



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) 402-7065

August 20, 2019

(b) (6)

Re: Nationwide Children's Hospital

Dear (b) (6)

The Office of Laboratory Animal Welfare (OLAW) has completed its investigation regarding allegations by People for the Ethical Treatment of Animals (PETA) concerning the Research Institute at Nationwide Children's Hospital as contained in your July 19, 2019 document to our Office and the related USDA inspection document. A review of our files revealed that the institution had promptly and properly reported the non-compliances listed in your letter to OLAW along with corrective and preventive actions. This report was accepted and acknowledged by OLAW.

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)

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



July 19, 2018

Brent Morse, DVM

Acting Director
Office of Laboratory Animal Welfare
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

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

Dear Dr. Morse:

I am 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 your office investigate possible noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) and the *Guide for the Care and Use of Laboratory Animals* (the *Guide*) related to the treatment of animals at Research Institute at Nationwide Children's Hospital (NCH, PHS Assurance # D16-00331, A3544-01), located at 700 Children's Drive, Columbus, Ohio.

According to an inspection report, dated June 20, 2019 and posted by the U.S. Department of Agriculture (USDA), an unnamed Principal Investigator (PI) at NCH deviated from a protocol that had been approved by NCH's Institutional Animal Care and Use Committee (IACUC)—and in doing so, subjected an animal to more pain, discomfort, and distress than had been permitted. The protocol specified that the animal would undergo two procedures separated by a recovery period of four weeks. However, according to the USDA inspection report, the animal was subjected to both procedures “combined into a single procedure” and no recovery time was allowed. Because of this serious deviation, the animal “experienced a negative outcome” and was euthanized.

It appears to us that the issues raised in the USDA's inspection report—failure to minimize pain, discomfort, and distress experienced by animals; failure to ensure that all activities involving animals adhere to those in the IACUC-approved protocols; and failure on the part of the IACUC to ensure that proposed protocols include a complete description of the proposed use of the animals—indicate noncompliance with PHS Policy and the *Guide*.

I. Failure to adhere to protocol approved by the IACUC and failure to minimize discomfort, distress, and pain experienced by animals

The *Guide* specifies that the “oversight functions [of the IACUC] include review and approval of proposed animal use (protocol review) and of proposed significant changes to animal use.” Principle IV of the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training emphasizes the “imperative” to avoid or minimize “discomfort, distress, and pain” to animals. The *Guide* endorses the principle of “avoidance or minimization of discomfort, distress, and pain” and bolsters the application of this principle through the establishment of an effective animal care and use program.

PEOPLE FOR
THE ETHICAL
TREATMENT
OF ANIMALS

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- PETA Foundation [U.K.]
- PETA Asia-Pacific
- PETA India
- PETA Germany
- PETA Netherlands

However, the USDA's inspection report for NCH identifies *two* significant deviations from the IACUC-approved protocol. The deviation in the timeline, wherein the animal was subjected to two different procedures combined into one, would have increased the pain, distress, and discomfort suffered by the animal used in the protocol. Furthermore, the failure to allow the animal a recovery period between those two procedures may also have also contributed to the animal's pain, distress, and discomfort. Together, the deviations contributed to additional suffering for the animal so severe that he or she had to be euthanized.

II. Failure on the part of the IACUC to ensure that a proposed protocol includes a complete description of the proposed use of animals

The *Guide* mandates that in preparing and reviewing a protocol, the PI and the IACUC must ensure that the protocol includes "a clear and concise sequential description of the procedures involving the use of animals." However, the failure on the part of the PI to include in the protocol a description of a second proposed timeline for the procedures; and on the part of the IACUC to require a modification of the protocol to include this essential detail represent noncompliance with the directive contained in the *Guide*.

In conclusion, we urge you to investigate the concerns summarized in this letter and to take swift and decisive action against the Research Institute at Nationwide Children's Hospital. While it is unclear from the USDA report whether the procedures were funded with taxpayer dollars, NIH's grants database (RePORTER) reveals that Research Institute at Nationwide Children's Hospital receives considerable public funding to perform several experiments on animals. Moreover, it may be the case that NCH's Public Health Service Assurance covers the experimental use of all vertebrate animals, irrespective of funding. If it is determined that the project described in the USDA's inspection report is funded by NIH, I ask that you please share these concerns with the specific agency funding the project to ensure that public funds are not used to pay for noncompliant activities that violate the NIH Grants Policy Statement.

Thank you for your time and consideration.

Sincerely,

(b) (6)



Morse, Brent (NIH/OD) [E]



Sent:

Morse, Brent (NIH/OD) [E]
Monday, July 22, 2019 7:19 AM

To:

(b) (6)

Subject:

RE: Request to investigate USDA's inspection findings at the Research Institute at Nationwide Children's Hospital

Your request has been received by OLAW. The Division of Compliance Oversight will investigate your concerns and take any corrective actions necessary.

Sincerely, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: (b) (6)

Sent: Friday, July 19, 2019 9:00 AM

To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>

Subject: Request to investigate USDA's inspection findings at the Research Institute at Nationwide Children's Hospital

Dear Dr. Morse,

I'm (b) (6) Please find attached my request to investigate USDA's inspection findings at the Research Institute at Nationwide Children's Hospital. Thanks in advance for your time and consideration.

Best regards,

(b) (6)



Inspection Report

Research Institute At Nationwide Childrens Hospita
700 Childrens Drive
Columbus, OH 43205

Customer ID: 18920

Certificate: 31-R-0116

Site: 001

COLUMBUS CHILDREN'S RESEARCH INSTITUTE

Type: FOCUSED INSPECTION

Date: 20-JUN-2019

2.31(c)(7) CRITICAL

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

An animal underwent a procedure which was performed with a significant deviation from the approved activities as outlined in the protocol – the timeline was not followed, and what was meant to be 2 procedures separated by 4 weeks' recovery was combined into a single procedure without the 4-week recovery time. As a result of this deviation, the animal experienced a negative outcome and was humanely euthanized. The IACUC was not able to review and approve this significant change prior to the procedure being performed. The purpose of the IACUC is to ensure the humane treatment of animals in research. To correct this, the IACUC must be allowed to review and either approve, require modifications, or withhold approval for proposed significant changes regarding the care and use of animals in ongoing activities.

This item has been corrected at the time of inspection.

This inspection and exit interview were conducted with the Attending and Clinical Veterinarians as well as the Institutional Official, IACUC and compliance personnel.

Prepared By: CAMPITELLI KATHRYN, D V M

CAMPITELLI KATHRYN, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 6085

Date:
20-JUN-2019

Received By:

Title:

Date:
20-JUN-2019



Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
18920	31-R-0116	001	COLUMBUS CHILDREN'S RESEARCH INSTITUTE	20-JUN-19

No Animals were Inspected.

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	



Division of Compliance Oversight

Record of Call for Case # A3544 -m

Date & Time	Message	Initials
7/31/19 2:53	Dr. Durbin left VM that the USDA report did involve a pig. Same incident as in OLAW case - J	Bgm