this Office since the research is not supported by PHS, NSF, and/or NASA funding.

The Inspection Report dated September 7, 2021, described an event that involved a compromised heart failure canine model that was unmonitored for several minutes. The animal destabilized and could not be resuscitated. Unexpired emergency drugs listed on the protocol were not available for administration. OLAW requested details of the corrective action plan in response to this event. The event was reviewed by the full IACUC and not reported to OLAW since the research was not supported by PHS, NSF and/or NASA funding. The corrective actions proposed by the PI included:

- A spreadsheet with emergency drugs will be generated specific to the weight of each animal prior to procedures to accelerate the administration of emergency drugs.
- A crash box with emergency drugs listed in the protocol will be present and stock will be verified prior to beginning procedures.
- Additional training of personnel by both experienced study staff and veterinary personnel will be conducted to ensure that best practices and rapid response to emergency situations will be followed.
- Additional training related to anesthesia monitoring and evaluation of depth of anesthesia by a board-certified veterinarian will be conducted with study personnel.
- If the person directly tasked with anesthesia monitoring leaves the room, another person will be
  assigned specifically to anesthesia monitoring, so one person will be specifically responsible for
  this task at all times while an animal is under anesthesia.

The IACUC agreed with the corrective actions and required the veterinary staff continue to be involved in the management of study animals during procedures. In addition, the Attending Veterinarian has required the involvement of the veterinarian when heart failure is surgically induced due to the instability of these canine models. It is noted the veterinary staff has worked with the laboratory to revise their anesthesia protocol, which has resulted in improved intra-operative stability and better outcomes for these canine models. Also, in-date emergency drugs are readily available if use is necessary.

Page 3 - Dr. Rothwell April 18, 2022 OLAW Case A3031-1L

Thank you for the detailed responses to each of OLAW's concerns. Based on its assessment of this explanation, OLAW understands that the University of Utah has implemented appropriate measures to correct and prevent recurrences of these problems and reported incidents to this Office as appropriate.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T. Tubbs -S Date: 2022.04.18

Digitally signed by Jacquelyn T. Tubbs -S

Jacquelyn Tubbs, DVM, DACLAM Senior Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact

April 4, 2022

Jacquelyn Tubbs, D.V.M., DACLAM Senior Animal Welfare Program Specialist Division of Compliance Oversight 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, Maryland 20892-6910

Re: Animal Welfare Assurance A3031-01 [OLAW Case 1L]

Dear Dr. Tubbs,

The University of Utah (UU) received your inquiry dated March 16, 2022, which opens case A3031-1L in response to an allegation of non-compliance from the organization People for the Ethical Treatment of Animals (PETA). We appreciate the prompt attention of the Office of Laboratory Animal Welfare (OLAW) to this allegation and commitment to safeguarding animal welfare.

We contend the UU is in full compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals and our PHS Animal Welfare Assurance.

We would like to provide a detailed response to the four points raised in the March 16, 2022 letter below:

Inspection Report dated October 22, 2020 describing the following incidents:

One marmoset underwent a surgical procedure, and multiple attempts at I.V. catheterization were
made. The left rear leg became swollen, and upon recovery the animal was dragging the leg and
lacked a pain response. Necropsy findings confirmed the presence of deep vein thrombosis.

Please provide further information on corrective actions taken and confirmation of properly
trained personnel.

In response to these incidences, the Office of Comparative Medicine has hired an American College of Laboratory Animal Medicine boarded senior Clinical Veterinarian, with over ten years of experience using common marmosets for preclinical research. Her expertise includes providing specialized training to personnel and experimental support to investigators as well as advanced clinical care and colony management. She has previously served as Clinical Director of an established colony of approximately 250 common marmosets used for breeding as well as awake behavior, visual and auditory-based neurophysiology investigations. During this time, she optimized a variety of protocol-specific anesthetic, analgesic and supportive care regimens that were successfully used for major/minor survival operating procedures, longitudinal awake (fMRI) and anesthetized advanced imaging studies. Her standard practices included pre-operative physical examinations and diagnostics, peripheral venous and arterial catheter placement, endotracheal intubation, advanced intra-operative vital parameter monitoring, specialized surgical support (stereotaxic frame placement, cranial and cochlear implants, vagal nerve isolation/stimulations) and rigorous post-operative care. She has successfully trained veterinary technicians, residents in laboratory animal medicine, investigators and laboratory personnel at her previous academic institution to perform all or a combination of these techniques. In addition, she

periodically consults and travels to support marmoset researchers at several other academic institutions in the United States. She is an active member of the Association of Primate Veterinarians and a regular contributor to several national marmoset working groups and collaborative efforts.

She will work directly with the Principal Investigator who uses marmosets at the University of Utah to oversee and conduct all experiments that require animals to be anesthetized for advanced imaging alone or in combination with a major or minor operating procedure. She has trained and evaluated the proficiency of the Principal Investigator and her laboratory manager and confirmed they are both capable of successfully performing the procedures that previously resulted in the incidences reported to OLAW, specifically endotracheal intubation and peripheral vein catheter placement. She and/or another Clinical Veterinarian will often be present when these procedures are performed irrespective of her role as primary versus secondary assistant to the individuals she has trained and authorized accordingly.

In addition, the IACUC has verified study personnel capabilities and training via post-approval monitoring and the review of the required surgical progress reports. As previously stated in UU correspondence with OLAW regarding resolved case A3031-01 [OLAW Case 1C], the IACUC determined that no additional action is needed. Moreover, as indicated in OLAW's official response letter regarding resolved case A3031-01 [OLAW Case 1C], OLAW agreed no additional corrective actions are required. At the time of the occurrence, this project was funded by NSF grant 1755431.

2. A male marmoset was anesthetized and reported as partially difficult to intubate. During recovery the animal developed respiratory difficulties resulting in euthanasia. Necropsy findings revealed acute laryngitis/pharyngitis due to trauma from intubation as the cause of death. *Please provide further information on corrective actions, verification of properly trained personnel and verification by the IACUC that a noncompliance was not identified regarding this incident.* 

As described above, the Office of Comparative Medicine has hired an American College of Laboratory Animal Medicine boarded senior Clinical Veterinarian with over ten years of experience using common marmosets for preclinical research. She will work directly with the Principal Investigator who uses marmosets at the University of Utah to oversee and conduct all experiments that require animals to be anesthetized for advanced imaging alone or in combination with a major or minor operating procedure. She has trained and evaluated the proficiency of the Principal Investigator and her laboratory manager and confirmed they are both capable of successfully performing the procedures that previously resulted in the incidences reported to OLAW, specifically endotracheal intubation and peripheral vein catheter placement. She and/or another Clinical Veterinarian will often be present when these procedures are performed irrespective of her role as primary versus secondary assistant to the individuals she has trained and authorized accordingly.

In addition, the IACUC has verified study personnel capabilities and training via post-approval monitoring and the review of the required surgical progress reports. As indicated in the final report submitted to OLAW by the Institutional Official, the IACUC determined that this was a serious adverse event. Protocol non-compliance was not identified. Moreover, as indicated in OLAW's official response letter regarding resolved case A3031-01 [OLAW Case 1C], OLAW

agreed no additional corrective actions are required. At the time of the occurrence, this project was funded by NSF grant 1755431.

3. Eight rabbits underwent an unapproved protocol procedure. The Inspection Report states the protocol was amended, and the renewal now includes a second procedure. *Please clarify whether this study is supported by PHS, NSF and/or NASA funding.* 

As stated in the USDA Inspection Report summary, eight rabbits underwent a 2nd surgery to implant a supplemental lens after a first surgery was conducted 14 days earlier. The second surgery was not included in the IACUC approved protocol. The protocol was amended and the renewal includes the second surgery. The details of the protocol non-compliance were reviewed by the full IACUC at a convened meeting. The IACUC determined that this was a serious protocol non-compliance and that this event will not be reported to the Office of Laboratory Animal Welfare (OLAW) since this study is not supported by PHS, NSF and/or NASA funding.

Inspection Report dated September 7, 2021 describing the following incident:

4. A compromised heat failure dog was left unmonitored for several minutes, and the SOP states a compromised individual must have a dedicated individual constantly monitoring its status. The animal destabilized and was not able to be resuscitated. It is also stated that unexpired emergency response drugs listed in the protocol were not available for administration. Please provide further information on the corrective action plan regarding this incident to prevent future recurrence.

As stated in the USDA Inspection Report summary, a compromised heart failure dog was left unmonitored for several minutes (per SOP, a compromised individual must have a dedicated individual constantly monitoring status), destabilized, and was not able to be revived. Unexpired emergency response drugs listed in the protocol were not available for administration. The details of the event were reviewed by the full IACUC at a convened meeting. The IACUC determined that this event will not be reported to the Office of Laboratory Animal Welfare (OLAW) since this work is not supported by PHS, NSF and/or NASA funding.

The corrective actions proposed by the Principal Investigator included:

A spreadsheet with emergency drugs will be generated specific to the weight of each animal prior to procedures to accelerate the administration of emergency drugs. A crash box with emergency drugs listed in the protocol will be present and stock will be verified prior to beginning procedures. Additional training of personnel by both experienced study staff and veterinary personnel will be conducted to ensure that best practices and rapid response to emergency situations will be followed. Additional training related to anesthesia monitoring and evaluation of depth of anesthesia by a board-certified veterinarian will be conducted with study personnel. If the person directly tasked with anesthesia monitoring leaves the room, another person will be assigned specifically to anesthesia monitoring so that one person will be specifically responsible for this task at all times while an animal is under anesthesia.

The IACUC agreed with the corrective actions and in addition, required that the veterinary staff continue to be involved, at the discretion of the Attending Veterinarian, in the management of study animals during procedures. Furthermore, the Principal Investigator must continue to work closely with the Attending Veterinarian and his staff to augment the study needs, determine if the staff has adequate expertise, and provide direct oversight to anesthesia and recovery procedures.



As an additional action, the Attending Veterinarian has required the involvement of a veterinarian when heart failure is surgically induced due to the instability of these patients. As a result, the academic center performing these procedures is now partially supporting the salary of a staff veterinarian to cover their direct involvement in these projects. Veterinary staff has worked with this laboratory to revise their anesthesia protocol, which has resulted in improved intraoperative stability and better patient outcomes. In-date emergency drugs are readily available in the event they are needed.

Please know that the UU appreciates the crucial role of the OLAW in safeguarding animal welfare and is fully committed to responsible and ethical research and follows rigorous guidelines to meet the highest standards of animal welfare. We appreciate the opportunity to respond to these allegations. Please let us know if you have further questions or require additional information in relation to this inquiry.

Sincerely,

(b) (6)

Erin Rothwell, Ph.D. Interim Vice President for Research

# Ward, Joan (NIH/OD) [E]

From:

(b) (6)

Sent:

Monday, April 4, 2022 7:05 PM

To:

OLAW Division of Compliance Oversight (NIH/OD)

Subject:

[EXTERNAL] University of Utah - Animal Welfare Assurance A3031-01 [OLAW Case 1L] UU A3031-1 Case 1L OLAW Response 4-5-2022\_ER signed.pdf; SIGNED Investigative

Attachments:

Depart for The University of Heart House and State of Heart House and State of Heart Heart

Report for The University of Utah 1L (open case).pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Tubbs,

The University of Utah received your inquiry dated March 16, 2022 regarding two USDA APHIS Inspection Reports dated October 22, 2020 and September 7, 2021. Attached please find a detailed response to the four points raised in the March 16 letter.

We appreciate the opportunity to respond to this inquiry. Please let me know if you need any additional information.

Thank you,
Erin Rothwell, PhD
Interim Vice President for Research
Professor of Obstetrics & Gynecology | School of Medicine
University of Utah
erin.rothwell@hsc.utah.edu



#### DEPARTMENT OF HEALTH & HUMAN SERVICES

#### PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

March 16, 2022

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

Re: Animal Welfare Assurance A3031-01 [OLAW Case 1L]

Erin Rothwell, Ph.D. Vice President for Research The University of Utah (b) (4) Park Building Salt Lake City, UT 84112

Dear Dr. Rothwell,

The Office of Laboratory Animal Welfare (OLAW) has received from People for the Ethical Treatment of Animals (PETA) allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Utah regarding two USDA APHIS Inspection Reports dated October 22, 2020 and September 7, 2021 (see attached). It is possible that such occurrences should have been reported directly to our office as required by the PHS Policy and per your commitment to do so in your Animal Welfare Assurance.

We request information regarding the Inspection Report dated October 22, 2020 describing the following incidents:

- One marmoset underwent a surgical procedure, and multiple attempts at I.V. catheterization were made. The left rear leg became swollen, and upon recovery the animal was dragging the leg and lacked a pain response. Necropsy findings confirmed the presence of deep vein thrombosis. Please provide further information on corrective actions taken and confirmation of properly trained personnel.
- A male marmoset was anesthetized and reported as partially difficult to intubate. During recovery the animal developed respiratory difficulties resulting in euthanasia. Necropsy findings revealed acute laryngitis/pharyngitis due to trauma from intubation as the cause of death. Please provide further information on corrective actions, verification of properly trained personnel and verification by the IACUC that a noncompliance was not identified regarding this incident.
- Eight rabbits underwent an unapproved protocol procedure. The Inspection Report states the protocol was amended, and the renewal now includes a second procedure. Please clarify whether this study is supported by PHS, NSF and/or NASA funding.

We request information regarding Inspection Report dated September 7, 2021 regarding the following incident:

• A compromised heat failure dog was left unmonitored for several minutes, and the SOP states a compromised individual must have a dedicated individual constantly monitoring its status. The animal destabilized and was not able to be resuscitated. It is also stated that unexpired emergency response drugs listed in the protocol were not available for administration. Please provide further information on the corrective action plan regarding this incident to prevent future recurrence.

Page 2 - Dr. Rothwell March 16, 2022 OLAW Case A3031-11.

Please instruct the IACUC, avoiding any conflict of interest, to send a report, signed by you as the Institutional Official, to the following OLAW email inbox: OLAWdco@od.nih.gov and provide a description of the occurrences and all corrective/preventive actions. Please have them consider if any of the occurrences represented programmatic failures. Please also include information regarding any PHS/NSF/DHHS funding of activities related to the occurrences, including grant or contract numbers. If other reportable non-compliances have occurred during this period, please also include them with the report.

We appreciate your cooperation and ask that you please provide the requested information by April 30, 2022. Please contact me if I can be of assistance at jacquelyn.tubbs@nih.gov.

Sincerely,

Jacquelyn Digitally signed by Jacquelyn T. Tubbs -S
T. Tubbs -S Date: 2022.03.16
08:19:43 -04:00

Jacquelyn Tubbs, DVM, DACLAM Senior Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

enclosures cc: IACUC contact

PETA



February 3, 2022

Brent C. Morse, D.V.M.
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Via e-mail: MorseB@mail.nih.gov

Dear Dr. Morse:

We believe that the federal Animal Welfare Act violations documented in the attached U.S. Department of Agriculture inspection reports and official warning posted against the University of Utah constitute violations of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). Last year, the University of Utah received \$229,692,858 from the National Institutes of Health (NIH), and according to NIH, an estimated 47% of those funds supported projects that involved experiments on animals.

In 1985, members of Congress from both sides of the aisle worked together to strengthen protections for animals in laboratories in order to address deep-seated ethical concerns held by the American public regarding the use of animals in experiments. Polling by the Pew Research Center found that more than 50% of U.S. adults oppose the use of animals in experiments, and other surveys suggest that the support of the shrinking group that continues to accept animal experimentation is contingent on the existence and enforcement of stringent regulations aimed at protecting animals.

As you know, institutions that receive funding from Public Health Service agencies—including NIH—are required to comply with PHS Policy. Failure to comply violates not only federal animal welfare guidelines and policies but also public expectations that facilities receiving tax dollars to use animals—who are capable of experiencing pain, distress, love, and companionship and value their lives just as we value ours—at the very least, comply with minimal standards aimed at ensuring some modicum of animal welfare.

We ask that your office investigate the incidents outlined in the attached reports.

Thank you for your time and consideration.

Sincerely,

(b) (6)

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

Washington 1536 16th St. N.W. Washington, DC 20036 202-483-PETA

Los Angeles 2154 W., Sunset Blvd., Los Angeles, CA 90026 323-644-PETA

Norfolk 501 Front St. Norfolk, VA 23510 757-622-PETA

Info@peta.org PETA.org

#### infilias:

- · PETA Asia
- \* PETA India
- · PETA France
- PETA Australia
- PETA Germany
- PETA Switzerland
- PETA Notherlands
   PETA Foundation (U.K.)



AGOPLEN 2016090000707035 Insp id

## Inspection Report

UNIVERSITY OF UTAH

OFFICE OF COMPARATIVE MEDICINE 75 SOUTH 2000 EAST, (b) (4) SALT LAKE CITY, UT 84112 Customer ID: 12

Certificate: 87-R-0001

Site: 003

UNIVERSITY OF UTAH

Type: ROUTINE INSPECTION

Date: 07-SEP-2021

#### 2.31(d)(1)(iv)(A)

#### Institutional Animal Care and Use Committee (IACUC).

Critical

A protocol amendment was approved by VVC (Veterinary Verification and Consultation) process on 26 Feb 2021 for a change in anesthesia to ketamine/ xylazine that was listed as "ketamine/xylazine (x mg/kg)" with no numeric dosage or route listed. Without an actual dose and route for anesthetic agents, a complete review to ensure adequate and safe anesthesia for the animal cannot be made of the proposed changes. This could lead to inappropriate amounts or route of anesthesia being used and the animal to suffer pain, distress, or death. A thorough review of proposed changes, containing complete information, by the IACUC is needed to ensure appropriate anesthetic use. Corrected by the time of inspection.

#### 2.32(c)(3)

## Personnel qualifications.

Three animals died while under anesthesia due to improper use of anesthesia or anesthesia equipment. On 3/8/2021 an anesthetized rabbit (#21-009) was connected to an anesthetic machine with the pop off valve closed. At 23 minutes post induction it was noticed that the animal was not breathing. The rabbit was unable to be revived. On 3/9/2021, a compromised heart failure dog (C20-035) was left unmonitored for several minutes (per SOP, a compromised individual must have a dedicated individual constantly monitoring status), destabilized, and was not able to be revived. Unexpired

Prepared By: ANN GOPLEN Date:

USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL

OFFICER

Received by Title: Attending Veterinarian Date: 13-DEC-2021

13-DEC-2021



AGOPLEN **2016090000707035** Insp\_id

## Inspection Report

emergency response drugs listed in the protocol were not available for administration. On 7/1/2021, a Guinea pig (#GP1) was given the appropriate anesthetic dose of ketamine/xylazine. Lab staff did not think it was responding and thought they had miscalculated the initial dose. A second dose was administered that equaled 10x the correct dose. The guinea pig died of an anesthetic overdose.

These animal deaths due to improper anesthetic monitoring, anesthetic drug dosing or equipment setup indicate that personnel had not received adequate training and guidance in proper use of anesthetics and equipment, monitoring anesthesia, or emergency procedures.

Per the regulations, training and instruction of personnel must include guidance in at least the following areas: Proper use of anesthetics, analgesics, and tranquilizers for all species used by the facility. These items were corrected prior to this inspection with retraining conducted by Clinical Veterinarians which included anesthetic dosages and calculations, monitoring, and emergency procedures and preparation. Protocol amendments clarified anesthetic doses and the refinement of anesthetic protocols for compromised animals.

This inspection and exit interview were conducted with facility representatives.

Prepared By: ANN GOPLEN

USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL

OFFICER

Received by Title: Attending Veterinarian Date: 13-DEC-2021

Date:

13-DEC-2021



Cust No

080000

000014

000003

000201

Cert No

Site

Oryctolagus cuniculus

Macaca fascicularis

Cavia porcellus

Total

Site Name

# United States Department of Agriculture Animal and Plant Health Inspection Service

Customer: 12

**RABBIT** 

DOMESTIC GUINEA PIG CRAB-EATING MACAQUE /

CYNOMOLGUS MONKEY

Inspection Date: 07-Sep-2021

Inspection

## **Species Inspected**

12	87-R-0001 003 UNIVERSITY OF UTAH	07-SEP-2021
Count	Scientific Name	Common Name
000020 000005	Canis lupus familiaris Felis silvestris catus	DOG ADULT CAT ADULT
000044 000006	Callithrix jacchus Macaca mulatta	COMMON MARMOSET RHESUS MACAQUE
000016	Sus scrofa domestica	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000013	Ovis aries aries	SHEEP INCLUDING ALL DOMESTIC BREEDS
000000	Onyotologue gunioulus	DOMESTIC RABBIT / EUROPEAN



**AGOPLEN** 2016090000458931 Insp. id

## Inspection Report

UNIVERSITY OF UTAH

OFFICE OF COMPARATIVE MEDICINE 75 SOUTH 2000 EAST, SALT LAKE CITY, UT 84112

Customer ID: 12

Certificate: 87-R-0001

Site: 003

UNIVERSITY OF UTAH

Type: FOCUSED INSPECTION

Date: 22-OCT-2020

3.80(a)(2)(ii)

Critical

Primary enclosures.

Two marmosets (male 601 858 271, female 844 827 014), were found dead entrapped in their nest box on August 12, 2020 at 8:04 am during the morning observation. At some point after the afternoon observation at 2:38 pm on August 11, the 2 animals entered their nest box in their home cage and the door to the nest box closed so they could not get out. The animals were entrapped in the box for ~18 hours. The cause of death was overheating and distress. Primary enclosures must be constructed and maintained so that they protect the nonhuman primate from injury and harm.

All the doors on the nest boxes in marmoset caging were removed prior to inspection. Corrected prior to inspection.

2.33(b)(5)

Critical

Attending veterinarian and adequate veterinary care.

Several incidents of deaths/illness due to anesthetic procedures have occurred in the marmosets.

1)On September 10, 2019, a male Marmoset (844 835 601) underwent a 6 hour surgical procedure. Multiple I.V. catheterization attempts were made prior to successful placement with visible bruising at the saphenous catheter site and lateral thigh muscle. One massage of hind limbs was recorded during the surgery. Upon recovery it was noted that his left rear leg was swollen and he was dragging it and lacked a pain response. The PI and the on-call veterinarian were notified within one hour of extubation and the veterinarian was to check on him in the am. On 9/11/2019, the marmoset

Prepared By: ANN GOPLEN

USDA, APHIS, Animal Care

Date: 19-NOV-2020

Title: VETERINARY MEDICAL

OFFICER

Received by Title: IACUC Representative

Date:

19-NOV-2020



AGOPLEN **2016090000458931** Insp. id

## Inspection Report

was found dead at the first check in the morning at ~ 8 am. Deep vein thrombosis was confirmed at necropsy.

2)On January 29, 2020, a male Marmoset(844 837 257) was anesthetized and the technician remembered that he was particularly difficult to intubate. During recovery an increased respiratory rate was noted and the animal developed respiratory difficulties resulting in euthanasia on 2/1/2020. Necropsy revealed acute laryngitis/pharyngitis due to trauma of intubation as cause of death. A marmoset (844 840 303) who had surgery 10/23/2019 also showed respiratory difficulty after recovery from surgery which gradually resolved.

Procedures like intubation, anesthesia support, and I.V. catheterization when not performed adequately can cause harm, injury and death to the animals.

Equipment utilized and care delivered including intubation and catheterization before, during and after procedures must be in accordance with current established veterinary medical and nursing procedures.

Corrected prior to inspections.

#### 2.31(e)(3)

#### Repeat

#### Institutional Animal Care and Use Committee (IACUC).

On January 17, 2020, Eight (8) rabbits (ID 20-101,-102,-103,-104,-105,-106,-109,-110) underwent a 2nd surgery to implant a supplemental lens after a first surgery was conducted 14 days earlier. The second surgery was not included in the IACUC approved protocol.

All proposed and approved animal use activities must include a complete description of the proposed use of the animals. Incomplete descriptions of all procedures do not allow the IACUC to fully assess the protocol to ensure the safe and humane use of the animals. The protocol was amended and the renewal includes the second surgery. Corrected by the time of inspection.

Prepared By: ANN GOPLEN

USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL
OFFICER

Date:
19-NOV-2020

Received by Title: IACUC Representative Date: 19-NOV-2020



AGOPLEN **2016090000458931** Insp\_id

# Inspection Report

This inspection and exit interview were conducted with facility representatives.

Prepared By: ANN GOPLEN

USDA, APHIS, Animal Care

Date: 19-NOV-2020

Title: VETERINARY MEDICAL

**OFFICER** 

Date:

Received by Title: IACUC Representative

19-NOV-2020



Customer: 12

Inspection Date: 22-Oct-2020

# **Species Inspected**

Cust No	Cert No	Site	Site Name	Inspection
12	87-R-0001	003	UNIVERSITY OF UTAH	22-OCT-2020

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	



UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

# OFFICIAL WARNING NOTICE OF ALLEGED VIOLATION

CASE NUMBER: UT220001-AC

ALLEGED VIOLATOR: UNIVERSITY OF UTAH

ADDRESS (City, State, ZIP Code): SALT LAKE CITY, UT 84112

The U.S. Department of Agriculture has evidence that on or about the date(s) listed below, you or your organization committed the following alleged violation(s) of Federal laws:

Date of Alleged Violation: September 7, 2021

9 C.F.R. § 2.32(c)(3) Personnel qualifications.

2.32(c)(3) Personnel qualifications. Training and instruction of personnel must include guidance in at least the following areas: Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;

Date of Alleged Violation: October 22, 2020

9 C.F.R. § 2.33(b)(5) Attending veterinarian and adequate veterinary care.

2.33(b)(5) Attending veterinarian and adequate veterinary care. Each research facility shall establish and maintain programs of adequate veterinary care that include: Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

Date of Alleged Violation: October 22, 2020 9 C.F.R. § 3.80(a)(2)(ii) Primary enclosures.

3.80(a)(2)(ii) Primary enclosures for nonhuman primates must meet the following minimum requirements: Protect the nonhuman primates from injury;

An Equal Opportunity Provider and Employer

Reference Number: UT220001-AC Issuance Date: January 14, 2022

The Animal and Plant Health Inspection Service (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 the public interest, APHIS is providing you with an Official Warning for the alleged violation(s) described above. This Official Warning is not to be construed as a final agency action, or as an adjudicated finding of a violation. If APHIS obtains evidence of any future violation of these federal regulations, APHIS may pursue civil penalties, criminal prosecution, or other sanctions for this alleged violation(s) and for any future violation(s). If you have any questions concerning this Official Warning or alleged violation(s), please contact the APHIS official listed in this notice.

APHIS OFFICIAL (Name): Dr. Elizabeth Goldentyer, D.V.M.	OFFICE ADDRES 4700 River F Riverdale, M	Road, (b) (4)
APHIS OFFICIAL (Title): Deputy Administrator, APHIS, Animal Care	January 14, 2022	TELEPHONE NUMBER: (b) (6)

APHIS FORM 7060

Previous editions may be used

Rev. 4-23-21