



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

May 1, 2020

Re: Animal Welfare Assurance
#A3082-01 (OLAW Case 1C)

Dr. Joanna Turner
Vice President for Research
Texas Biomedical Research Institute
8715 West Military Drive
San Antonio, Texas 78227-5302

Dear Dr. Turner,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 20, 2020 letter in response to allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Texas Biomedical Research Institute (TBRI). These allegations were received from People for the Ethical Treatment of Animals (PETA) regarding several USDA APHIS Inspection Reports dated March 2, 2017, April 5, 2018 and December 19, 2019.

The Inspection Report dated March 2, 2017 stated one male baboon was treated for 2nd degree burns to his hands and feet after contacting the heater pipe. The report states a new heater system had been added to the enclosures housing outdoor baboons, delivery of the heat is through a metal pipe that extends into the animal enclosure to the shelter used by the baboons. As a result, the baboon received and was treated for 2nd degree burns. Corrective actions included the following:

- Fitting all metal pipes with protective barriers to prevent animal contact with the pipe.
- Regulating heater temperature and time heater to prevent the metal pipe surface from becoming excessively hot.
- The pipes were made inaccessible to the animals when the heater is operating to protect animals from injury.

The Inspection Report dated April 5, 2018 described two male macaques that received immediate veterinary care for injuries acquired when they comingled after they were able to open a divider between their enclosures. The report states new cages were obtained with different locking mechanisms and latch locations. A staff member failed to properly secure the divider latch after a cage change out, resulting in injuries. Corrective actions included the following:

- All staff were promptly retrained on how to secure latches on all types of enclosures.
- A daily log is maintained in animal rooms to indicate enclosures have been properly latched.

The Inspection Report dated December 19, 2019 described a marmoset that gained access to the top enclosure through the enclosure tray and caused severe trauma to another marmoset. The report states a marmoset (B) gained access to the top enclosure through the tray that separates the upper and lower cages. The tray is secured by a latch which was unsecured resulting in trauma to marmoset (A) necessitating euthanasia of the marmoset (A). Marmoset (B) was able to manipulate the latch/divider and gain access to the top enclosure resulting in trauma to Marmoset (A). The incident was immediately reviewed by the Attending Veterinarian and area supervisor, no evidence of deviance from SOPs was found per the report. It is stated that afternoon rounds prior to the injuries did not notate any unlatched dividers. Preventive actions included the following:

- Modifying observation sheets to ensure latch dividers are verified to be in a locked position.
- Retraining on latches was performed.
- Enhancements were made by the implementation of using cage clips as a visual aid and locking mechanisms for dividers.

This Office understands that the IACUC was provided an overview of each incident by the Attending Veterinarian and that these animals were supported by PHS funds. Also, it is understood that TBRI will now report all incidents (e.g. incidents like the one that occurred on April 5, 2018) to OLAW as required by the PHS Policy and your Animal Welfare Assurance. Based on its assessment of this explanation, OLAW understands that the Texas Biomedical Research Institute has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

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

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM, DACLAM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact



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May 1, 2020

Magnolia Martinez, Ph.D.
Special Projects Manager
Laboratory Investigations Department
People for the Ethical Treatment of Animals
501 Front Street
Norfolk, VA 23510

Dear Dr. Martinez,

The Office of Laboratory Animal Welfare (OLAW) has completed its investigation regarding allegations by People for the Ethical Treatment of Animals (PETA) concerning Texas Biomedical Institute (TBRI) as contained in your January 20, 2020 letter to our Office. Background information was reviewed, and the results of the investigation included a review of several USDA APHIS Inspection Reports dated March 2, 2017, April 5, 2018 and December 19, 2019. These incidents have been reported to our office and OLAW has accepted the institution's corrective and preventive actions. TBRI now understands that the April 5, 2018 incident required reporting to OLAW. All other allegations included in your January 20, 2020 letter have either been properly reported to OLAW; did not meet the reporting criteria, or; any reports received would no longer be in OLAW's possession due to document longevity retention policies.

OLAW shares your concern for the welfare of laboratory animals. We find no cause for further action by this office at this time.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare



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

February 25, 2020

Re: Animal Welfare Assurance
#A3082-01 (OLAW Case 1C)

Dr. Joanna Turner
Vice President for Research
Texas Biomedical Research Institute
8715 West Military Drive
San Antonio, Texas 78227-5302

Dear Dr. Turner,

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 Texas Biomedical Research Institute regarding several USDA APHIS Inspection Reports dated March 2, 2017, April 5, 2018 and December 19, 2019 (**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 Inspection Report dated March 2, 2017 concerning one male baboon treated for 2nd degree burns to his hands and feet after contacting the heater pipe. Please provide further information on corrective actions.

We request information regarding Inspection Report dated April 5, 2018 regarding two male macaques that received immediate veterinary care for injuries acquired when they comingled after they were able to open a divider between their enclosures. Please provide further information on corrective actions.

We request information regarding Inspection Report dated December 19, 2019 regarding a marmoset that gained access to the top enclosure through the enclosure tray and caused severe trauma to another marmoset (euthanasia was necessary). Please provide further information on corrective actions.

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 **March 31, 2020**. Please contact me if I can be of assistance at jacquelyn.tubbs@nih.gov.

Page 2 - Dr. Turner
February 25, 2020
OLAW Case A3082-1C

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM, DACLAM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

enclosures
cc: IACUC contact

Morse, Brent (NIH/OD) [E]



Sent: Brown, Patricia [OLAW] (NIH/OD) [E]
Friday, January 24, 2020 10:54 AM
To: Dr. Magnolia Martinez
Cc: Morse, Brent (NIH/OD) [E]
Subject: RE: Request regarding Texas Biomedical Research Institute's PHS Animal Welfare Assurance

Dear Dr. Martinez,

This is to acknowledge receipt of your letter concerning Texas Biomedical Research Institute. At this time your concerns are under review by the OLAW Division of Compliance Oversight.

Sincerely yours,

Patricia Brown, VMD, MS
Director, Office of Laboratory Animal Welfare,
Office of Extramural Research,
Office of the Director, NIH
6700B Rockledge Drive
Bethesda, MD 20892-6910
301-496-7163, fax: 301-480-3394
brownp@mail.nih.gov

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From: Dr. Magnolia Martinez <MagnoliaM@peta.org>
Sent: Tuesday, January 21, 2020 10:44 AM
To: Brown, Patricia [OLAW] (NIH/OD) [E] <brownp@od.nih.gov>
Subject: Request regarding Texas Biomedical Research Institute's PHS Animal Welfare Assurance

Dear Dr. Brown,

Please find attached my request to withdraw OLAW's approval for the Public Health Service Animal Welfare Assurance granted to Texas Biomedical Research Institute.

Thanks in advance for your time and consideration.

Best regards,

Magnolia Martínez, Ph.D.
Special Projects Manager, Laboratory Investigations Department | PETA
magnoliam@peta.org | (b) (6)



PEOPLE FOR
THE ETHICAL
TREATMENT
OF ANIMALS

January 21, 2020

Patricia A. Brown, VMD, MS, DACLAM
Director
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Dr.
Suite 2500, MSC 6910
Bethesda, MD 20892

Via e-mail: brownp@od.nih.gov

Dear Dr. Brown,

I'm writing on behalf of People for the Ethical Treatment of Animals (PETA) and our more than 6.5 million members and supporters to request that in light of egregious, ongoing violations of federal animal protection guidelines and regulations, the Office of Laboratory Animal Welfare (OLAW) withdraw its approval for the Public Health Service (PHS) Animal Welfare Assurance granted to Texas Biomedical Research Institute (TBRI; PHS Assurance D16-00048 [A3082-01]).

Inspections performed at TBRI's facilities in the last decade have found that its staff members are incapable of ensuring that the conditions under which they confine the animals are safe enough to avoid injury and death. Federal authorities have also pointed out the lack of transparency in TBRI's annual reports, especially when it comes to those animals subjected to the most painful and stressful experiments. It's clear that any actions taken by TBRI after each inspection have failed to improve animal welfare standards in the long term. TBRI has disregarded animal protection provisions afforded by the "Guide for the Care and Use of Laboratory Animals" ("the *Guide*") and the federal Animal Welfare Act (AWA), and has ignored the mandate of the "PHS Policy on Humane Care and Use of Laboratory Animals" ("PHS Policy").

Documents obtained by PETA describe multiple incidents of noncompliance with the PHS Policy and several violations of the AWA from 2009 to 2019. For instance:

1. On December 17, 2019, two separate US Department of Agriculture (USDA) inspections revealed the following:

Washington, D.C.
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

Berkeley
2855 Telegraph Ave.
Ste. 301
Berkeley, CA 94705
510-763-PETA

info@peta.org
PETA.org

Affiliates:

- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Netherlands

- a. A female macaque had a finger amputated after an employee confined her in an inadequate cage in which she had her finger stuck and injured.
 - b. A marmoset was euthanized due to injuries he/she suffered when another marmoset, who was able to escape from his/her confinement area, attacked him/her.
 - c. A female baboon died by strangulation with a door cable she was able to pull into the area in which she was confined. *open case - 1B*
 - d. A juvenile baboon fractured his arm when it became stuck in a fence of an enclosure previously used to confine chimpanzees.
2. On April 2, 2018, a USDA inspection found that two male macaques sustained injuries after a staff member failed to properly secure the latch on the divider between their cages.
3. On February 28, 2017, a USDA inspection revealed that a male baboon sustained second degree burns to his hands and feet after contacting a heater pipe running through an animal enclosure.
4. On January 28, 2016, a USDA inspection revealed the following:
 - a. Experimenters used different scoring sheet and euthanasia criteria than those described in the approved protocol.
 - b. Experimenters used more animals than those specified in two protocols.
 - c. In two separate incidents, a female baboon suffered injuries when three male baboons gained access to her in the chute system while being transferred, and an infant baboon died when he/she was attacked by a male baboon who was able to lift a chute door. According to the IACUC, lack of communication between employees was the cause of these incidents.
 - d. Experimenters failed to include diet exceptions (pregnant animals were fed 70% of the normal diet) and sanitation exceptions (confinement areas for primates were cleaned every 28 days, not every 14 days) in the 2015 Annual Report.
 - e. Experimenters failed to include in the 2015 Annual Report the number of animals subjected to painful or stressful procedures without receiving any anesthetics, analgesics, or tranquilizers (Category E).
5. On September 29, 2014, a USDA inspection revealed that a juvenile baboon was killed when a guillotine door became dislodged and fell on the animal.
6. On June 2, 2014, a USDA inspection revealed the following:
 - a. A young male baboon died as a result of septicemia from trauma wounds. Three weeks prior to his death, this baboon had been confined in a new enclosure with many male baboons. A necropsy found that the animal was emaciated at time of death and had multiple scabs from bite wounds on the body and a large abscess on the leg and ankle. The description of the wounds and body condition indicated

- that the animal had injuries for many days before his death. The animal received no care for his injuries as he was not identified or reported to the veterinary staff.
- b. An adult female macaque suffered a tail degloving injury, multiple lacerations to her face and body, and an amputation of a portion of her tail after she was placed in a newly formed group of macaques.
 - c. Experimenters failed to include in the 2013 Annual Report the actual number of animals subjected to painful or stressful procedures without receiving any anesthetics, analgesics, or tranquilizers (Category E).
7. On January 29, 2014, a USDA inspection revealed the following:
- a. A juvenile baboon died by strangulation when he/she was caught in the cable for a guillotine door.
 - b. Food left inadequately stored, clutter, and tools scattered.
8. On June 10, 2013, a USDA inspection revealed the following:
- a. Experimenters failed to include in the 2012 Annual Report the actual number of animals subjected to painful or stressful procedures without receiving any anesthetics, analgesics, or tranquilizers (Category E).
 - b. Several broken PVC pipe perches in the confinement areas of macaques that could have injured the animals.
 - c. Several stainless steel feeders attached to baboon cages that were worn, bent, and had sharp edges that could have injured the animals.
9. On June 24, 2013, a USDA inspection revealed the following:
- a. Two juvenile macaques died as a result of becoming entangled in the cable for the guillotine door between the indoor and outdoor sections of the enclosures. The animals were able to reach the cable because it was not secured.
 - b. Enclosures with cracked and broken panels that could have injured the animals.

These documented violations and noncompliance issues are in addition to enforcement actions taken against TBRI. In 2011, the USDA fined TBRI \$25,714 for repeatedly allowing primates to escape from their cages and injure themselves and others, including humans. This penalty followed PETA's formal complaint regarding a 2010 incident in which two baboons escaped from their cages and attacked a caretaker—an incident that landed the laboratory, then known as the Southwest Foundation for Biomedical Research, two violations of the Animal Welfare Act, including failure to safely handle or house animals. The fine also addressed a 2009 incident in which a young monkey had to be euthanized after escaping from a cage into the freezing cold and suffering severe hypothermia.

OLAW's mandate includes monitoring facilities privileged to receive federal grants for compliance with the PHS Policy "to ensure the humane care and use of animals ... thereby contributing to the quality of PHS-supported activities."

Besides causing animal suffering and death, the violations at TBRI constitute a waste of public resources. In the 2019 financial year, TBRI received around \$29 million from the National Institutes of Health (NIH), and it is estimated that nearly half of these grants fund experiments on animals. As you know, the privilege of securing public funds comes with the responsibility of adhering to federal regulations and guidelines.

The “NIH Grants Policy Statement” (NIHGPS)—which outlines the rules governing activity in federally funded research projects—clearly specifies that the PHS Policy “requires that an approved Animal Welfare Assurance be on file with the Office of Laboratory Animal Welfare (OLAW) at the time of award for all recipient organizations receiving PHS support for research or related activities using live vertebrate animals.” In order to maintain this approval, research organizations must comply “with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals,” and confirm that they have “established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals*.”

The NIHGPS states, “OLAW is responsible for requesting, negotiating, approving or disapproving, and, as necessary, restricting or withdrawing approval of Assurances.” And Section IV.A of the PHS Policy gives NIH the discretion to “condition, restrict, or withdraw approval” for animal experimentation to take place at any facility receiving NIH funding.

Every time a research organization fails to protect the animals confined in their facilities according to the AWA and the *Guide*, the efficacy of the oversight system is questioned. We urge you to use the tools at your disposal to let TBRI know that its chronic irresponsibility and lack of transparency are duly noted and will not be allowed any longer. Please withdraw the approval of TBRI’s PHS Animal Welfare Assurance, as OLAW has the authority and obligation to do.

Thank you for your time and consideration. I look forward to hearing from you regarding your next steps. I can be contacted at MagnoliaM@peta.org.

Sincerely,

(b) (6)

Magnolia Martínez, Ph.D.
Special Projects Manager, Laboratory Investigations Department
People for the Ethical Treatment of Animals
1536 16th St. N.W.
Washington, DC 20036

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Wednesday, January 22, 2020 7:33 AM
To: Brown, Patricia [OLAW] (NIH/OD) [E]
Subject: RE: Request regarding Texas Biomedical Research Institute's PHS Animal Welfare Assurance

Will do.

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Brown, Patricia [OLAW] (NIH/OD) [E]
Sent: Tuesday, January 21, 2020 11:40 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: FW: Request regarding Texas Biomedical Research Institute's PHS Animal Welfare Assurance

Dear Brent,

Please review and take appropriate action.

Sincerely,

Pat

Patricia Brown, VMD, MS
Director, Office of Laboratory Animal Welfare,
Office of Extramural Research,
Office of the Director, NIH
6700B Rockledge Drive
Bethesda, MD 20892-6910
301-496-7163, fax: 301-480-3394
brownp@mail.nih.gov

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From: Dr. Magnolia Martinez <MagnoliaM@peta.org>
Sent: Tuesday, January 21, 2020 10:44 AM
To: Brown, Patricia [OLAW] (NIH/OD) [E] <brownp@od.nih.gov>
Subject: Request regarding Texas Biomedical Research Institute's PHS Animal Welfare Assurance

Dear Dr. Brown,



Please find attached my request to withdraw OLAW's approval for the Public Health Service Animal Welfare Assurance granted to Texas Biomedical Research Institute.

Thanks in advance for your time and consideration.

Best regards,

Magnolia Martínez, Ph.D.

Special Projects Manager, Laboratory Investigations Department | PETA

magnoliam@peta.org | (b) (6)