



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

March 27, 2019

Re: Animal Welfare Assurance
#A3272-01 (OLAW Case 2I)

Dr. Denis Wirtz
Vice Provost for Research
Johns Hopkins University
3400 N. Charles Street
Baltimore, MD 21218

Dear Dr. Wirtz,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 5, 2019 letter reporting the suspension of a PHS-funded protocol at Johns Hopkins University. We received the initial report via a phone call from the ACUC Chair on February 21, 2019. According to the information provided, OLAW understands that on that date, a quorum the committee voted unanimously at a convened meeting to suspend the protocol due to concerns regarding the success of the canine model of "Smart spinal cord stimulation for gastroparesis". Concerns were brought to the ACUC on January 21, 2019 that of the 19 dogs that had undergone surgery between February 7, 2017 and November 8, 2018, nine had unexpected complications that led to them being euthanized for humane reasons. It was stated that the animal work was funded by the PHS (NCATS 1U18TR001920-01).

The actions by the ACUC were recommended by the ACUC compliance subcommittee after they met with the Principal Investigator and members of the research team and considered whether certain modifications to the methodology were likely to resolve the concerns given the history of the project.

The prompt consideration of this matter by Johns Hopkins University was consistent with the philosophy of institutional self-regulation. Similarly, the action taken by the ACUC to protect animal welfare was appropriate. We appreciate being informed of this matter and find no cause for further action by this office at this time.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact
Irene Haas, Director, Office of Grants Management, NCATS



March 5, 2019

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

Re: Animal Welfare Assurance A3272

Dear Dr. Morse:

I am writing to follow up on the telephone report made to you by Dr. Nancy Ator, Chair of the Johns Hopkins University Animal Care and Use Committee (ACUC) on February 21 of this year. On that date, in a full committee meeting with a quorum present and following extensive discussion, the ACUC voted to suspend the protocol of a grant funded by the National Center for Advancing Translational Science (NCATS), 1U18 TR 001920-01, "Smart spinal cord stimulation for gastroparesis." This project was to develop in dogs a novel method of spinal cord stimulation to treat gastroparesis, a common gastrointestinal disorder without effective treatment.

Concerns regarding the success of the model were brought to the ACUC on January 21, 2019. That is, 19 dogs had the planned surgery to enable monitoring and stimulation of gastric emptying between February 7, 2017 and November 8, 2018; and, of those, 9 had unexpected complications that led to dogs being euthanized for humane reasons.

The ACUC performed its proper duty in convening a compliance subcommittee, which met with the Principal Investigator and members of the research team on February 13 to discuss the model itself and the unpredicted need for euthanasia. The compliance subcommittee also considered whether certain modifications to the methodology were likely to resolve the concerns given the history of the project. The subcommittee concluded that it would recommend permanent suspension of the protocol to the full committee. The full committee voted unanimously for suspension. As of February 21, Johns Hopkins University took over the finances of supporting remaining dogs and arranging suitable adoptions.

The funding agency and the Animal and Plant Health Inspection Service of the USDA are also being informed of this suspension in compliance with the requirements of the Animal Welfare Regulations.

Please let me know if you would like further information.

Sincerely,

(b) (6)

A large grey rectangular box redacting the signature of the sender.



Denis Wirtz, Ph.D.
Institutional Official
Vice Provost for Research

cc: Kathryn K. Bayne, D.V M., Chief Executive Officer, AAALAC International
Anna L. Ramsey-Ewing, Ph.D., Director, Office of Grants Management and Scientific
Review, NCATS

(b) (6)

Nancy A. Ator, Ph.D., Chair, Johns Hopkins University ACUC

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, March 6, 2019 6:41 AM
To: Nancy Ator
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Johns Hopkins University Protocol suspension report to OLAW

Thank you for this report, Dr. Ator. Dr. Morse will address this shortly.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

-----Original Message-----

From: Nancy Ator <ator@jhmi.edu>
Sent: Tuesday, March 5, 2019 11:45 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Denis Wirtz <wirtz@jhu.edu>; (b) (6) kbayne@aaalac.org; Ramsey Ewing, Anna (NIH/NCATS) [E] <anna.ramseyewing@nih.gov>
Subject: Johns Hopkins University Protocol suspension report to OLAW

Attached please find our report of a protocol suspension to OLAW.

Nancy A. Ator, Ph.D.
Professor and Director, Division of Behavioral Biology Department of Psychiatry and Behavioral Sciences Johns Hopkins School of Medicine Chair, Johns Hopkins University Animal Care and Use Committee
(b) (6)
ator@jhmi.edu



Initial Report of Noncompliance

By: egmDate: 2/21/19Time: 4:00Name of Person reporting: Nancy A. Tor chairTelephone #: (b) (6)Fax #: [REDACTED]Email: [REDACTED]Name of Institution: Johns Hopkins Univ.Assurance number: A3272Did incident involve PHS funded activity? NCATSFunding component: [REDACTED]Was funding component contacted (if necessary): will be

What happened? 19 dogs have had surgery. 9 euthanized* prematurely, 3 within 5 days after surgery. Lameness + gastric electrode implantation.

Species involved: Canine

Personnel involved: *Acute paralysis

Dates and times: most recent end of Jan. 2019

Animal deaths: [REDACTED]

Projected plan and schedule for correction/prevention (if known): [REDACTED]JHU will contact NCATS + USDA

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # [REDACTED]