



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

June 28, 2021

Re: Animal Welfare Assurance
#A3272-01 (OLAW Case 2K]

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 June 21, 2021 letter reporting the suspension of an animal activity at Johns Hopkins University, following up on an initial telephone report on March 22, 2021. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action after determining that a pig sustained an injury following an approved cardiopulmonary resuscitation procedure. The injury occurred during transfer from the transport to home cage but the veterinarian was not notified as required in the protocol.

The corrective action consisted of euthanizing the pig the next day and suspending the protocol. The laboratory staff was retrained, the Attending Veterinarian will continue to determine oversight of animal activities, and the Principal Investigator's other protocols will be evaluated for compliance. The animal use privileges were revoked for the laboratory member responsible and the individual was subsequently terminated. Following completion of the corrective actions, the IACUC lifted the suspension.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC contact
Robert Gibbens, D.V.M., USDA-APHIS-AC



June 21, 2021

Axel Wolff, M.S., D.V.M.
Deputy Director, Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-6910

Subject: Final Report of Protocol Suspension – PHS Assurance D16-00173 (A3272-01)

Dear Dr. Wolff:

I am writing to follow up on the prompt telephone report made by Dr. Nancy Ator, then Chair of the Johns Hopkins Animal Care and Use Committee (ACUC), to you on March 20, 2021. In a convened meeting of a quorum of the ACUC, the ACUC voted unanimously to suspend the protocol of a project funded by Subaward 174710-00 "Mechanics of cardiopulmonary resuscitation" of Prime Award 1R01HL147031 to the University of Illinois at Chicago by the Heart, Lung, and Blood Institute of the National Institutes of Health (the "Study"). The protocol suspension was promptly reported to the prime awardee, to OLAW verbally, and to the USDA by letter dated April 21, 2021, and charges to the account ceased pending lifting of the suspension.

The purpose of the Study, carried out in adult swine, is to investigate the mechanics of cardiopulmonary resuscitation (CPR). A number of questions exist regarding the circumstances under which chest compression alone provides adequate ventilation and delivery of oxygen to tissues and related issues. This work is crucial to further medical understanding of whether chest compression should be delayed until an adequate airway can be established.

In the evening of March 3, a pig was injured following recovery from experimental CPR, likely during transfer from the transport to home cage. On discovering the injury that night, a senior research team staff member elected to plan euthanasia for the next morning rather than notifying the 24/7 veterinarian on call or euthanizing the animal immediately as specified in the ACUC-approved protocol. The animal was found the next morning by veterinary staff and promptly euthanized. The Attending Veterinarian (AV) referred the matter to the ACUC.

The ACUC Chair convened a compliance subcommittee on March 15, which met with the Principal Investigator to discuss necropsy findings and their evaluation by the AV as well as relevant communications among lab members and with veterinary staff. The ACUC subcommittee determined that the staff member failed to adhere to the protocol in not summoning veterinary staff to consult on the animal's condition or promptly euthanizing the animal. The subcommittee further determined that lab staff had improperly instituted changes in procedure without review and approval by the ACUC. The findings of the subcommittee were presented to the full ACUC during the regularly convened meeting on March 18th. After discussion, the full committee voted unanimously to suspend the protocol pending completion of the following corrective actions: (1) all personnel were required to undergo re-training and continued supervision of animal work as determined by the AV, and (2) evaluation of

Office of the Provost

265 Garland Hall 3400 N. Charles Street Baltimore, MD 21218 410-516-8070 <http://web.jhu.edu/administration/provost>

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 07/11/2022



compliance under other of the principal investigator's active protocols. Furthermore, (3) given the failure of the senior lab member either to alert veterinary staff about the animal's injury or to carry out prompt euthanasia as specified in the protocol, the ACUC voted to permanently exclude this staff person from working with research animals at Johns Hopkins.

The staff member's employment was ended soon after suspension of the protocol; and the corrective actions required by the ACUC for lifting the protocol suspension were fulfilled in the following weeks. In accordance with the ACUC decision, upon completion of the corrective actions, the protocol suspension was ended on April 29, 2021. By copy of this letter, JHU is notifying the USDA of the completion of the corrective actions.

Please let me know if you would like further information.

Sincerely,

(b) (6)

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

cc: Elizabeth Goldentver, D.V.M. Deputy Administrator, USDA, APHIS, Animal Care

(b) (6)

Kathryn K. Bayne, D.V.M., Chief Executive Officer, AAALAC International
Brendan J. Canning, Ph.D., Chair, Johns Hopkins University ACUC
Eric Hutchinson, D.V.M., DACLAM, Attending Veterinarian and Assistant Provost for
Animal Research and Resources

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Assurances (NIH/OD)
Sent: Monday, June 21, 2021 4:31 PM
To: Wolff, Axel (NIH/OD) [E]; Ward, Joan (NIH/OD) [E]
Cc: OLAW Division of Assurances (NIH/OD)
Subject: FW: Final report regarding a protocol suspension - Johns Hopkins University
Attachments: Johns Hopkins Univ OLAW Final Report-ProtocolSuspension 2021 DW.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Axel and Joan,

This report is for you.

Warmest Regards,

T. Maritza Carrasco
Program Analyst, Division of Assurances
Office of Laboratory Animal Welfare, NIH 6700B Rockledge Drive, Suite 2500 - MSC 6910 Bethesda, Maryland 20892
Phone: (301) 402-5913
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-----Original Message-----

From: Nancy Ator <ator@jhmi.edu>
Sent: Monday, June 21, 2021 3:35 PM
To: OLAW Division of Assurances (NIH/OD) <olawdoa@od.nih.gov>
Cc: Denis Wirtz <wirtz@jhu.edu>; animalcare@usda.gov; AAALAC International <accredit@AAALAC.org>; Brendan Canning <bjc@jhmi.edu>; Eric Hutchinson <ehutchi8@jhmi.edu>; (b) (6)
Subject: Final report regarding a protocol suspension - Johns Hopkins University

On behalf of Dr. Denis Wirtz, I am submitting the final report on a protocol suspension, previously reported by phone, March 20, 2021 during my term as Chair of the IACUC.

Best regards,
Nancy A. Ator, Ph.D.
Immediate Past Chair, Johns Hopkins University Animal Care and Use Committee



Initial Report of Noncompliance

By: (b) (6)

Date: 3/22/21

Time: 1:15

Name of Person reporting: Nanni Aton
 Telephone #: (b) (6)
 Fax #:
 Email: aton@jhandmy.edu

Name of Institution: Johns Hopkins U
 Assurance number: A3272

Did incident involve PHS funded activity? Yes Subcontract
 Funding component: NHLBI
 Was funding component contacted (if necessary): _____

What happened?

Protocol suspension of pig study. Staff didn't follow protocol leading to early euthanasia of pig. Subcontract from U of Illinois.

Species involved:

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

I have developing corrective action plan.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____