



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 11, 2023

Re: Animal Welfare Assurance  
A3272-01 [OLAW Case 2V]

MEMORANDUM FOR RECORD

The Office of Laboratory Animal Welfare (OLAW) received the November 10, 2022 letter from (b) (6) (b) (6) of People for the Ethical Treatment of Animals (PETA) regarding the USDA APHIS Inspection Report dated September 27, 2022. The incident was properly reported to OLAW; therefore, an additional investigation is not required. This case is thereby administratively closed as of this date.

Signed,

Jacquelyn T.  
Tubbs -S

Digitally signed by Jacquelyn T.  
Tubbs -S  
Date: 2023.05.11 13:33:23 -0500

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



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Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

March 30, 2023

Re: Animal Welfare Assurance  
A3272-01 [OLAW Case 2V]

MEMORANDUM FOR RECORD

The Office of Laboratory Animal Welfare (OLAW) has determined that the November 10, 2022 letter from (b) (6) of People for the Ethical Treatment of Animals (PETA) regarding the USDA APHIS Inspection Report dated September 27, 2022. The incident was properly reported to OLAW; therefore, an additional investigation is not required. This case is thereby administratively closed as of this date.

Signed,

Jacquelyn T.  
Tubbs -S

Digitally signed by Jacquelyn T.  
Tubbs -S  
Date: 2023.03.30 07:48:24 -04'00'

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



A3272-2V

March 8, 2023

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Bethesda, Maryland 20892-6910

RE: Animal Welfare Assurance #A3272-01, OLAW Case 2V

Dear Dr. Wolff:

Please accept this letter as the final report on a finding of serious noncompliance with the Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals*. In accordance with federal guidelines, the circumstances in question were described to you in a prompt report from Dr. Brendan Canning, Chair of the Johns Hopkins University (JHU) Animal Care and Use Committee (ACUC) on February 13, 2023 (OLAW Case #A3272-2V).

The study in question involves dogs and is designed to assess the neurological consequences of hypothermic circulatory arrest (HCA). HCA is a life-saving procedure used in patients that permits corrective cardiovascular surgeries that is unfortunately associated with considerable morbidity and mortality. The goal of this NIH-funded research (2R01HL091541-24A1) performed by accomplished human cardiac surgeons is to develop better approaches for neurologic protection in patients. The experiments are described in a protocol that had been reviewed and approved by the JHU ACUC with several amendments to the protocol that aimed to refine the experimental approaches. This research and members of the research team have been active for many years at Johns Hopkins with no prior history of adverse events aside from the anticipated morbidity and mortality associated with the procedure.

After initial protocol approval, a total of 6 experiments were completed over the course of 5 months (August 2022-January 2023). Throughout this time, the research team worked closely with RAR veterinarians and with the ACUC to discuss case specifics and to refine their protocol narrative with specific attention to post-procedural monitoring and resuscitation. Despite these efforts, three animals failed to recover from the procedure and were euthanized after veterinary consultation and just one animal reached the planned experimental endpoint. The veterinarians alerted the ACUC and requested and received from the lab a commitment to halt further experimentation until an advisory meeting could be convened and the clinical circumstances discussed. On January 18, 2023, the PI and lab members met via zoom with veterinarians and the ACUC Chair. During the advisory meeting, unsuccessful experiments were discussed for process and possible noncompliance and compared to the process used with the animal that reached the experimental endpoint. This preliminary assessment and advisory meeting revealed no evidence of deviations from protocol narratives. The ACUC Chair in consultation with the veterinarians nevertheless concluded that the circumstances required a more formal review in the form of a compliance subcommittee meeting. The lab was informed of the need to convene a subcommittee. A prompt report was prepared and issued to OLAW based on the findings of the advisory

meeting. A compliance subcommittee was held on February 1, 2023. The fact finding completed by the subcommittee focused on the experience of lab personnel involved, the process for training new team members, the appropriateness of the animals used with a particular emphasis on body weight, an assessment of evidence for protocol deviation, post-procedural monitoring, documentation, and involvement of veterinarians.

The subcommittee voted unanimously that the research team was adequately skilled and that new members received appropriate training prior to involvement in the procedures and post-procedural monitoring. The subcommittee voted unanimously that no protocol deviations were apparent but that human error directly contributed to the death of one animal (bolus KCl administration instead of slow infusion to correct cardiac rhythm). Body weight (and more specifically low body weights/ small size) did not contribute to the poor outcomes. The weights of the 6 animals used varied minimally and the single successful experiment involved the smallest animal in the cohort. The subcommittee voted unanimously that post-procedural monitoring followed protocol narrative and that veterinary support was appropriately solicited when complications emerged. Documentation/ clinical records were thorough and complete. The subcommittee also voted unanimously that veterinary support would be most efficiently provided if veterinary staff would be present during the post-procedure/ recovery phase of the experiment.

In a follow up discussion, the ACUC Chair summarized the results of the subcommittee meeting for the PI. An amendment was solicited that would address the following:

1. Mandatory veterinary attending/ resident and/ or staff involvement during the post-procedural monitoring/ recovery phase of the experiment
2. Broadening of targeted body weights to facilitate completion of the experiments both safely and humanely and to better match with available supply
3. Refinement of the imaging plans to better accommodate monitoring

The findings of the subcommittee were presented at our next scheduled committee meeting. A quorum of committee members voted unanimously in support of the findings of the subcommittee and the corrective actions requested. A protocol amendment was submitted and approved on February 23, 2023. In parallel, the research team established a more formal chain of custody to prevent inappropriate dosing/ infusion rates of drugs and therapies. This included posting a medication chart in the surgical suite and a verification process for all administered reagents. An experiment was completed on February 28, 2023 and the animal recovered without complications. Although we will be closely monitoring outcomes in this study going forward, the ACUC considers this matter closed.

Please do not hesitate to contact me if you have additional questions.

Sincerely,

(b) (6)

**Denis Wirtz, Ph.D.**

Vice Provost for Research  
Theophilus H. Smoot Professor in Engineering Science  
Johns Hopkins University

cc:

(b) (6)  
Brendan J. Canning, Ph.D., Chair, Johns Hopkins University Animal Care and Use Committee,  
Eric Hutchinson, D.V.M., DACLAM, Attending Veterinarian and Assistant Vice Provost for Animal  
Research and Resources, Johns Hopkins University

**McCoy, Devora (NIH/OD) [E]**

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, March 10, 2023 9:33 AM  
**To:** Brendan Canning  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Final report Case#2V

Good morning Dr. Canning,

Thank you for sending us this final report for case A3272-2V and we will send an official response soon.

Best,  
Devora

Devora McCoy, BS, MBA ([pronunciation](#))  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Phone: 301-435-2390  
Email: [devora.mccoy@nih.gov](mailto:devora.mccoy@nih.gov)

**From:** Brendan Canning <[bjc@jhmi.edu](mailto:bjc@jhmi.edu)>  
**Sent:** Thursday, March 9, 2023 7:14 PM  
**To:** Wolff, Axel (NIH/OD) [E] <[WolffA@OD.NIH.GOV](mailto:WolffA@OD.NIH.GOV)>; Denis Wirtz <[wirtz@jhu.edu](mailto:wirtz@jhu.edu)>; (b) (6)  
(b) (6)  
**Subject:** [EXTERNAL] Final report Case#2V

Dear Dr. Wolff,

Attached please find our final report on case #2V.

Please do not hesitate to contact me directly if you have any questions.

Brendan J. Canning, Ph.D.  
Professor of Medicine  
Chair, Johns Hopkins University Animal Care and Use Committee  
Johns Hopkins Asthma and Allergy Center  
5501 Hopkins Bayview Circle  
Baltimore, Maryland 21224  
(b) (6)  
e-mail: [bjc@jhmi.edu](mailto:bjc@jhmi.edu)

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November 10, 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](mailto:MorseB@mail.nih.gov)

Dear Dr. Morse:

We believe that the "critical" violation of the federal Animal Welfare Act documented in the attached U.S. Department of Agriculture (USDA) inspection report concerning Johns Hopkins University (JHU) constitutes a violation of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). This year, JHU received \$817,967,024 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 intended to ensure some modicum of animal welfare.

We ask that your office investigate the incidents outlined in the attached report. Thank you for your time and consideration.

Sincerely yours,

[Redacted signature block] (b) (6)

**Enclosure**  
USDA inspection report of JHU, dated September 27, 2022

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](mailto:info@peta.org)  
[PETA.org](http://PETA.org)

- Entities:
- PETA Asia
  - PETA India
  - PETA France
  - PETA Australia
  - PETA Germany
  - PETA Switzerland
  - PETA Netherlands
  - PETA Foundation (U.K.)



**Inspection Report**

Johns Hopkins University  
720 Rutland Avenue  
Ross 459  
Baltimore, MD 21205

Customer ID: 81  
Certificate: 51-R-0006  
Site: 003  
JOHNS HOPKINS UNIVERSITY,  
THE

Type: ROUTINE INSPECTION  
Date: 27-SEP-2022

**2.33(b)(3) Critical**

**Attending veterinarian and adequate veterinary care.**

The Laboratory study notes for Rabbit Study A show insufficient documentation of daily observations following tumor implantation on 8/18/22. According to the protocol animals will be observed for signs of distress such as lethargy, lack or response to stimuli, food and water intake, feces and urine output, respiratory distress, guarding incision, hiding in the corner, aggression, and physical examination at the incision site. The records provided at the time of inspection showed little documentation of fecal output, feed consumption and the other parameters for signs of distress. Weights were only recorded on 8/18/22, 8/23/22, and 8/31/22. On 8/31/2022, there were observation notes that indicated the rabbit did not accept treats, had decreased fecal output, and decreased energy. The rabbit's symptoms were not reported to the veterinary staff as indicated in the protocol.

The Animal Caretaker contacted the RAR Veterinary Staff on 9/1/22 after noting the rabbit was lethargic and the fecal/urine output was decreased. RAR Veterinary Staff examined the rabbit. The rabbit was euthanized and the body condition score at necropsy was 1 of 5.

Monitoring parameters stated in the protocol were not appropriately followed and documented by the research staff. The research staff did not notify the RAR veterinary staff on 8/31/22 that the rabbit's weight had decreased and the health of the animal had declined. As a result, the examination of the rabbit by a facility veterinarian was delayed.

Prepared By:

(b) (6)

Title:

Date:  
12-OCT-2022

Received by Title: Attending Veterinarian

Date:  
12-OCT-2022



### Inspection Report

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Animals must be observed daily to assess their physical and psychological well-being. Any abnormalities noted must be reported to the veterinarian. Should the daily observations be done by someone other than the attending veterinarian, a mechanism of direct and frequent communication must be employed to ensure that problems of animal health are conveyed to the attending veterinarian in a timely and accurate manner.

At the time of inspection the IACUC was developing a corrective action plan that had not been implemented.

To Be Corrected by: November 30, 2022

This inspection and exit interview were conducted with Attending Veterinarian and facility representatives.

This inspection was conducted 09/27/2022 to 09/30/2022.

Additional Inspectors:

[Redacted] (b) (6)

---

Prepared By:

[Redacted] (b) (6)

Date:  
12-OCT-2022

Title:

Received by Title: Attending Veterinarian

Date:  
12-OCT-2022





### Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
81	51-R-0006	003	JOHNS HOPKINS UNIVERSITY, THE	27-SEP-2022

Count	Scientific Name	Common Name
000025	<i>Mesocricetus auratus</i>	SYRIAN / GOLDEN HAMSTER (COMMON PET/RESEARCH TYPE)
000004	<i>Canis lupus familiaris</i>	DOG ADULT
000043	<i>Cavia porcellus</i>	DOMESTIC GUINEA PIG
000203	<i>Callithrix jacchus</i>	COMMON MARMOSET
000071	<i>Macaca mulatta</i>	RHESUS MACAQUE
000013	<i>Macaca nemestrina</i>	PIG-TAILED MACAQUE
000049	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000065	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000048	<i>Rousettus aegyptiacus</i>	EGYPTIAN FRUIT BAT
000093	<i>Eptesicus fuscus</i>	BIG BROWN BAT
000025	<i>Chinchilla lanigera</i>	CHINCHILLA (DOMESTICATED)
000020	<i>Mustela putorius furo</i>	DOMESTIC FERRET
000002	<i>Felis silvestris catus</i>	CAT ADULT
000025	<i>Cricetulus griseus</i>	CHINESE HAMSTER
000081	<i>Carollia perspicillata</i>	SEBA'S SHORT-TAILED BAT
000027	<i>Papio anubis</i>	OLIVE BABOON
000007	<i>Ovis aries aries</i>	SHEEP INCLUDING ALL DOMESTIC BREEDS
000801	<b>Total</b>	

**McCoy, Devora (NIH/OD) [E]**

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**From:** Morse, Brent (NIH/OD) [E]  
**Sent:** Monday, November 14, 2022 4:38 PM  
**To:** McCoy, Devora (NIH/OD) [E]  
**Subject:** FW: For Dr. Brent Morse, from PETA – AWA violation complaint  
**Attachments:** 2022-11-10-complaint-to-olaw-re-jhu-awa-violations.pdf

Devora,

Please use this email and the attached letter to open a case file. Please assign it to Dr. Tubbs. Thank you.

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

**From:** Morse, Brent (NIH/OD) [E]  
**Sent:** Monday, November 14, 2022 4:36 PM  
**To:** (b) (6)  
**Subject:** RE: For Dr. Brent Morse, from PETA – AWA violation complaint

Good afternoon,

OLAW acknowledges receipt of your letter. We will review the complaint and determine if noncompliance occurred and take any action required by the PHS Policy.

Sincerely, Brent Morse

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

**From:** (b) (6)  
**Sent:** Thursday, November 10, 2022 10:28 AM  
**To:** Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>  
**Subject:** [EXTERNAL] For Dr. Brent Morse, from PETA – AWA violation complaint  
**Importance:** High

November 10, 2022

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

Dear Dr. Morse,

Please find enclosed a letter on behalf of People for the Ethical Treatment of Animals—PETA entities have more than 9 million members and supporters worldwide—regarding a critical violation of the Animal Welfare Act at Johns Hopkins University, which is corroborated by the enclosed inspection report issued by the United States Department of Agriculture.

Thank you for your consideration of this important issue, and we look forward to your response.

Sincerely yours,

(b) (6)

(b) (6)



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